STATEMENT

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Assessment of the risk to human health through the pesticide active substance dimethoate and its metabolites in food

European Food Safety Authority (EFSA)

Abstract

Following a request by France relating to emergency measures with regard to the use of dimethoate on vegetables and orchards/fruits and the placing on the market of cherries from Member States or third countries where the use of such plant protection products is authorised, the European Commission asked EFSA in accordance with Article 69 of Regulation (EC) No 1107/2009 and Article 53 of Regulation (EC) No 178/2002 to perform a preliminary acute and chronic risk assessment for dimethoate. Based on the supporting information provided by France and other relevant sources, EFSA concluded that the data are not sufficient to clearly exclude a consumer health risk. A comprehensive review of the existing EU MRLs would be appropriate to derive a final opinion on possible risks for consumers resulting from residues of dimethoate and its metabolites in food. EFSA has established a list of data/information that would be required to address the identified gaps.

Keywords: dimethoate, omethoate, metabolites, cherries, consumer risk assessment

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Summary

Following a request by France for taking emergency measures with regard to the use of dimethoate on vegetables and orchards/fruits ("sur les cultures légumières et en arboriculture") and the placing on the market of cherries from Member States or third countries where the use of such plant protection products is authorised, EFSA was asked by the European Commission to perform a preliminary chronic risk assessment for dimethoate, considering the existing EU MRLs and all available information on residues of dimethoate-related metabolites, in particular omethoate; all available information useful for this assessment should be taken into account. In addition, a preliminary acute risk assessment for dimethoate in cherries, and other crops mentioned in the background document provided by France (i.e. asparagus, chicory roots, head cabbage, Brussels sprouts, carrots, turnips, onions, garlic, shallots, celery, celeriac, herbs, sugar beets, olives) should be performed.

Based on the limited information available to EFSA at this time, EFSA concludes that a potential long-term consumer health risk resulting from residues related to the use of dimethoate-containing plant protection products cannot be excluded. There are indications that the exposure related to the parent compound and omethoate may not exceed the ADI, taking into account information that can be used for refinement of the intake calculation (estimated exposure: 87% of the ADI). As essential information on the actual uses in the EU and on the occurrence of additional metabolites that may contribute to the overall long-term exposure is not available at time, and considering the narrow safety margin of the ADI, these calculations cannot be understood as evidence that dimethoate-related residues are not posing a long-term consumer health risk.

As regards the acute risk resulting from all dimethoate-related residues in the crops under consideration, a final conclusion cannot be derived without detailed information on the occurrence of residues of dimethoate, omethoate and other metabolites present on crops treated in accordance with Good Agricultural Practices.

As regards dimethoate and omethoate residues, there is currently no evidence of consumer risks for asparagus, chicory roots, head cabbage, Brussels sprouts, onions, garlic, shallots, celeriac, herbs, based on the risk assessment screening and the analysis of pesticide monitoring data. The contribution of other relevant metabolites may alter that assessment. The risk assessment screening however indicated that the current MRLs set for a number of crops (i.e. spring onions, table olives, fennel seed, potatoes, melons, oranges, olives for oil production, cherries, watermelons, and pineapples) for the current legal residue definition may not be sufficiently protective for consumers. A more detailed risk assessment would be required to confirm or reject the possible concerns.

The French observation that the results of the pesticide monitoring programmes show a higher MRL exceedance rate for dimethoate compared with other pesticides is confirmed by EFSA. The reasons for these findings are not completely clear; possible explanations are:

- Use of dimethoate-containing pesticides that do not respect the authorised Good Agricultural Practices;
- The existing MRLs are set at inappropriate levels; thus, if farmers use the products in accordance with Good Agricultural Practices, the harvested products may contain residues that exceed the legal limit.

In order to elucidate the reasons for the increased frequency of MRL exceedances, the competent national authorities should establish follow-up actions at the level of the pesticide users. If a misuse of dimethoate can be excluded, these findings suggest that, for certain crops, the current EU MRLs are set at inappropriate levels.

EFSA concludes that a comprehensive review of the existing EU MRLs would be appropriate. This review is planned under Article 12 of Regulation (EC) No 396/2005. However, for this review the following information would be required:

- Toxicological data that allow the assessment of which metabolites need to be included in the residue definitions for acute and chronic risk assessment;

- Toxicity of the metabolites relevant for risk assessment resulting from the use of dimethoate (e.g. toxicity equivalence factors (TEFs)) for acute and chronic risk assessment to compare the toxicity of the metabolite with the toxicity of dimethoate;
- A comprehensive list of authorised uses in the EU;
- GAPs for the use of dimethoate and omethoate in third countries for which import tolerances are requested/required;
- Supervised filed trials to estimate the residue concentrations of the parent compound and the relevant dimethoate metabolites in treated crops;
- Processing studies to derive the residue concentrations of the parent compound and of relevant dimethoate metabolites in processed products;
- Feeding studies to derive residue concentrations of dimethoate and omethoate in food of animal origin.

Some of the information required, in particular toxicological data on the relevant metabolites, may have been submitted to the RMS with the supplementary dossier for the renewal of the approval under Regulation (EC) No 1107/2009. The RMS should be contacted to verify if the required information is already available. The toxicological information would be required to initiate a comprehensive MRL review, including the decision on the most appropriate residue definitions and the TEFs. Following agreement on the residue definitions, the remaining data (e.g. supervised field trials on crops with registered GAPs covering all components of the residue definitions) need to be assessed in detail.

A risk management decision needs to be taken whether the current evidence on possible consumer risks related to dimethoate residues (including metabolites) requires other measures which would have an immediate effect.

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1. Background and Terms of Reference

Dimethoate is an active substance included in Annex I to Directive 91/414/EEC[1] and deemed to be approved under Regulation (EC) No 1107/2009[2].

On 29 March 2016, the French authorities informed the European Commission of a request to take emergency measures as regards

- the use of plant protection products (PPPs) containing dimethoate on vegetables and orchards/fruits ("sur les cultures légumières et en arboriculture") and
- the placing on the market of cherries from Member States or third countries where the use of such plant protection products is authorised.

The note of the French authorities outlining the rationale for the request is provided in Annex I of this document.

In support of the request, France also provided a summary report on the results of the national control programme for cherries of 2014 and 2015 (France, 2016), leading to consumer health concerns related to dimethoate residues.

EFSA was requested by the European Commission under Article 69 of Regulation (EC) No 1107/2009 and Article 53 of Regulation (EC) No 178/2002[3] in conjunction with Article 29 of that Regulation, to assess the available information on dimethoate and its residues and metabolites, and conclude on

1. whether it is clear that the use of PPPs containing dimethoate on vegetables and orchards/fruits is likely to constitute a serious risk to human health;

2. whether it is evident that cherries from Member States or third countries where the use of PPPs containing dimethoate is authorised are likely to constitute a serious risk to human health.

The French authorities were asked to make their assessment that was the basis for the withdrawal of the authorisation of a concerned plant protection product in France available to EFSA. The French summary assessments for the plant protection products Dimate BF 400 and Danadim Excelle were submitted to EFSA on 31 March 2016. A detailed risk assessment performed by the French authorities, leading to the decision to withdraw the authorisation for these products, was not made available to EFSA.

Given the urgency of the matter, EFSA was requested to deliver its opinion by Monday, 4 April, 12.00.

The request was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00255 and the following subject:

Dimethoate – Request for an opinion on possible risk regarding dimethoate residues and residues of related metabolites.

1.1. Interpretation of the Terms of Reference

After discussing the mandate in more detail with the contact person in DG SANTÉ on 1 April 2016, EFSA accepted the mandate, clarifying the need for additional time and that due to the very short deadline it is not feasible to consider the involvement of the PPR Panel. EFSA also highlighted that the questions raised in the mandate cannot be addressed without information on the uses of dimethoate containing plant protection products authorised in the Member States.

As previously stated by EFSA in a related context (EFSA, 2015a) the magnitude of a risk that qualifies as serious is not only a scientific issue, but also a societal and risk management issue; therefore, when the definition of serious risk is not clearly stated in the legislation or guidance documents, it

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 031 , 01/02/2002, p. –24.

requires a dialogue between risk assessors and risk managers. Thus, EFSA proposed to prepare an EFSA statement, which will address the following issues:

- Preliminary chronic risk assessment for dimethoate, considering the existing EU MRLs and, as far as available information on residues of dimethoate related metabolites, in particular omethoate; all available information that can be useful for this assessment will be taken into account.
- Preliminary acute risk assessment for dimethoate in cherries, and the crops mentioned in the background document provided by France (France, 2015a, 2015b) (i.e. asparagus, chicory roots, head cabbage, Brussels sprouts, carrots, turnips, onions, garlic, shallots, celery, celeriac, herbs, sugar beets, olives), using the available information. Due to the limited time available, EFSA will not be in a position to assess all crops on which dimethoate might be used.

For this evaluation, EFSA will consider the information received for this mandate as well as the relevant previous EFSA conclusions and reasoned opinions.

In the acceptance of this mandate, EFSA highlighted that it will not be able to perform a final risk assessment, since essential information is not available at the moment to EFSA (e.g. comprehensive list of approved GAPs, relative toxicity of relevant metabolites identified in the peer review, residue concentrations of dimethoate, omethoate and relevant metabolites in treated crops, residues in food of animal origin) and cannot be retrieved within the short period of time available to respond to the mandate. Thus, the assessments will be affected by uncertainties that will be explicitly highlighted in the EFSA statement.

2. Regulatory background information on 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 structures of the active substance and its main metabolites are reported in Appendix D.

Dimethoate is an organo-phosphorous insecticide and acaricide for the control of a wide range of pests. It acts by contact and systemic action by inhibiting the enzyme acetylcholinesterase.

Dimethoate has been assessed in the framework of Directive 91/414/EEC in the second stage with the United Kingdom being the designated Rapporteur Member State. The representative uses submitted for the peer review were foliar application of dimethoate on wheat, olives, sugar beet, tomatoes and lettuce. In the EFSA conclusion several critical areas of concern were identified; as regards consumer safety it was not possible to perform a robust risk assessment due to the lack of information on the relative toxicity to parent compound and actual levels of metabolites XX, XII and III in plant commodities (EFSA, 2006).

The active substance was included in Annex I to Directive 91/414/EEC by Commission Directive 2007/25/EC. The approval was granted for 10 years, expiring on 30 September 2017. The Annex I inclusion was restricted to the use as insecticide only. It was a specific provision of the approval that the notifier was required to submit to the European Commission by 1 October 2009 further studies to confirm the risk assessment for birds, mammals and non-target arthropods, as well as to confirm the toxicological assessment on metabolites potentially present in crops.

The Commission requested EFSA to provide scientific and technical assistance on the assessment of the confirmatory data; the EFSA conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance dimethoate was published in July 2013 (EFSA, 2013).

In 2015, the approval period for dimethoate was extended by Regulation (EU) No 2015/404[4] until 31 July 2018.

The dossier for renewal of the approval of dimethoate has been submitted to the Rapporteur Member State Italy. Italy confirmed on 1 April 2016 that the supplementary dossier is still under admissibility check. Therefore, the supplementary dossier is not available to EFSA.

