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REASONED OPINION

Reasoned Opinion on the modification of the existing MRLs for malathion in various crops[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy (evaluating Member State (EMS)), received an application from the company Cheminova to modify the existing MRLs for malathion in citrus and pome fruits, plum, strawberry and lettuce. In order to accommodate intended Southern European Union uses on lettuce, strawberries and citrus fruits and the authorized use on apples, pears and plums in the third countries, the EMS proposed to raise the existing MRLs for malathion in all crops under consideration, including other salad plants. According to EFSA, the submitted residue data are sufficient to derive MRL proposals for citrus fruit, strawberries, apples, plums and lettuce. Residue data were not sufficient to derive a MRL proposal for pears. An extrapolation of residue data from lettuce to the whole group of salad plants is not supported by residue data. EFSA notes that for the MRL proposals on apples, plums, strawberries and lettuce additional data gaps were identified during the assessment. Based on the combined risk assessment, which was performed for malathion and its metabolites with similar toxicity (DMM desmethyl-malathion, MMCA malathion monocarboxylic acid and MDCA malathion dicarboxylic acid) and separately for malaoxon and taking into account the currently available information for the crops under consideration, the existing MRLs and the lack of detailed information on the actual approved uses of malathion, a potential long-term consumer health risk cannot be excluded. Setting a MRL on provisional basis might be acceptable by risk managers for citrus fruits, strawberries and lettuce, taking into account the low contribution of these crops to the overall long-term exposure and high level of uncertainties of the risk assessment which were compensated by using conservative assumptions leading to an overestimation of the calculated dietary exposure.

KEY WORDS

malathion, fruits, MRL application, Regulation (EC) No 396/2005, organothiophosphate insecticide, malaoxon

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005[3], Italy, herewith referred to as the evaluating Member State (EMS), received an application from the company Cheminova to modify the existing MRLs for the active substance malathion in citrus and pome fruits, plum, strawberry and lettuce. In order to accommodate intended SEU uses on lettuce, strawberries and citrus fruit and the authorized use on apples, pears and plums in the third countries, the EMS Italy proposed to raise the existing MRLs for malathion from the LOQ of 0.02 mg/kg to 5 mg/kg in citrus fruit, 1 mg/kg in pome fruit, 1 mg/kg in plum, 0.3 mg/kg in strawberry and 0.5 mg/kg in lettuce and other salad plants. The EMS drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 3 September 2012.

On 12 April 2013 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, partially addressing those data requirements, was submitted by the EMS on 16 May 2013. Following the assessment of the submitted data, EFSA concluded that certain issues related to the toxicity of malathion and its metabolites have to be discussed in the EFSA Pesticides Peer Review Experts` Meeting (hereafter-Experts` Meeting), held on 9-12 September 2013. The conclusions of this meeting were taken into consideration by EFSA for the finalization of this reasoned opinion.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report and Additional Report prepared under Council Directive 91/414/EEC[4] and the conclusion on the peer review of the pesticide risk assessment of the active substance malathion.

The toxicological profile of malathion was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.03 mg/kg bw per day and an ARfD of 0.3 mg/kg bw. These toxicological reference values are applicable for malathion containing maximum 0.2 % of isomalathion. According to the EMS, the isomalathion content in malathion used in the third countries for which the import tolerance is requested now for apples, pears and plums, is 0.4 %. The impact of higher isomalathion content on the toxicity of malathion was discussed by the Experts` Meeting, but no conclusion could be derived. Thus, using the toxicological reference values mentioned above for the current MRL application leads to an additional uncertainty in the risk assessment, in particular for the risk related to malathion residues on imported apples, pears and plums. The metabolite malaoxon was found to be more toxic than the parent compound. On the basis of the toxicological studies a toxicity equivalence factor (TEF) of 30 was derived.

The metabolism of malathion in primary crops was investigated in four crop groups and the peer review derived the residue definition for risk assessment as “malathion and its metabolites malaoxon, desmethyl-malathion (DMM), malathion monocarboxylic acid (MMCA) and malathion dicarboxylic acid (MDCA) expressed as malathion toxic equivalents”. For enforcement the residue was defined as “the sum of malathion and malaoxon, expressed as malathion”. The current residue definition set in Regulation (EC) No 396/2005 is identical. For the uses on the crops under consideration, EFSA concludes that the metabolism of malathion is sufficiently addressed. However, EFSA is of the opinion, that the residue definition for enforcement shall be set separately for malathion and malaoxon, considering their different toxicological profile. For reasons of transparency, EFSA also recommends two separate residue definitions for the exposure assessment where residue definition (1) would cover all compounds with a similar toxicity of malathion (“malathion and DMM, MMCA and MDCA, expressed as malathion”) and residue definition (2) would refer to all compounds with a similar toxicity of malaoxon; in the final risk assessment the combined exposure for the two residue definitions should be calculated. EFSA proposes to discuss this proposal in the framework of Article 12 of Regulation (EC) No 396/2005.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

[4] 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.