In 1993, MRLs for dimethoate/omethoate have been set at European level for tea. Directive 2002/71/EC established EC MRLs for fruits and vegetables and for cereals which were amended by Directive 2008/17/EC[5]. According to Article 21 of Regulation (EC) No 396/2005 these MRLs have been transferred to Annex II of the mentioned Regulation. Since then, the EU MRLs have been amended twice, in 2008[6] and 2009[7].

The amendments in 2009 followed an EFSA opinion (EFSA, 2009) assessing the safety of existing MRLs of dimethoate. EFSA recommended to lower the MRLs for sugar beets, head cabbage, lettuce, cauliflower, cherries, fennel seeds, spice seeds, peas with pods, Brussels sprouts to the limit of quantification (LOQ) because of acute intake concerns or because there was no evidence that the MRLs are linked to existing authorisations. For a number of additional crops (i.e. spring onions, table olives, celeriac, wheat, potatoes, olives for oil production, rye) the lowering of the MRLs to the LOQ should be considered by risk managers in order to solve the chronic intake concern. For potatoes and melons, EFSA found that the LOQ was not sufficiently protective and therefore it was recommended to develop more sensitive analytical methods allowing to set the MRL at a lower LOQ level. A risk management decision was taken to lower some of the existing MRLs as proposed by EFSA or to set the MRLs at a lower level reflecting less critical GAPs. The MRL for cherries has been established temporarily at the level of 0.2 mg/kg pending the finalisation of the review under Article 12(2) of Regulation (EC) No 396/2005. It is noted that Regulation (EC) No 396/2005 does not contain MRLs for products of animal origin. The current EU MRLs for dimethoate are listed in Appendix B.

Between 2010 and 2012 EFSA issued several reasoned opinions in response to MRL applications[8] for dimethoate (EFSA 2010a, 2010b, 2011, 2012). However, the MRL applications did not result in an amendment of the existing EU MRLs since in all of the cases the data gaps regarding the metabolites of dimethoate identified in the framework of the peer review did not allow to finalise the consumer risk assessment.

The MRL review under Article 12(2) of Regulation (EC) No 396/2005 has been postponed awaiting the outcome of the assessment of confirmatory data requested in the framework of the peer review, which concluded that additional information on some metabolites was still missing (EFSA, 2013), and the renewal of the approval.

Codex MRLs have been set for dimethoate (enforcement residue definition parent dimethoate, residue definition for risk assessment: dimethoate and omethoate) for a number of crops (Appendix C). Most of the CXLs have been established before the EU MRLs have been set under Regulation (EC) No 396/2005. The CXLs derived after the entry into force of the before mentioned EU Regulation (i.e.

[4] Commission Implementing Regulation (EU) 2015/404 of 11 March 2015 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, captan, dimethoate, dimethomorph, ethoprophos, fipronil, folpet, formetanate, glufosinate, methiocarb, metribuzin, phosmet, pirimiphos-methyl and propamocarb. OJ L 67, 12.3.2015, p. 6–8.

[5] Commission Directive 2008/17/EC of 19 February 2008 amending certain Annexes to Council Directives 86/362/EEC, 86/363/EEC and 90/642/EEC as regards maximum residue levels for acephate, acetamiprid, acibenzolar-S-methyl, aldrin, benalaxyl, benomyl, carbendazim, chlormequat, chlorothalonil, chlorpyrifos, clofentezine, cyfluthrin, cypermethrin, cyromazine, dieldrin, dimethoate, dithiocarbamates, esfenvalerate, famoxadone, fenhexamid, fenitrothion, fenvalerate, glyphosate, indoxacarb, lambda-cyhalothrin, mepanipyrim, metalaxyl-M, methidathion, methoxyfenozide, pymetrozine, pyraclostrobin pyrimethanil, spiroxamine, thiacloprid, thiophanate-methyl and trifloxystrobin, OJ L 50, 23.2.2008, p. 17–50

[6] Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products OJ L 234, 30.8.2008, p. 1–216.

[7] Commission Regulation (EC) No 1097/2009 of 16 November 2009 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethoate, ethephon, fenamiphos, fenarimol, methamidophos, methomyl, omethoate, oxydemeton-methyl, procymidone, thiodicarb and vinclozolin in or on certain products. OJ L 301, 17.11.2009, p. 6–22.

[8] The requested new GAPs referred to cherries, Brussels sprouts, cauliflower, broccoli, barley grain, oat grain, table olives, carrots, parsnips, parsley root, tomatoes, asparagus and globe artichokes.

CXLs citrus fruits, lettuce and peppers) have not been taken over in the EU legislation, except the MRLs for certain spices.

According to the database on active substances maintained by the European Commission, dimethoate containing plant protection products are authorised in 23 Member States (status 1 April 2016). The details on the approved GAPs are not available to EFSA.

3. Assessment

For addressing the questions raised in the mandate set by the European Commission, EFSA based its assessment on the information received for this mandate France (2015a, 2015b, 2016) and the relevant previous EFSA conclusions and reasoned opinions (EFSA, 2006, 2009, 2010a, 2010b, 2011, 2012, 2013).

4. Nature of residues in treated crops/food consumed

4.1. Primary crops

The metabolism of dimethoate in primary crops was investigated in potatoes (tubers and foliage) and wheat in the framework of the peer review (EFSA, 2006). An additional study on olives was submitted and assessed under an MRL application (EFSA, 2011).

An overview of the available metabolism studies is presented in Table 1.

Table 1: Summary of available metabolism studies in plants

Crop groups	Crop(s)	Application(s)	Sampling	Comments
Fruit crops	Olives	Foliar (4 × 720 g/ha)	After each application and 28 d after last treatment	Study not assessed in the peer review
Root crops, Leafy crops	Potato	Foliar (2 × 340 g/ha)	0, 2, 7, 14, 21, 28 d after last treatment	Samples: tubers and foliage
Cereals/grass crops	Wheat	Foliar (1 × 680 g/ha BBCH 24; 1 × 400 g/ha at BBCH 69)	0, 14, 26 d after 1st application, 21 and 32 d after last treatment	Samples: whole plant, grains, hulls, straw

The metabolism of dimethoate was explained to proceed as follows:

- oxidation to yield omethoate (metabolite II)
- O- and N-demethylation of omethoate to yield O-desmethyl-N-desmethyl omethoate (metabolite XXIII)
- hydrolysis of the amide bond to give dimethoate carboxylic acid (metabolite III) and subsequent degradation to give O,O-dimethyl dithiophosphoric acid (metabolite XV)
- demethylation and rearrangement to yield O-desmethyl dimethoate (metabolite X) or des-O-methyl isodimethoate (metabolite XII)
- demethylation of omethoate to give O-desmethyl omethoate (metabolite XI) and subsequent hydrolysis of the amide bond to give O-desmethyl omethoate carboxylic acid (metabolite XX) (EFSA, 2006).

The metabolic profile in the foliar parts of plants investigated consists of a complex mixture of the parent compound and the above mentioned metabolites and is varying in time (with longer PHIs, the metabolic pattern consists of a complex mixture of compounds, depending on the crop and plant part) (EFSA, 2006).

A schema of the proposed metabolic pathway of dimethoate in plants is presented in Appendix A.

In the crop groups investigated, dimethoate is rapidly degraded to yield a wide range of metabolites; the predominant residue in all plant matrices was metabolite XXIII accounting for 43% TRR in potato tuber, 26% TRR in wheat whole plant, up to 40% TRR in wheat straw and grain and up to 60% TRR in olive fruit. The metabolites XX, XII and XI were also identified in significant proportions in potato tuber and wheat plant parts (>10% TRR). Metabolite III was found in olive fruits at higher levels compared to dimethoate and omethoate (EFSA, 2006, 2013).

4.2. Processed products

The effects of processing on the nature of dimethoate were investigated in the framework of the peer review through hydrolysis studies simulating sterilisation, baking, brewing, boiling and pasteurization (EFSA, 2006). These studies demonstrated that dimethoate and omethoate are degraded depending on the pH and temperature conditions.

Dimethoate is degraded to des-O-methyl isodimethoate (metabolite XII) (max 5.3% in sterilisation) and to desmethyl dimethoate (metabolite X) (28.1% in pasteurisation and 59.5% in sterilisation). Omethoate is degraded to metabolite O-desmethyl omethoate (metabolite XI) (36.2% in pasteurisation and 62.6% in sterilisation) and to O-O-dimethyl phosphoric acid (19.2% in sterilisation). Dimethoate and omethoate were at the end of the processing the major constituents of the residue, except under the most severe processing conditions (sterilisation) where desmethyl dimethoate (metabolite X) and O-desmethyl omethoate (metabolite XI) were the major components.

4.3. Rotational crops

A confined rotational crop study has been submitted in the framework of the peer review. The occurrence of dimethoate and omethoate residues in rotational crops was investigated. As both substances rapidly degrade in the soil and no other relevant soil metabolites were identified, significant residues resulting from the use of dimethoate are not likely to occur in rotational crops (EFSA, 2006).

4.4. Food of animal origin

Animal metabolism studies were assessed in the framework of the peer review (goat and hen). Dimethoate was not found in any tissue analysed. The only related metabolites identified were omethoate in goat liver, hen liver and egg whites, and dimethoate carboxylic acid (metabolite III) in milk, liver and egg withes. Although no significant residues were expected in products of animal origin taking into account the representative uses assessed in the peer review, it was noted that a feeding study in ruminants should be carried out at the expected exposure level (EFSA, 2006).

5. Mammalian toxicology

The toxicological profile of the active substance dimethoate was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2006). The data were sufficient to derive toxicological reference values for the parent compound and for the metabolite omethoate (Table 2).

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Dimethoate					
ADI	EFSA	2006	0.001 mg/kg bw per d	Overall NOAEL from 2 yr rat, multigeneration rat, rat neurotoxicity and rat developmental neurotoxicity study	100
ARfD	EFSA	2006	0.01 mg/kg bw	Acute neurotoxicity	100
Metabolite: omethoate					
ADI	EFSA	2006	0.0003 mg/kg bw per d	Rat multi generation study and 2 yr rat	100

	Source	Year	Value	Study relied upon	Safety factor
ARfD	EFSA	2006	0.002 mg/kg bw	Acute neurotoxicity	100

For omethoate, toxicological equivalence factors (TEFs) were derived to be used in acute and chronic risk assessments for dimethoate ($TEF_{omethoate/acute\ RA}$ =6, $TEF_{omethoate/chronic\ RA}$=3).

As regards the other metabolites identified in plant metabolism studies or processing studies, the following conclusions could be derived in the framework of the peer review under Directive 91/414/EEC (EFSA, 2006) and confirmatory data assessment (EFSA, 2013):

Metabolite III: In the framework of the confirmatory data assessment, toxicological information has been submitted for this metabolite to show that the metabolite has a lower toxicity than the parent compound; however, the reliability of the data was found to be limited. Metabolite III is a major metabolite in the rat and in humans. Based on its chemical structure and *in vivo* metabolism data, it was considered unlikely that the metabolite would present higher toxicity than dimethoate. Consequently, it was concluded that the toxicological reference values set for dimethoate should be applied for this metabolite (EFSA, 2013).