EFSA considers that the submitted supervised residue trials are sufficient to derive MRL proposals for citrus fruits, apples, plums, strawberries and lettuce. Residue data were not sufficient to derive a MRL proposal for pears. An extrapolation of residue data from lettuce to the whole group of salad plants is not appropriate since no data are available for open leaf varieties of lettuce. The derived risk assessment values for apples, plums and lettuce are driven by uncertainties related to the storage stability of metabolite DMM. The applicant has to investigate the magnitude of metabolite DMM in high water content matrices during freezer storage. Adequate analytical enforcement methods are available to control the residues of malathion and malaoxon in the crops under consideration.

Studies investigating the nature of malathion residues in processed commodities were assessed in the peer review and indicated that relevant residues are malathion and desmethyl-malathion (DMM). Under current application new studies were submitted on the nature of MMCA and MDCA in processed commodities. MMCA under pasteurization and sterilisation degrades to desmethyl malathion monocarboxylic acid (DM-MMCA), whereas MDCA under all processing conditions degrades to desmethyl malaoxon dicarboxylic acid (MoxDCA). The toxicity of these metabolites was investigated in the Experts` Meeting where it was concluded that for DM-MMCA the reference values of malathion can be applied; the toxicity potential of MoxDCA lies between malaoxon and malathion, but lacking data no TEF could be derived. According to a theoretical estimation, residues of both metabolites can be formed above 0.1 mg/kg in strawberries, apples, pears and plums under various processing conditions and therefore these metabolites should be included in the risk assessment residue definition of processed commodities. EFSA concludes that for the current application on a provisional basis the enforcement residue definition in processed commodities is the same as in raw commodities; however, in future the residue definition for processed commodities should be reconsidered. The applicant has to submit adequate processing studies investigating the magnitude of metabolites DM-MMCA and MoxDCA in the processed commodities. EFSA proposes that the risk assessment residue definition for processed commodities is split, considering different toxicological potencies of malathion and malaoxon and including relevant metabolites formed during processing.

The applicant submitted processing studies with apples, plums and oranges. A reduction of residues (sum of malathion and malaoxon, expressed as malathion) was observed in all processed commodities, except in wet and dry apple pomace. Although the processed citrus fruit were not analysed for metabolites DM-MMCA and MoxDCA, the available studies are considered sufficient to derive processing factors that can be recommended for inclusion in Annex VI of Regulation (EC) No 396/2005, as these metabolites are not expected to occur at significant levels in processed citrus fruit commodities. The processing factors for apple and plum commodities are associated by uncertainties related to storage stability of metabolite DMM and possible presence of metabolites MoxDCA and DM-MMCA and are thus not proposed for inclusion in Annex VI of the above mentioned Regulation. The proposed processing factors are:

- Citrus fruit, peeled: <0.15
- Oranges, pasteurized juice: <0.18
- Oranges, wet pomace: 0.44
- Oranges, dry pomace: 0.41

Lettuce and strawberries can be grown in rotation with other plants. However, malathion and its soil metabolites MMCA and MDCA degrades rapidly in the soil and thus further investigation of malathion residues in rotational/succeeding crops is not required.

The contribution of malathion residues in citrus and pome fruit pomace to the current livestock dietary burden from the intended and authorized uses was also assessed. The calculated livestock dietary burdens exceeded the trigger value of 0.1 mg/kg (dry matter) for all animal species and were driven by the existing uses on cereals. Thus, the nature and magnitude of malathion residues in livestock was not further assessed in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). The consumer exposure calculation was performed for the two separate risk assessment residue definitions proposed by EFSA ((1): "malathion, DMM, MMCA and MDCA, expressed as malathion"; (2): "malaoxon"), which were combined at the end in a cumulative assessment to estimate the overall exposure to all malathion related residues, taking into account the toxicological potency of the individual compounds.

In the long-term exposure calculation EFSA used the median residue values as derived from the residue trials on oranges, mandarins, apples, plums, lettuce and strawberries. For citrus fruit no peeling factor was applied as data were available on residues in the pulp. For pears the existing MRL was used as an input value as no MRL proposal was derived in the framework of the current application. For camomile and cereals the risk assessment values for malathion and malaoxon were available to refine the calculation. For the remaining commodities of plant and animal origin for which the existing MRLs in Regulation (EC) No 396/2005 are set at the combined LOQ of 0.02 mg/kg for malathion and malaoxon, the input value was the enforcement LOQ for each of these compounds (0.01 mg/kg), depending on the exposure calculation scenario.

The calculated exposure for residue definition (1) was then compared with the toxicological reference value derived for malathion; the calculated exposure for residue definition (2) was compared with a toxicological reference value derived for malaoxon which was 30 times lower than the ADI for parent malathion, to take into account the TEF. The acute exposure assessment was performed only with regard to the commodities under consideration. Also in this case the short term exposure was calculated separately for the two residue definitions.