Metabolite X: In 2006 EFSA identified this metabolite and degradation product observed in hydrolysis studies representative for sterilisation as a potential candidate for being included in the residue definition for risk assessment (EFSA, 2006). Currently, no toxicological information is available for this metabolite. For uses on crops that are subject to heat treatment, in particular sterilisation, data on the toxicological properties would be required (EFSA, 2013).

Metabolite XI (O-desmethyl omethoate) was found to be a weak choline esterase inhibitor in the acute toxicity study indicating that it is less acutely toxic than dimethoate (EFSA, 2006). In 2013, EFSA noted that a toxicological assessment would be required and a data gap was identified for this metabolite, in particular for uses on crops that undergo heat treatment (EFSA, 2013). Thus, data that enable the assessment of the chronic toxicity profile of metabolite XI, including genotoxicity, reproductive and developmental toxicity would be needed to conclude on its toxicological profile.

Metabolite XII: Data were presented in the framework of the confirmatory data assessment to demonstrate that it is less acutely toxic than dimethoate (at least 200 times lower acute toxicity), based on acute toxicity studies measuring acetylcholinesterase inhibition. However, EFSA concluded that data needed to assess the chronic toxicity profile of metabolite XII, including genotoxicity, reproductive and developmental toxicity are still missing (EFSA, 2013).

Metabolite XV was not expected to be a choline esterase inhibitor considering its chemical structure (EFSA, 2006).

Metabolise XX: Data were presented in the framework of confirmatory data assessment to demonstrate that this metabolite is less acutely toxic than dimethoate (at least 200 times less toxic), based on acute toxicity studies measuring acetylcholinesterase inhibition. No studies were provided that enable conclusions on the relative chronic toxicity compared with dimethoate. Further information to address the chronic toxicity profile of metabolite XX, including genotoxicity, reproductive and developmental toxicity is required (EFSA, 2013).

Metabolite XXIII (O-desmethyl-N-desmethyl omethoate) has no anticholinesterase activity in the rat on the basis of toxicological testing at 30 mg/kg bw (EFSA, 2006). In 2013, EFSA noted that a toxicological assessment would be required and a data gap was identified for this metabolite (EFSA, 2013). Thus, data that enable the assessment of the chronic toxicity profile of metabolite XXIII, including genotoxicity, reproductive and developmental toxicity would be needed to conclude on its toxicological profile.

6. Residue definitions

6.1. Residue definitions for risk assessment

Considering the results of metabolism studies indicating that metabolite XX, XII and III are present in amounts significantly higher than dimethoate and omethoate in cereal grains and in leafy parts of treated crops, EFSA proposed in 2006 that the risk assessment residue definition should comprise dimethoate, omethoate and, depending on their relative toxicity, metabolites XX, XII and III also. Pending the data on the toxicity of metabolites XX, XII and III, two provisional residue definitions for acute and chronic risk assessment were proposed taking into account that both compounds share a common toxicological mode of action but with different potencies:

- 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).

For animal products, the following residue definitions for acute and chronic risk assessment have been proposed in 2006:

- 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)

For processed products, metabolites X and XI should also be considered as potential candidates for inclusion in the residue definition for risk assessment (EFSA, 2013).

In conclusion, it is highlighted that the residue definitions derived in 2006 are still considered as provisional, since the requested toxicological data for all metabolites having a potential for contributing to the overall dietary burden are not yet available. A final conclusion on the risk assessment residue definitions can be derived when the toxicological data gaps described in Section 5 are addressed with appropriate data.

6.2. Residue definitions for enforcement purpose

For plant commodities, the peer review concluded that the residue definition for enforcement can be set separately as:

- Dimethoate and
- Omethoate (EFSA, 2006).

This residue definition has not yet been implemented in Regulation (EC) No 396/2005; the current enforcement residue definition is:

- Dimethoate (sum of dimethoate and omethoate expressed as dimethoate.

For animal products, the peer review proposed the same residue definition as for plant products (EFSA, 2006). Currently, no legal limits are set for animal products.

For processed products, no specific residue definitions for enforcement were proposed; the residue definitions for raw commodities should be applied (EFSA, 2006).

In conclusion, EFSA still supports the approach of setting separate residue definitions for compounds with significantly different toxicological properties. A combined residue definition for the sum of dimethoate and omethoate does not enable one to derive a conclusion on whether the residues detected in MRL enforcement are likely to pose a consumer health risk triggering risk management actions, as there is the uncertainty whether the detected residues refer to the more toxic omethoate or the less toxic dimethoate. Even if the individual components of the residue definition are analysed separately, a sample might be found to be compliant with the MRL, but may lead to exceedances of the ARfD (see also Section 9.2). In addition, the enforcement residue definition should comprise

suitable marker substances that allow the derivation of robust conversion factors for the risk assessment.

Lacking information on the residue concentrations for the additional metabolites described in the previous section and the information on the relative potency of these metabolites, a final decision on the most appropriate enforcement residue definition can be derived only, once all these data gaps are closed.

7. Basis for existing MRLs set in the EU

EFSA does not have detailed information on the authorised GAPs and the residue trials for dimethoate and omethoate that were the basis for setting the current EU MRLs. Thus, EFSA cannot verify whether the existing EU MRLs were set at a level ensuring that crops treated in compliance with the authorised GAP would contain residues compliant with the MRL.

8. Monitoring results on dimethoate and omethoate

Among the 60,910 samples analysed for dimethoate residues in 2013, 258 samples (0.4%) exceeded the legal limits. 91 of these samples originated from EU Member States (EFSA, 2015b). This high MRL exceedance rate for EU products may be the result of frequent misuse of dimethoate containing plant protection products or give an indication that the current legal limits were set at inappropriate levels.

The detailed evaluation of the monitoring results of 2014 is not yet completed. However, the first analysis of the 2014 monitoring data showed a similar picture. In total, 63,778 samples were analysed for dimethoate residues. In 493 samples (0.8%), dimethoate residues were detected in concentrations greater than the limit of quantification (LOQ); in 203 (0.3%) of these samples the residues exceeded the legal limit.

As regards the crops for which EFSA agreed with the European Commission to perform an acute risk assessment (see Background and Terms of Reference), 6,459 samples were analysed in 2014 for the legal enforcement residue definition (i.e. sum of dimethoate and omethoate, expressed as dimethoate). The majority of results referred to carrots (1,696 samples), head cabbage (580 samples), cherries (566 samples), olives for oil production (559 samples); in addition, samples of asparagus, garlic, celeries, celeriac, Brussels sprouts, witloofs, turnips, shallots, table olives, sugar beet roots, chicory roots and certain herbs were analysed (Table 3).

Dimethoate residues were detected in 194 samples in 12 of the crops in focus for this assessment. The legal limits were exceeded in 36 samples (0.6% of the samples analysed for dimethoate). Details on the number of samples with detectable residues, and the MRL exceedance rates are presented in the table below.

Table 3: Summary of the 2014 monitoring results for dimethoate (RD) provided by EU Member States, Norway and Iceland on the selected crops (agreed with the European Commission)[9]

Crops	No of samples analysed	No of samples with residues > LOQ	% detection rate	No of samples with residues > MRL	% MRL exceedance rate
Carrots	1696	8	0.5	4	0.2
Cherries	566	139	26.4	14	2.5
Head cabbages	580	7	1.2	1	0.2
Olives for oil production	559	13	2.3	0	0.0
Onions	470	0	0.0	0	0.0
Asparagus	460	0	0.0	0	0.0
Basil and edible flowers	390	2	0.5	2	0.5
Garlic	319	2	0.6	0	0.0
Celeries	286	4	1.4	3	1.0

[9] As the assessment of the 2014 monitoring data is not yet completed, the results presented in this table should be considered as provisional. Minor changes may be expected following the detailed assessment of the data.

Crops	No of samples analysed	No of samples with residues > LOQ	% detection rate	No of samples with residues > MRL	% MRL exceedance rate
Celeriac	250	6	2.4	0	0.0
Celery leaves	151	1	0.7	1	0.7
Brussels sprouts	141	0	0.0	0	0.0
Parsley	140	1	0.7	1[(a)]	0.7
Witloofs	133	0	0.0	0	0.0
Turnips	70	8	10.4	7	10.0
Shallots	77	0	0.0	0	0.0
Table olives	45	0	0.0	0	0.0
Bay leave	34	3	8.8	3	8.8
Thyme	22	0	0.0	0	0.0
Chives	18	0	0.0	0	0.0
Rosemary	15	0	0.0	0	0.0
Sugar beet roots	12	0	0.0	0	0.0
Tarragon	11	0	0.0	0	0.0
Chervil	8	0	0.0	0	0.0
Sage	4	0	0.0	0	0.0
Chicory roots	2	0	0.0	0	0.0

(a) A RASFF notification was made for this parsley sample originating from Romania.

Among the crops assessed, the highest MRL exceedance rates were noted for turnips (3 samples originating from Belgium, 1 sample from Italy, 3 samples with unknown origin), bay leaves (all from Dominican Republic), cherries (6 samples from France, 3 from Germany, 2 from the Netherlands, 1 sample from Italy, Belgium and Greece, respectively) and celeries (2 samples from Belgium, 1 sample from France).

In the framework of this request to assess dimethoate residues, France reported the results of the national control programme for cherries of 2014 and 2015 (France, 2016). The results are summarised in the Table 4.

Table 4: Summary of the French monitoring results for dimethoate (RD) 2014 and 2015 in cherries

Year/crop	No of samples analysed[(a)]	No of samples with residues > LOQ	% detection rate	No of samples with residues > MRL	% MRL exceedance rate
2014 Cherries	36	27	75	3	8.3
2015 Cherries	30	19	63	1	3.3

(b) Samples taken in accordance with Directive 2002/63

Comparing the results of the overall EU monitoring with the results for the French monitoring in cherries, it becomes evident that in 2014 and 2015 dimethoate was frequently used in French cherry production, leading almost 3-times higher detection rates. In addition, the MRL exceedance rate seems to be significantly higher in France.

Based on these findings, EFSA concludes that there is some evidence that for food products produced in Europe dimethoate is a pesticides leading frequently to MRL exceedances. The reason for the non-compliances should be further elucidated by more detailed analysis of the results and follow-up actions of the competent national authorities responsible for MRL enforcement. If a misuse of dimethoate can be excluded, these findings suggest that for certain corps like cherries, turnips or celery the current EU MRLs have been set at inappropriate levels. Thus, a review of the existing MRLs would be required to ensure that the MRLs reflect the residue levels expected under Good Agricultural Practices and are sufficiently protective for consumers considering also the residues of relevant metabolites.

9. Consumer risk assessment

In the framework of the peer review (EFSA, 2006, 2013) only provisional risk assessments could be carried out for the representative uses (i.e. wheat, olives, sugar beets, tomatoes and lettuce in 2006, sugar beet and lettuce in 2013), considering only dimethoate and omethoate; information on the other relevant metabolites (magnitude of residues, relative toxicity of the metabolites) or residues in other commodities were not available or relevant in the context of the peer review. These risk assessments are therefore not representative for the actual residues occurring in food placed on the European market.

Also in the framework of previously assessed MRL applications, the risk assessments were of provisional nature, due to these data gaps.

In order to conclude on the safety of the use of dimethoate in food, the following information would be required:

- Comprehensive list of authorised uses in the EU;
- GAPs for the use of dimethoate and omethoate in third countries for which import tolerances are requested/required;
- Toxicological data that allow to decide which metabolites need to be included in the residue definitions for acute and chronic risk assessment;
- Toxicity of the metabolites relevant for risk assessment resulting from the use of dimethoate (e.g., toxicity equivalence factors (TEFs)) for acute and chronic risk assessment to compare the toxicity of the metabolite with the toxicity of dimethoate;
- Supervised filed trials to estimate the residue concentrations of the parent compound and the relevant dimethoate metabolites in treated crops;
- Processing studies to derive the residue concentrations of the parent compound and of relevant dimethoate metabolites in processed products;
- Feeding studies to derive residue concentrations of dimethoate and omethoate in food of animal origin.

On 1 April 2016, Italy confirmed that the supplementary dossier for the renewal of the approval had been submitted to Italy as Rapporteur Member State but was still under admissibility check, and therefore not distributed to EFSA, other MSs and the European Commission. Consequently EFSA cannot check at this moment if the additional information required for conducting a proper consumer risk assessment as listed above has been submitted in the supplementary dossier.

In order to perform the assessment as agreed with the European Commission, EFSA calculated the following risk assessment scenarios:

- An acute risk assessment screening on the basis of MRLs without refinements (dimethoate scenario and omethoate scenario);
- An acute risk assessment on the basis of monitoring data for the crops that were explicitly mentioned in the note of the French authorities;
- A chronic risk assessment screening on the basis of MRLs without refinements (dimethoate scenario and omethoate scenario);

In addition, EFSA refers to a previously performed chronic risk assessment that was calculated in the framework of an MRL application.

9.1. Acute risk assessment screening on the basis of MRLs

The existing EU MRLs were used as input values in the EFSA PRIMo rev. 2 (EFSA, 2007); the calculated short term exposure was then compared with the ARfD of dimethoate (dimethoate scenario) and the ARfD of omethoate (omethoate scenario). The results of the omethoate scenario are expected to overestimate the real exposure because it is based on the assumption that all commodities covered by the EFSA PRIMo contain exclusively residues of omethoate at the legal limit,

which is not very likely. The dimethoate scenario, however, may underestimate the risk because the presence of the more toxic omethoate in treated crops is not taken into account.

In the dimethoate scenario no exceedance of the ARfD was noted. The highest exposure (expressed as percentage of the ARfD) was calculated for spring onions (91%), followed by table olives (67%), fennel seed (36%), potatoes (31%) and melons (30%). Cherries accounted for 25% of the ARfD.

In the omethoate scenario, the ARfD was exceeded for ten commodities (i.e. spring onions (457%), table olives (337%), fennel seed (180%), potatoes (154%), melons (152%), oranges (133%), olives for oil production (128%), cherries (122%), watermelons (122%) and pineapples (101%). It should be highlighted that the MRLs for potatoes, melons, oranges, watermelons and pineapples are set at the LOQ. Thus, if a no-use/no-residue situation can be confirmed for these crops, the calculations could be revised. For the remaining crops, options for further refined intake calculations would be required, e.g. ratio of dimethoate/omethoate, peeling factors etc. Lacking detailed information on the use patterns and the respective residue trials, EFSA is currently not in a position to perform these calculations.

The details of the calculations are presented in the Appendix F.

9.2. Acute risk related to dimethoate residues found in monitoring samples

For the acute risk assessment for the agreed crops (cherries, asparagus, chicory roots, head cabbage, Brussels sprouts, carrots, turnips, onions, garlic, shallots, celery, celeriac, herbs, sugar beets, olives) EFSA used the 2014 monitoring data; to derive the input values for the risk assessment the following approach was applied:

- The acute exposure was calculated only for the 194 samples with detectable residues of dimethoate (sum of dimethoate and omethoate, expressed as dimethoate);
- In 48 samples of these 194 samples, the results were reported not only according to the legal residue definition, but also the concentrations of the individual components. In additional 36 samples the total residues and one of the components was reported, with the second component of the complex residue definition being at the LOQ. For samples where the residue concentrations were reported separately for dimethoate and omethoate, the short-term exposure was calculated according to the risk assessment residue definition (sum of dimethoate and 6 times omethoate);
- If only one component occurred in concentrations above the LOQ, for the second component it was assumed that the residue concentration was occurring at the numerical value of the LOQ; the input value was again calculated as the sum of dimethoate and 6 times omethoate;
- For samples were only the total dimethoate residues were reported, without information on the individual components, EFSA assumed that the ratio of dimethoate/omethoate was 1[10];
- The short-term exposure was calculated with the EFSA PRIMo rev. 2 (EFSA, 2007); the results are expressed as percentage of the ARfD of dimethoate.

The details of the monitoring results for cherries are presented in Appendix E.

The results reflecting the estimated exposure for the 12 different commodities with detectable residues are presented in Figure 1.

The estimated short-term exposure exceeded the ARfD in 21 samples, all originating from the EU (13 samples of cherries, three samples of carrots, three samples of celeries and two samples of turnips). The highest exposure was calculated for a sample of cherries that was found to exceed the legal limit (1 mg/kg, 627% of the ARfD). Most of the exceedances of the ARfD were related to samples that contained residues exceeding the legal limit. However, it should be highlighted that a potential short-term risk was identified also for two cherry samples where the residues according to the legal residue

[10] The 2014 monitoring data in cherries with results reported for dimethoate and omethoate separately were analysed in more detail to derive a ratio of dimethoate/omethoate. Based on these data, a median ratio of 1 was derived. However, considering the wide spread of the results, this ratio is an assumption that in reality may differ significantly. This factor should therefore be considered as a source of uncertainties.

definition were within the permitted level (0.16 mg/kg and 0.19 mg/kg leading to acute exposure of 106% and 114% of the ARfD, respectively).

Similar observations were reported by France (France, 2016) concerning not only the 2014 monitoring results on cherries, but also for one sample of the 2015 monitoring.

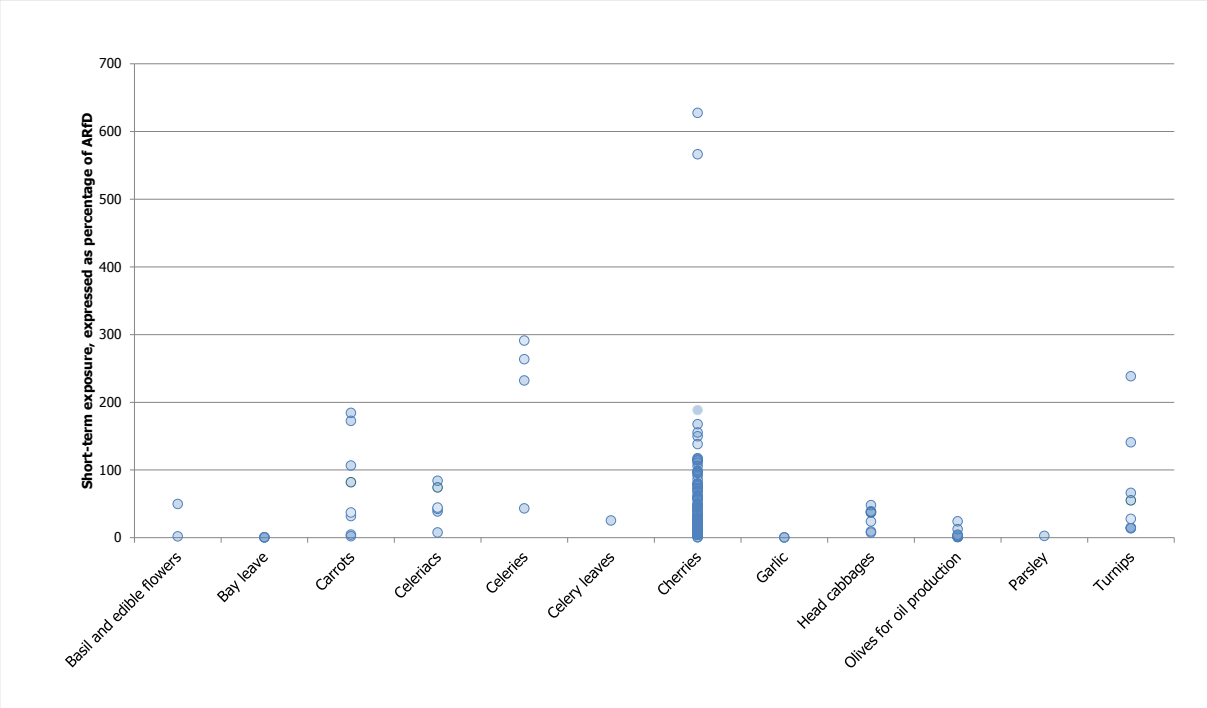

Figure 1: Result of the acute risk assessment for a selected group of commodities based on monitoring data 2014

9.3. Chronic risk assessment screening on the basis of MRLs

The existing EU MRLs[11] were used as input values in the EFSA PRIMo rev. 2; the calculated long-term exposure was then compared with the ADI of dimethoate (dimethoate scenario) and the ADI of omethoate (omethoate scenario). Both scenarios are expected to grossly overestimate the real exposure because it is based on the assumption that all commodities covered by the EFSA PRIMo contain residues of dimethoate or omethoate at the legal limit, which is not very likely. According to the internationally agreed methodology for long-term exposure assessment the STMR value derived from supervised residue trials should be used in such a calculation. Lacking the information on the actual use pattern and the residue concentrations expected in treated crops, EFSA calculated this screening to provide risk managers additional information on possible safety margins.

In the dimethoate scenario, the estimated exposure exceeded the ADI for seven diets accounting for up to 517% of the ADI; the main contributors in these calculations were olives for oil production, wheat and table olives. MRLs at the LOQ contributed approximately 50% to the long term exposure in the most critical diet.

In the omethoate scenario the ADI was exceeded for 23 diets; the highest estimated exposure accounted for over 1700% of the omethoate ADI.

Considering the results, it is concluded that more refined calculations would be required, taking into account the information on authorised uses and the related residues of dimethoate, omethoate and other relevant metabolites. Based on the screening calculations, a chronic intake concern cannot be excluded.

[11] The MRL of 1 mg/kg for sugar beet was not used for the calculation of the long-term exposure, considering that the residues in sugar will be negligible.

9.4. Results of a previously performed chronic risk assessment

In 2011, in the framework of an MRL application, EFSA performed an indicative chronic risk assessment which was based on the limited information available; making several assumptions that are described in detail in the reasoned opinion of EFSA (EFSA, 2011). Overall, the calculations were affected by a high level of uncertainties, due to the lack of information listed in the introduction to Section 9.

Since no new data became available, EFSA cannot perform a more accurate risk assessment at the moment. The estimated chronic intake in the scenario described in the 2011 EFSA reasoned opinion accounted for 87% of the ADI. The contribution of residues in the crops for which France expressed a concern (exposure as percentage of the ADI) accounted for a maximum of 5.8% for cherries (DE child diet), 5% for head cabbage, 0.7% for olives for oil production and 0.5% for table olives.

Although the estimated exposure did not exceed the ADI, the results cannot be used as a proof that there is no potential long-term consumer risk related to dimethoate, because the calculations did not take into account the contribution of the additional metabolites and other relevant information described earlier.

Considering the short timelines to finalise this statement, no chronic risk assessment based on monitoring data could be performed.

10. Conclusions and recommendations

Based on the limited information available to EFSA at the moment, a potential long-term consumer health risk resulting from residues related to the use of dimethoate containing plant protection products cannot be excluded. High exceedances of the ADI are observed in the screening chronic assessments using the MRLs, however, there are indications that the exposure related to the parent compound and omethoate may not exceed the ADI, taking into account information that can be used for refinement of the intake calculation (see Section 9.4). As essential information on the actual uses approved in the EU and the occurrence of additional metabolites that may contribute to the overall long-term exposure is not available at the moment, these calculations cannot be understood as a proof that dimethoate related residues are not posing a long-term consumer health risk.

As regards the acute risk resulting from all dimethoate related residues in the crops under consideration, a final conclusion cannot be derived without the detailed information on the occurrence of residues of dimethoate, omethoate and other relevant metabolites present on crops treated in accordance with the Good Agricultural Practices.

As regards dimethoate and omethoate residues, there is currently no evidence of consumer risks for asparagus, chicory roots, head cabbage, Brussels sprouts, onions, garlic, shallots, celeriac, herbs, based on the risk assessment screening and the analysis of pesticide monitoring data. The contribution of other relevant metabolites may alter the outcome of this assessment. The risk assessment screening however indicated that the current MRLs set for a number of crops (i.e. spring onions, table olives, fennel seed, potatoes, melons, oranges, olives for oil production, cherries, watermelons, and pineapples) for the current legal residue definition are probably not sufficiently protective for consumers. A more detailed risk assessment would be required to confirm or reject the possible concerns.

Most of the cases, where a possible short-term consumer health risk was identified for products analysed in monitoring programmes, were related to MRL exceedances. However, there were also cases where the products analysed were compliant with the legal limit, but the risk assessment focussing on dimethoate and omethoate only already indicated a consumer health concern. Thus, this gives an indication that the current residue definition for enforcement (sum of dimethoate and omethoate) is not sufficiently protective for consumers. As proposed in previous EFSA outputs, the setting of separate residue definitions for compounds with significantly different toxicological properties would be more appropriate.

The French observation that the results of the pesticide monitoring programmes show a higher MRL exceedance rate for dimethoate compared with other pesticides is confirmed by EFSA. The reasons for these findings are not completely clear; possible explanations are:

- Use of dimethoate containing plant protection products not respecting the authorised Good Agricultural Practices;
- The existing MRLs are set at inappropriate levels; thus, if farmers us the products in accordance with the Good Agricultural Practices, the harvested products may contain residues exceeding the legal limit.

In order to elucidate the reasons for the increased frequency of MRL exceedances, the competent national authorities should establish follow-up actions at the level of the pesticide users. If a misuse of dimethoate can be excluded, these findings suggest that for certain corps the current EU MRLs are set at inappropriate levels.

EFSA concludes that a comprehensive review of the existing EU MRLs would be appropriate. This review is planned under Article 12 of Regulation (EC) No 396/2005. However, for this review the following information would be required:

- Toxicological data that allow to decide which metabolites need to be included in the residue definitions for acute and chronic risk assessment;
- Toxicity of the metabolites relevant for risk assessment resulting from the use of dimethoate (e.g. toxicity equivalence factors (TEFs)) for acute and chronic risk assessment to compare the toxicity of the metabolite with the toxicity of dimethoate;
- Comprehensive list of authorised uses in the EU;
- GAPs for the use of dimethoate and omethoate in third countries for which import tolerances are requested/required;
- Supervised filed trials to estimate the residue concentrations of the parent compound and the relevant dimethoate metabolites in treated crops;
- Processing studies to derive the residue concentrations of the parent compound and of relevant dimethoate metabolites in processed products;
- Feeding studies to derive residue concentrations of dimethoate and omethoate in food of animal origin.

Some of the information required, in particular toxicological data on the relevant metabolites, may have been submitted to the RMS with the supplementary dossier for the renewal of the approval under Regulation (EC) No 1107/2009. The RMS should be contacted to verify if the required information is already available. The toxicological information would be required to initiate a comprehensive MRL review, including the decision on the most appropriate residue definitions and the TEFs. Following agreement on the residue definitions, the remaining data (e.g. supervised field trials on crops with registered GAPs covering all components of the residue definitions) need to be assessed in detail.

EFSA considers that due to the large uncertainties of this assessment, a science-driven dialogue with risk managers on the seriousness of the identified potential risks is not feasible at this moment.

A risk management decision needs to be taken whether the current evidence on possible consumer risks related to dimethoate residues (including metabolites) requires other measures which would have an immediate effect.

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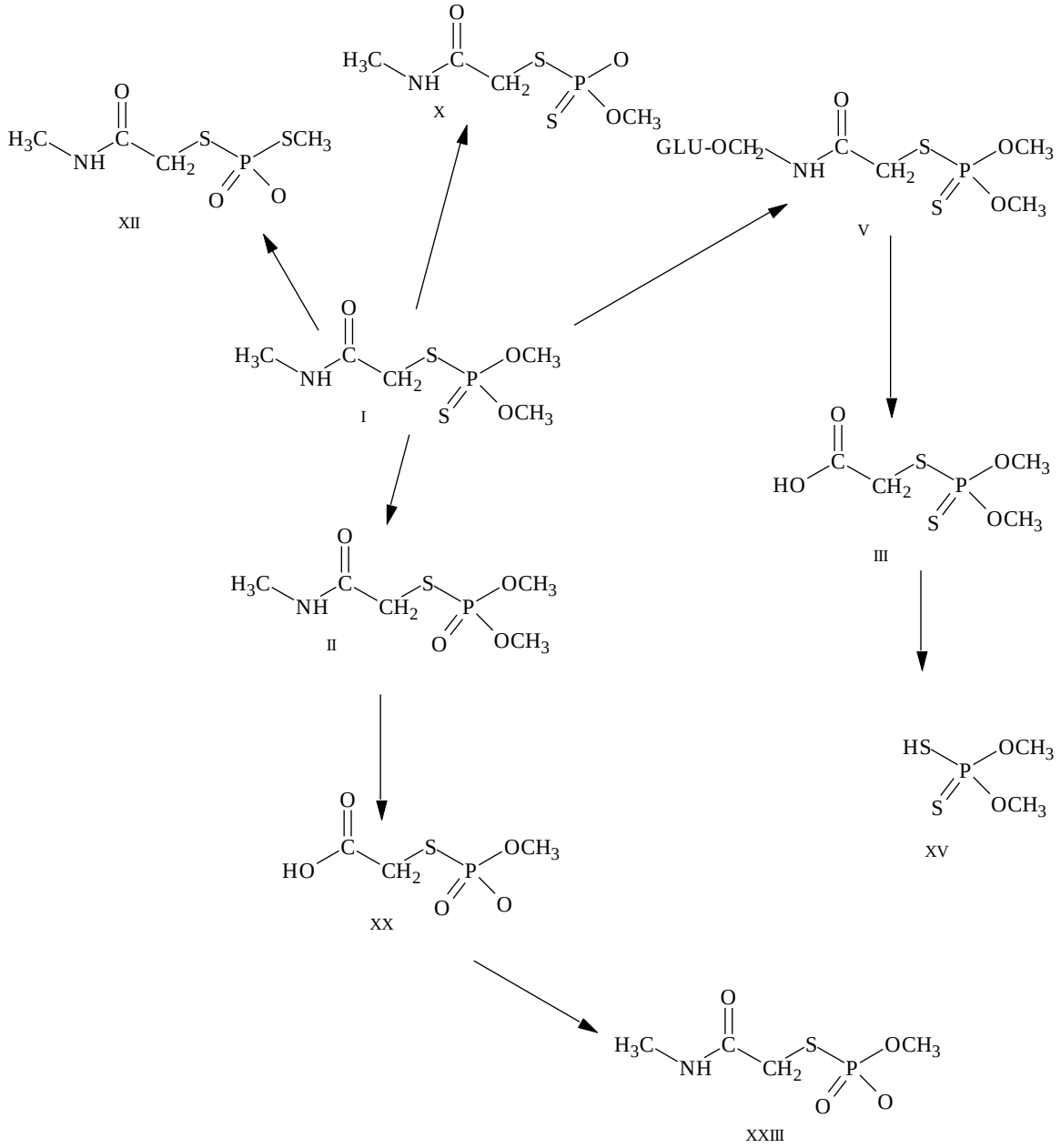
Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
GAP	Good Agricultural Practice
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State

Appendix A – Metabolic pathway in plants and domestic animals



Metabolite		Metabolite	
I	Dimethoate	XI	O-desmethyl omethoate
II	Omethoate	XII	Des-O-methyl dimethoate
III	Dimethoate carboxylic acid	XV	dimethyl dithiophosphate
V	Conjugate of hydroxy dimethoate	XX	O-desmethyl omethoate carboxylic acid
X	desmethyl dimethoate	XXIII	O-desmethyl N-desmethyl omethoate

Source: Draft Assessment Report (DAR) on dimethoate (United Kingdom, 2004)

Appendix B – Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 30/03/2016)

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)
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*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	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), pomerac, rose apple, Brazilean 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*
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*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
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 (Scorzonera, 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*
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 corn	0.02*
239000	(e) Other fruiting vegetables	0.02*
240000	(iv) Brassica vegetables	0.02*
241000	(a) Flowering brassica	0.02*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.02*
241020	Cauliflower	0.02*
241990	Others	0.02*
242000	(b) Head brassica	0.02*
242010	Brussels sprouts	0.02*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.02*
242990	Others	0.02*
243000	(c) Leafy brassica	0.02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0.02*
243020	Kale (Borecole (curly kale), collards)	0.02*
243990	Others	0.02*
244000	(d) Kohlrabi	0.02*
250000	(v) Leaf vegetables & fresh herbs	0.02*
251000	(a) Lettuce and other salad plants including Brassicacea	0.02*
251010	Lamb´s lettuce (Italian cornsalad)	0.02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0.02*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved 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, glassworth)	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 cisely 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*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
256080	Basil (Balm leaves, mint, peppermint)	0.02*
256090	Bay leaves (laurel)	0.02*
256100	Tarragon (Hyssop)	0.02*
256990	Others	0.02*
260000	(vi) Legume vegetables (fresh)	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*
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*
500020	Buckwheat	0.02*
500030	Maize	0.02*
500040	Millet (Foxtail millet, teff)	0.02*
500050	Oats	0.02*
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 Camellia sinensis)	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

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
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
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*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
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	
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	

Code number	Groups and examples of individual products to which the MRLs apply	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)
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 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).

Appendix C – CXLs for dimethoate

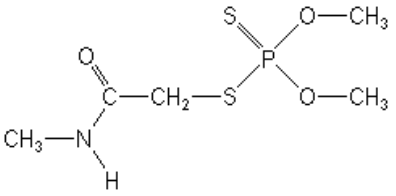
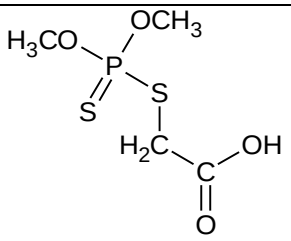
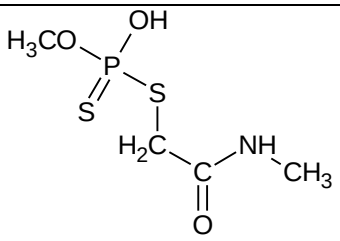
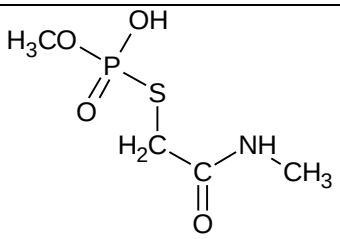
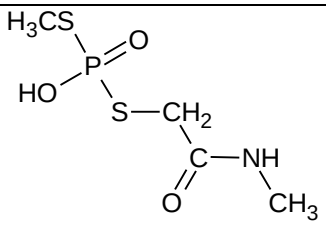
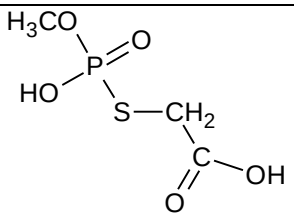
Commodity	MRL	Year of Adoption	Symbol	Note
Artichoke, Globe	0.05 mg/Kg	2005		
Asparagus	0.05 mg/Kg	2003	(*)	
Barley	2 mg/Kg	2006		
Brussels sprouts	0.2 mg/Kg	2005		
Cabbage, Savoy	0.05 mg/Kg	2003	(*)	
Cattle, Edible offal of	0.05 mg/Kg	2003	(*)	
Cauliflower	0.2 mg/Kg	2005		
Celery	0.5 mg/Kg	2005		
Cherries	2 mg/Kg			
Citrus fruits	5 mg/Kg	2013		(excluding kumquats)
Eggs	0.05 mg/Kg	2003	(*)	
Lettuce, Head	0.3 mg/Kg	2009		
Mammalian fats (except milk fats)	0.05 mg/Kg	2003	(*)	
Mango	1 mg/Kg	2005	Po	
Meat of cattle, goats, horses, pigs & sheep	0.05 mg/Kg	2003	(*)	
Milk of cattle, goats & sheep	0.05 mg/Kg	2003	(*)	
Olives	0.5 mg/Kg	2005		
Pear	1 mg/Kg	1991		
Peas (pods and succulent=immature seeds)	1 mg/Kg	2005		
Peppers Chili, dried	3 mg/Kg	2009		
Peppers, Sweet (including pimento or pimiento)	0.5 mg/Kg	2009		
Potato	0.05 mg/Kg			
Poultry fats	0.05 mg/Kg	2003	(*)	
Poultry meat	0.05 mg/Kg	2003	(*)	
Poultry, Edible offal of	0.05 mg/Kg	2003	(*)	
Sheep, Edible offal of	0.05 mg/Kg	2003	(*)	
Spices, Fruits and Berries	0.5 mg/Kg	2005		
Spices, Roots and Rhizomes	0.1 mg/Kg	2005	(*)	
Spices, Seeds	5 mg/Kg	2005		
Sugar beet	0.05 mg/Kg			
Turnip greens	1 mg/Kg	2005		
Turnip, Garden	0.1 mg/Kg	2005		
Wheat	0.05 mg/Kg	2005		
Wheat straw and fodder, Dry	1 mg/Kg	2005		

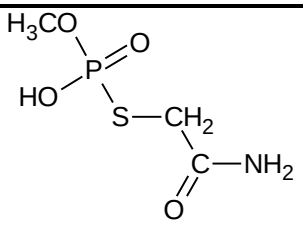
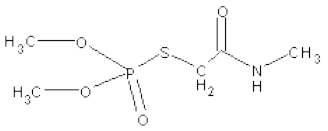
(*): At or about the limit of determination.
Po: The MRL accommodates post-harvest treatment of the commodity.

Other information
JMPR-related information

ADI/PTDI:	0.002 mg/kg body weight for sum of dimethoate and omethoate expressed as dimethoate (1996)
Residue definition:	For compliance with MRLs: dimethoate. For estimation of dietary intake: dimethoate and omethoate.

Appendix D – Used compound codes

Code/Trivial name*	Chemical name**	Structural formula**
Dimethoate	*O,O*-dimethyl *S*-methylcarbamoylmethyl phosphorodithioate or 2-dimethoxyphosphinothioylthio-*N*-methylacetamide	
Metabolite III *dimethoate carboxylic acid*	[(dimethoxyphosphorothioyl)sulfanyl] acetic acid	
Metabolite X *desmethyl dimethoate*	*O*-methyl *S*-[2-(methylamino)-2-oxoethyl] hydrogen phosphorodithioate	
Metabolite XI *O-desmethyl omethoate*	*O*-methyl *S*-[2-(methylamino)-2-oxoethyl] hydrogen phosphorothioate	
Metabolite XII *des-O-methyl isodimethoate*	*S*-methyl *S*-[2-(methylamino)-2-oxoethyl] hydrogen phosphorodithioate	
Metabolite XX *O-desmethyl-omethoate-carboxylic acid*	{[hydroxy(methoxy)phosphoryl]sulfanyl} acetic acid	

Code/Trivial name*	Chemical name**	Structural formula**
Metabolite XXIII *O-desmethyl-N-desmethyl omethoate*	*S*-(2-amino-2-oxoethyl) *O*-methyl hydrogen phosphorothioate	
Omethoate	2-dimethoxyphosphinoylthio-*N*-methylacetamide	

* The metabolite name in bold is the name used in the conclusion.

** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

Appendix E – 2014 monitoring results for dimethoate (RD) and result of acute risk assessment for cherries

Origin of the sample	Sum of dimethoate and omethoate (expressed as dimethoate)	Omethoate (mg/kg)	Dimethoate (mg/kg)	Exposure (as % of ARfD)
France	1	0.83	0.15	627.4
France	0.89	0.76	0.07	566.2
Belgium	0.34	0.24	0.1	188.3
Italy	0.83	0.11	0.71	167.6
France	0.33	0.19	0.13	155.3
Germany	0.35			149.8
France	0.44	0.14	0.29	138.2
Greece	0.84	0.02[(a)]	0.84	117.4
Netherlands	0.36	0.12	0.23	116.2
Germany	0.268			114.7
France	0.19	0.15	0.03	113.7
Netherlands	0.22	0.14	0.067	110.9
France	0.16	0.14	0.024	105.7
Germany	0.23			98.5
France	0.26	0.11	0.14	97.8
Greece	0.16	0.13	0.02	97.8
France	0.19	0.12	0.063	95.8
France	0.24	0.11	0.12	95.4
Belgium	0.15	0.12	0.028	91.5
Romania	0.2			85.6
France	0.16	0.1	0.054	80.0
Germany	0.186			79.6
France	0.16	0.1	0.048	79.3
Canada	0.184			78.8
France	0.14	0.099	0.029	76.2
Belgium	0.11	0.097	0.014	72.9
Greece	0.1694			72.5
Germany	0.162			69.3
France	0.17	0.074	0.1	66.5
Germany	0.144			61.6
Belgium	0.081	0.081	0.01[(a)]	60.7
Germany	0.14			59.9
Germany	0.138			59.1
Germany	0.134			57.4
France	0.095	0.073	0.016	55.5
Germany	0.117			50.1
Belgium	0.077	0.065	0.012	49.2
France	0.088	0.061	0.022	47.5
Belgium	0.061	0.061	0.01[(a)]	46.0
France	0.1	0.054	0.047	45.4
Belgium	0.08	0.06	0.011	45.4
Serbia	0.103			44.1
Germany	0.103			44.1
Germany	0.1			42.8
Germany	0.1			42.8
Germany	0.1			42.8
Germany	0.1			42.8
Germany	0.096			41.1
Germany	0.095			40.7
Germany	0.095			40.7
Italy	0.08	0.05	0.03	40.4
Germany	0.094			40.2
Germany	0.094			40.2
Germany	0.086			36.8
Belgium	0.081			34.7
Italy	0.062	0.042	0.017	32.9

Origin of the sample	Sum of dimethoate and omethoate (expressed as dimethoate)	Omethoate (mg/kg)	Dimethoate (mg/kg)	Exposure (as % of ARfD)
Germany	0.074			31.7
France	0.05	0.04	0.01[(a)]	30.6
France	0.045	0.04	0.01[(a)]	30.6
Spain	0.04	0.04	0.01[(a)]	30.6
Italy	0.04	0.04	0.01[(a)]	30.6
Germany	0.07			30.0
Belgium	0.039	0.039	0.01[(a)]	29.8
Germany	0.064			27.4
Germany	0.062			26.5
Germany	0.062			26.5
Germany	0.0614			26.3
Germany	0.06			25.7
Germany	0.058			24.8
Italy	0.03	0.03	0.01[(a)]	23.2
Unknown	0.052			22.3
Italy	0.051			21.8
Spain	0.05			21.4
Germany	0.05			21.4
Germany	0.05			21.4
Germany	0.046			19.7
Belgium	0.024	0.024	0.01[(a)]	18.8
Unknown	0.044			18.8
Germany	0.043			18.4
Spain	0.04			17.1
Germany	0.04			17.1
Germany	0.04			17.1
Italy	0.039			16.7
France	0.053	0.017	0.034	16.6
France	0.023	0.021	0.01[(a)]	16.6
France	0.047	0.017	0.029	16.0
Italy	0.02	0.02	0.01[(a)]	15.9
Italy	0.035	0.018	0.016	15.2
Serbia	0.033	0.018	0.014	14.9
Germany	0.034			14.6
Germany	0.034			14.6
Germany	0.033			14.1
Germany	0.0323			13.8
Belgium	0.016	0.016	0.01[(a)]	13.0
Germany	0.03			12.8
Germany	0.03			12.8
Germany	0.03			12.8
Germany	0.029			12.4
France	0.015	0.015	0.01[(a)]	12.2
Germany	0.028			12.0
Italy	0.027			11.6
Spain	0.029	0.013	0.015	11.4
Germany	0.025			10.7
Germany	0.025			10.7
Italy	0.027	0.01[(a)]	0.027	10.6
Germany	0.023			9.8
Unknown	0.023			9.8
Italy	0.03	0.01	0.02	9.8
Italy	0.02	0.01	0.01	8.6
Germany	0.02			8.6
Italy	0.01	0.01[(a)]	0.01	8.6
Italy	0.01	0.01[(a)]	0.01	8.6
Italy	0.01	0.01[(a)]	0.01	8.6
Germany	0.018			7.7
Germany	0.018			7.7
Poland	0.018			7.7
Germany	0.0172			7.4
Germany	0.0172			7.4
Germany	0.017			7.3
Romania	0.015			6.4

Origin of the sample	Sum of dimethoate and omethoate (expressed as dimethoate)	Omethoate (mg/kg)	Dimethoate (mg/kg)	Exposure (as % of ARfD)
Germany	0.014			6.0
Unknown	0.014			6.0
Germany	0.013			5.6
Germany	0.013			5.6
Germany	0.012			5.1
Unknown	0.012			5.1
Germany	0.0118			5.1
Germany	0.011			4.7
Germany	0.011			4.7

(a) Result <LOQ

Origin of the sample	Sum of dimethoate and omethoate (expressed as dimethoate)	Omethoate (mg/kg)	Dimethoate (mg/kg)	Exposure (as % of ARfD)
Germany	0.0108			4.6
Germany	0.01			4.3
Italy	0.01			4.3
Serbia	0.01			4.3
Turkey	0.01			4.3
Germany	0.01			4.3
France	0.01			4.3
Germany	0.002			0.9
Italy	0.001			0.4

Appendix F – Results of risk assessment screening

Dimethoate

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.001**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2006**	Year of evaluation:	**2006**

the calculations were performed with the MRLs set for dimethoate, without refinement.

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

The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
21	518
No of diets exceeding ADI:	7

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
518.2	WHO Cluster diet B	383.3	Olives for oil production	42.7	Wheat	16.0	Table olives	52.2
206.0	ES child	146.5	Olives for oil production	22.2	Wheat	8.8	Table olives	23.2
123.4	ES adult	84.4	Olives for oil production	11.7	Wheat	6.8	Table olives	17.8
123.2	PT General population	51.0	Olives for oil production	19.6	Wheat	11.0	Table olives	36.5
117.8	DE child	25.4	Pome fruit	20.6	Wheat	9.9	Olives for oil production	60.8
109.1	WHO cluster diet E	33.3	Olives for oil production	19.7	Wheat	8.1	Oilseeds	31.9
107.7	UK Toddler	45.7	Sugar beet (root)	19.6	Wheat	14.2	Oilseeds	73.5
94.6	IE adult	12.2	Table olives	11.5	Wheat	9.3	Spring onions	55.3
85.5	WHO regional European diet	26.0	Olives for oil production	14.8	Wheat	9.3	Table olives	27.0
84.4	NL child	23.7	Wheat	13.5	Pome fruit	11.8	Potatoes	54.2
82.2	FR all population	40.0	Olives for oil production	16.4	Wheat	8.4	Berries & small fruit	19.9
75.8	DK child	27.5	Wheat	22.1	Rye	6.0	Pome fruit	25.8
73.9	WHO cluster diet D	32.5	Wheat	8.1	Potatoes	5.1	Fruiting vegetables	26.6
70.4	UK Infant	20.2	Sugar beet (root)	13.1	Wheat	6.6	Oilseeds	49.0
64.2	WHO Cluster diet F	18.0	Wheat	6.8	Potatoes	5.4	Oilseeds	23.9
60.7	SE general population 90th percentile	16.0	Wheat	10.0	Table olives	8.3	Potatoes	32.6
59.7	FR toddler	13.1	Wheat	10.1	Potatoes	5.8	Pome fruit	43.4
58.4	IT kids/toddler	33.2	Wheat	4.0	Fruiting vegetables	3.0	Other cereal	19.1
42.1	IT adult	20.7	Wheat	3.6	Fruiting vegetables	3.5	Table olives	15.6
39.6	FR infant	8.3	Potatoes	5.6	Pome fruit	5.3	Carrots	32.8
39.2	UK vegetarian	10.2	Wheat	7.6	Sugar beet (root)	3.0	Spring onions	23.7
38.4	UK Adult	8.4	Wheat	8.0	Sugar beet (root)	6.0	Oilseeds	21.3
38.1	NL general	10.4	Wheat	5.5	Potatoes	3.7	Citrus fruit	22.9
28.1	DK adult	10.1	Wheat	3.4	Rye	3.0	Berries & small fruit	14.2
27.4	LT adult	6.3	Potatoes	5.4	Rye	5.3	Wheat	16.0
23.5	FI adult	4.9	Wheat	3.4	Rye	2.8	Table olives	11.0
21.1	PL general population	6.9	Potatoes	4.6	Pome fruit	2.2	Fruiting vegetables	19.1

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 21.1 % to 518 % of the ADI.

For 7 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

Acute risk assessment /children

Acute risk assessment / adults / general population

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 variabilty 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	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)
91.3	Spring onions	2 / -	91.3	Spring onions	2 / -	26.7	Table olives	2 / -	26.7	Table olives	2 / -
67.4	Table olives	2 / -	67.4	Table olives	2 / -	18.6	Spring onions	2 / -	18.6	Spring onions	2 / -
35.9	Fennel seed	5 / -	35.9	Fennel seed	5 / -	15.5	Olives for oil	2 / -	15.5	Olives for oil production	2 / -
30.8	Potatoes	0.02 / -	30.3	Melons	0.02 / -	10.6	Pumpkins	0.02 / -	10.6	Pumpkins	0.02 / -
30.3	Melons	0.02 / -	25.6	Olives for oil	2 / -	8.5	Cherries	0.2 / -	8.5	Cherries	0.2 / -
26.5	Oranges	0.02 / -	24.5	Cherries	0.2 / -	8.1	Watermelons	0.02 / -	8.1	Watermelons	0.02 / -
25.6	Olives for oil	2 / -	24.5	Watermelons	0.02 / -	7.9	Melons	0.02 / -	7.9	Melons	0.02 / -
24.5	Cherries	0.2 / -	22.0	Potatoes	0.02 / -	7.1	Chinese cabbage	0.02 / -	7.1	Chinese cabbage	0.02 / -
24.5	Watermelons	0.02 / -	20.2	Pineapples	0.02 / -	6.3	Cauliflower	0.02 / -	6.3	Cauliflower	0.02 / -
20.2	Pineapples	0.02 / -	19.2	Oranges	0.02 / -	6.3	Table grapes	0.02 / -	6.3	Table grapes	0.02 / -
19.6	Apples	0.02 / -	17.8	Grapefruit	0.02 / -	6.3	Head cabbage	0.02 / -	5.9	Mangoes	0.02 / -
18.2	Pears	0.02 / -	14.4	Apples	0.02 / -	6.0	Potatoes	0.02 / -	5.2	Sugar beet (root)	0.02 / -
17.8	Grapefruit	0.02 / -	13.2	Cauliflower	0.02 / -	5.9	Mangoes	0.02 / -	5.0	Aubergines (egg plants)	0.02 / -
17.5	Scarole (broad-leaf	0.02 / -	13.1	Pears	0.02 / -	5.4	Courgettes	0.02 / -	4.8	Swedes	0.02 / -
16.7	Bananas	0.02 / -	13.1	Table grapes	0.02 / -	5.2	Fennel	0.02 / -	4.7	Wine grapes	0.02 / -
15.7	Mangoes	0.02 / -	12.8	Sugar beet (root)	0.02 / -	5.2	Sugar beet (root)	0.02 / -	4.7	Potatoes	0.02 / -
14.7	Sweet corn	0.02 / -	12.1	Bananas	0.02 / -	5.1	Oranges	0.02 / -	4.5	Pineapples	0.02 / -
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:**		---			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
10.2	Apple juice	0.02 / -				2.2	Bread/pizza	0.05 / -			
9.9	Orange juice	0.02 / -				2.0	Orange juice	0.02 / -			
8.6	Carrot, juice	0.02 / -				1.3	Apple juice	0.02 / -			
6.6	Grape juice	0.02 / -				0.8	Wine	0.02 / -			
5.9	Wheat flour	0.05 / -				0.5	Pineapples preserved	0.02 / -			

*) 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 Dimethoate 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.

Omethoate

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.0003**	ARfD (mg/kg bw):	**0.002**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2006**	Year of evaluation:	**2006**

the calculations were performed with the MRLs set for dimethoate, without refinement.

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

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum: 71 - 1727

No of diets exceeding ADI: 23

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
1727.4	WHO Cluster diet B	1277.8	Olives for oil production	142.3	Wheat	53.3	Table olives	174.0
686.5	ES child	488.3	Olives for oil production	73.9	Wheat	29.3	Table olives	77.3
411.4	ES adult	281.2	Olives for oil production	39.1	Wheat	22.7	Table olives	59.4
410.6	PT General population	170.0	Olives for oil production	65.3	Wheat	36.7	Table olives	121.6
392.8	DE child	84.7	Pome fruit	68.5	Wheat	33.0	Olives for oil production	202.5
363.7	WHO cluster diet E	111.1	Olives for oil production	65.7	Wheat	26.9	Oilseeds	106.5
359.0	UK Toddler	152.5	Sugar beet (root)	65.3	Wheat	47.4	Oilseeds	245.0
315.5	IE adult	40.8	Table olives	38.3	Wheat	31.0	Spring onions	184.4
285.0	WHO regional European diet	86.7	Olives for oil production	49.4	Wheat	31.1	Table olives	90.0
281.3	NL child	79.0	Wheat	45.1	Pome fruit	39.3	Potatoes	180.5
274.1	FR all population	133.3	Olives for oil production	54.8	Wheat	28.0	Berries & small fruit	66.2
252.7	DK child	91.7	Wheat	73.6	Rye	20.0	Pome fruit	85.8
246.2	WHO cluster diet D	108.4	Wheat	27.1	Potatoes	16.9	Fruiting vegetables	88.8
234.6	UK Infant	67.2	Sugar beet (root)	43.7	Wheat	22.1	Oilseeds	163.3
213.9	WHO Cluster diet F	60.0	Wheat	22.7	Potatoes	18.1	Oilseeds	79.8
202.3	SE general population 90th percentile	53.4	Wheat	33.3	Table olives	27.8	Potatoes	108.7
199.2	FR toddler	43.7	Wheat	33.8	Potatoes	19.2	Pome fruit	144.6
194.7	IT kids/toddler	110.8	Wheat	13.3	Fruiting vegetables	10.0	Other cereal	63.8
140.2	IT adult	68.9	Wheat	12.2	Fruiting vegetables	11.8	Table olives	52.1
132.0	FR infant	27.6	Potatoes	18.8	Pome fruit	17.7	Carrots	109.3
130.7	UK vegetarian	34.1	Wheat	25.2	Sugar beet (root)	10.0	Spring onions	79.1
127.9	UK Adult	27.9	Wheat	26.6	Sugar beet (root)	20.1	Oilseeds	70.9
126.9	NL general	34.6	Wheat	18.3	Potatoes	12.4	Citrus fruit	76.3
93.6	DK adult	33.6	Wheat	11.4	Rye	10.1	Berries & small fruit	47.2
91.4	LT adult	21.2	Potatoes	17.9	Rye	17.5	Wheat	53.3
78.2	FI adult	16.4	Wheat	11.4	Rye	9.4	Table olives	36.5
70.5	PL general population	22.9	Potatoes	15.5	Pome fruit	7.3	Fruiting vegetables	63.7

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 70.5 % to 1727 % of the ADI.
For 23 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

Acute risk assessment /children

Acute risk assessment / adults / general population

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 variabilty 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):		**10**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**9**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**1**
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
456.6	Spring onions	2 / 0.43	456.6	Spring onions	2 / 0.43	133.3	Table olives	2 / 1.5	133.3	Table olives	2 / 1.5
337.1	Table olives	2 / 0.59	337.1	Table olives	2 / 0.59	93.0	Spring onions	2 / -	93.0	Spring onions	2 / -
179.6	Fennel seed	5 / 2.78	179.6	Fennel seed	5 / 2.78	77.7	Olives for oil	2 / -	77.7	Olives for oil production	2 / -
153.8	Potatoes	0.02 / 0.01	151.7	Melons	0.02 / 0.01	52.9	Pumpkins	0.02 / -	52.9	Pumpkins	0.02 / -
151.7	Melons	0.02 / 0.01	128.0	Olives for oil	2 / 1.56	42.4	Cherries	0.2 / -	42.4	Cherries	0.2 / -
132.6	Oranges	0.02 / 0.01	122.3	Cherries	0.2 / 0.16	40.6	Watermelons	0.02 / -	40.6	Watermelons	0.02 / -
128.0	Olives for oil	2 / 1.56	122.3	Watermelons	0.02 / 0.01	39.5	Melons	0.02 / -	39.5	Melons	0.02 / -
122.3	Cherries	0.2 / 0.16	109.8	Potatoes	0.02 / 0.01	35.7	Chinese cabbage	0.02 / -	35.7	Chinese cabbage	0.02 / -
122.3	Watermelons	0.02 / 0.01	101.2	Pineapples	0.02 / 0.01	31.7	Cauliflower	0.02 / -	31.7	Cauliflower	0.02 / -
101.2	Pineapples	0.02 / 0.01	95.8	Oranges	0.02 / -	31.7	Table grapes	0.02 / -	31.7	Table grapes	0.02 / -
98.0	Apples	0.02 / -	89.2	Grapefruit	0.02 / -	31.7	Head cabbage	0.02 / -	29.6	Mangoes	0.02 / -
91.1	Pears	0.02 / -	72.2	Apples	0.02 / -	29.8	Potatoes	0.02 / -	25.9	Sugar beet (root)	0.02 / -
89.2	Grapefruit	0.02 / -	66.1	Cauliflower	0.02 / -	29.6	Mangoes	0.02 / -	24.9	Aubergines (egg plants)	0.02 / -
87.4	Scarole (broad-leaf	0.02 / -	65.5	Pears	0.02 / -	27.0	Courgettes	0.02 / -	23.9	Swedes	0.02 / -
83.6	Bananas	0.02 / -	65.5	Table grapes	0.02 / -	26.2	Fennel	0.02 / -	23.7	Wine grapes	0.02 / -
78.7	Mangoes	0.02 / -	63.9	Sugar beet (root)	0.02 / -	25.9	Sugar beet (root)	0.02 / -	23.4	Potatoes	0.02 / -
73.4	Sweet corn	0.02 / -	60.6	Bananas	0.02 / -	25.6	Oranges	0.02 / -	22.7	Pineapples	0.02 / -
No of critical MRLs (IESTI 1)		10				**No of critical MRLs (IESTI 2)**		9			

Processed commodities

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)			
51.0	Apple juice	0.02 / -				11.0	Bread/pizza	0.05 / -			
49.5	Orange juice	0.02 / -				10.1	Orange juice	0.02 / -			
42.9	Carrot, juice	0.02 / -				6.6	Apple juice	0.02 / -			
32.9	Grape juice	0.02 / -				3.9	Wine	0.02 / -			
29.6	Wheat flour	0.05 / -				2.6	Pineapples preserved	0.02 / -			

*) 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 Omethoate IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 10 commodities.
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 9 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Annex A – Note of the French Authority

Paris, le 29 mars 2016

NOTE DES AUTORITÉS FRANÇAISES

à la Commission européenne

DG SANTE – Unité E4

Objet : Mesures d'urgence sur les produits phytopharmaceutiques à base de diméthoate ainsi que sur certaines denrées alimentaires d'origine européenne ou importées d'un pays tiers pour lesquels les risques pour le consommateur ne peuvent pas être finalisés.
P. J. : Courrier du demandeur

1- Mesures d'urgence en application du règlement (CE) n°1107/2009 du Parlement et du Conseil du 21 octobre 2009 concernant la mise sur le marché des produits phytopharmaceutiques

Le règlement d'exécution (UE) numéro 2015/404 de la Commission du 11 mars 2015 a prolongé l'approbation de la substance active dimethoate jusqu'au 31 juillet 2018.

A l'issue des conclusions de la première revue par les pairs de la substance active réalisée par l'EFSA et datant de 2006, il a été décidé que le pétitionnaire devait fournir différentes données confirmatoires dont celles relatives à l'évaluation des risques toxicologiques pour les métabolites potentiellement présents dans les cultures.

Dans les conclusions de sa revue par les pairs datant de 2013 et portant sur les données confirmatoires exigées, l'EFSA a conclu que les données disponibles ne permettent pas de statuer sur la pertinence toxicologique des métabolites XX (*O-desmethyl omethoate carboxylic acid*), XII (*des-O-methyl isodemethoate*), III (*dimethoate carboxylic acid*).

Ces conclusions n'ont donc pas permis de confirmer formellement, au niveau européen, que l'utilisation de la substance active diméthoate ne présentait pas de risque inacceptable pour le consommateur. L'absence de conclusion européenne a donc, de fait, renvoyée aux Etats membres la responsabilité de statuer, produit par produit et usage par usage sur la pertinence toxicologique des métabolites et, par conséquent, le niveau de risque pour le consommateur lié à l'utilisation de produits à base de diméthoate.

Les autorités françaises ont alerté la Commission européenne sur le fait que, dans le cadre du réexamen des produits phytopharmaceutiques autorisés en France, l'Agence nationale d'évaluation, l'Anses, avait conclu que le risque pour le consommateur ne pouvait pas être finalisé pour le produit DIMATE BF 400 à base de diméthoate (400 g/L). L'utilisation de ce produit a été revendiquée en France, comme dans d'autres Etats membres de la zone Sud (Espagne, Italie, Grèce) en arboriculture et en cultures légumières (asperge, chicorée, olivier, cerisier) pour lutter contre les mouches (et plus particulièrement *Drosophila Suzukii*). Ces usages ne sont pas ceux qui sont défendus dans le cadre des usages représentatifs du dossier de la substance active.

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Par ailleurs les autorités françaises relèvent que l'approbation n'a été accordée que sur la base d'un seul usage représentatif sur betterave sucrière pour lequel l'enjeu en terme de risque consommateur est limité sachant qu'aucun résidu n'est attendu dans le sucre raffiné.

L'intention de retirer les autorisations correspondantes a été notifiée à l'entreprise concernée, qui n'a pas émis d'observations. L'autorisation de mise sur le marché du DIMATE BF 400 a été retirée en France.

L'examen des autorisations délivrées par d'autres Etats membres pour des produits identiques, notamment au titre de l'article 53 du règlement (CE) n°1107/2009 a conduit les autorités françaises à solliciter auprès du pétitionnaire les données d'évaluation du risque pour le consommateur qui auraient pu être fournies dans d'autres Etats membres. Le détenteur a répondu (courrier en PJ) que l'ensemble de ses données avaient été transmises dans le cadre de la demande de réapprobation de la substance active, actuellement en cours d'examen par l'Italie, Etat membre rapporteur.

Aucune donnée du dossier de réapprobation ne concerne les usages concernés, ce qui ne permet donc pas de statuer sur les incertitudes relevées par l'avis de l'EFSA de 2013. Par ailleurs, aucun autre Etat membre contacté de la zone Sud ne dispose de données complémentaires de caractérisation des métabolites vis-à-vis des risques chroniques ou aigus pour le consommateur.

Au regard des températures hivernales, les fleurs sont déjà formées sur un très grand nombre d'arbres de la zone Sud. La pratique agricole courante consistant à intervenir en lutte contre les mouches au moment de la formation des premiers fruits, soit juste après la formation des fleurs, donc au cours du mois d'avril, il est demandé à la Commission européenne, en application de l'article 70 du règlement (CE) n°1107/2009, de bien vouloir prendre des mesures d'urgence visant à restreindre, sur l'ensemble du territoire européen, l'utilisation du diméthoate sur les cultures légumières et en arboriculture.

2- Mesures d'urgence en application des règlements (CE) n°178/2002 du Parlement européen et du Conseil du 28 janvier 2002 établissant les principes généraux et les prescriptions générales de la législation alimentaire et (CE) n°396/2005 du Parlement européen et du Conseil du 23 février 2005 concernant les limites maximales applicables aux résidus de pesticides présents dans ou sur les denrées alimentaires

Dans le cadre du suivi du programme national d'actions prévu par la directive 2009/128/CE, un indicateur d'exposition alimentaire chronique a été retenu, l'AJE (apport journalier estimé), et a été calculé pour les années 2009 à 2012. Il traduit l'exposition alimentaire des consommateurs aux résidus de produits phytopharmaceutiques, par le croisement des données de consommation alimentaire nationale et des résultats des plans de surveillance des résidus de pesticides dans les aliments.

Concernant l'AJE national, en termes de substances et de denrées contributrices, les fruits contribuent ensemble à près de 16% de l'AJE global (30% en 2011) pour différentes substances insecticides/acaricides ou fongicides. Parmi les principaux couples substance/denrée contributeurs, régulièrement identifiés et dont la contribution à l'AJE global augmentaient en 2012, on trouve le couple cerises/diméthoate à +1,8%.

En complément, les risques alimentaires chroniques et aigus sont évalués chaque année dans le cadre d'études qui intègrent des scénarios plus conservateurs, en vue d'identifier les substances devant être intégrées aux programmes nationaux de surveillance.

Les résultats de plans de contrôle nationaux ciblés sur les produits végétaux frais consommables issus de production utilisant des produits à base de diméthoate montrent régulièrement des dépassements de la limite maximale de résidus autorisée dans ces produits. De plus, le dernier rapport de l'EFSA (EFSA Journal 2015;13(3):4038) sur la surveillance des résidus de pesticides dans l'alimentation en 2013 montre que le diméthoate est la première substance en terme de nombre de

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dépassements de LMR (avec 258 dépassements sur un total de 2788 pour l'ensemble des substances et des échantillons d'origine UE et pays tiers).

Les cerises produites en provenance d'Etats membres ou de pays tiers où l'utilisation du diméthoate est autorisée aux fins de protéger les cerisiers contre les insectes ravageurs de cette culture étant susceptibles de constituer un risque sérieux pour la santé humaine, il est demandé à la Commission européenne, en application de l'article 53 du règlement (CE) n°178/2002, de bien vouloir prendre des mesures d'urgence visant à restreindre, sur l'ensemble du territoire européen, la mise sur le marché de cerises provenant de pays tiers ou d'Etats membres où l'utilisation du diméthoate est autorisée.

Le caractère sérieux du risque étant lié aux résidus de produits à base de diméthoate régulièrement détectés au-dessus des valeurs réglementaires dans les cerises fraiches, sans pour autant qu'un mésusage ait pu être établi, il est demandé à la Commission européenne de bien vouloir appliquer les dispositions prévues à l'article 35 du règlement (CE) n°396/2005 ramenant le délai à sept jours

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