For the residue definition (1) the long-term consumer exposure accounted for up to 77 % of the ADI (WHO Cluster diet B). The individual contribution of residues in the crops under consideration to the total consumer exposure (in the percentage of the ADI) accounted for a maximum of 12.9 % for apples (DE child diet), 1.2 % for strawberries (FR toddler diet), 0.8 % for lettuce (ES adult diet), 0.53 % for oranges (maximum of citrus fruit group; DE child diet) and 0.4 % for plums (IE adult diet). The acute exposure to the total malathion residues in the crops under consideration accounted for 30 % for lettuce and apples, respectively, 7 % for plums, 5 % for strawberries, 3 % for oranges and was below for other crops under consideration.

For the residue definition (2) the total calculated intake for malaoxon accounted for up to 71 % of the ADI (UK Infant diet). The contribution of residues in the crops under consideration to the total consumer exposure (in the percentage of the ADI) accounted for a maximum of 12.1 % for apples (DE child diet), 3.8 % for oranges (highest from all citrus fruits group; DE child diet), 0.6 % for strawberries (FR toddler diet), 0.5 % for lettuce (ES adult diet) and 0.3 % for plums (IE adult diet). The calculated maximum exposure (in percentage of the ARfD) accounted for 20 % for apples, 13 % for oranges, 9 % for grapefruit, 6 % for mandarins and was below 5 % for other crops under consideration.

The **combined long-term exposure** exceeded the ADI for five diets (**125 %** for WHO cluster diet B, **116 %** Danish child, **111 %** for Dutch child, **105 %** for UK infant and **103 %** for German child). Excluding the crops under consideration for MRL setting (citrus, apples, plums, strawberries and lettuce) from the exposure calculation does not have a significant effect on the overall dietary exposure (malathion 75 % of the malathion ADI; malaoxon 71 % of the malaoxon ADI, combined exposure: exceedance of the toxicological reference value for 4 diets (WHO Cluster diet B (124 %), DK child diet (113 %), UK infant (104 %), NL child diet (104 %)).

EFSA concludes that, based on the currently available information for the crops under consideration, taking into account the existing MRLs and the lack of detailed information on the actual approved uses of malathion, a potential long-term consumer health risk cannot be excluded. Risk managers should consider the following uncertainties in the assessment which may have lead to an over- or underestimation of the long-term exposure:

- a lower ADI might be required for the assessment of the long-term consumer exposure to malathion residues from the intake of apples and plums, considering that in the third countries for which the import tolerances are requested on these fruits, malathion with higher isomalathion content (0.4 %) is used;

- the residue data in plums, apples and lettuce are affected by uncertainties regarding storage stability of metabolite DMM; thus, the results of residue trials may underestimate the actual dietary burden for consumers;

- the possible formation of DM-MMCA and, in particular, the formation of a more toxic degradation product MoxDCA in processed commodities (relevant for apples, plums, strawberries) may lead to an underestimation of the risk for consumers resulting from the consumption of processed products;

- the lack of detailed information on the authorized uses of malathion in Europe and third countries. In the dietary exposure assessment for all crops except the crops under consideration EFSA assumed that they contribute to the dietary burden with residues at the LOQ of malathion and malaoxon, respectively. These “background” levels are accounting for the major part of the calculated long-term exposure. Thus, the calculations are considered to be conservative with regard to these crops, leading to a possible overestimation of the calculated exposure;

- The lack of detailed information on the authorised uses may also lead to an underestimation of the actual exposure, in particular related to the residues in cereals, where EFSA assumed that only post-harvest uses are approved which are not expected to lead to malaoxon residues. In case foliar treatments are approved, the malaoxon residues might occur in concentrations relevant for consumer exposure.

In the **combined short-term exposure** assessment for the malathion related compounds (malathion, malaoxon, DMM, MMCA and MDCA, expressed as malathion toxic equivalents), no consumer health concern was identified for the crops under consideration. The maximum short-term exposure for apples accounted for 50 % of the toxicological reference value for malathion, 33 % for lettuce, 16 % for oranges, 11 % for grapefruit, 10 % for plums, 7 % for strawberries and mandarins, respectively, 4 % for lemons and 2 % for limes. Also the short-term exposure assessment is affected by the above-mentioned uncertainties.

Taking into account these findings EFSA proposes to amend the existing MRLs as reported in the summary table.

SUMMARY TABLE

Code number (a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Malathion and malaoxon, expressed as malathion				
0110000	Citrus fruits	0.02*	2 (provisional)	The MRL proposal is sufficiently supported by residue data. Although a long-term consumer health risk could not be excluded, setting a MRL on provisional basis might be acceptable for risk managers, taking into account the low contribution of citrus fruits to the overall long-term exposure and high level of uncertainties of the risk assessment which were compensated by using conservative assumptions leading to an overestimation

Code number (a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
				of the calculated dietary exposure.
0130010	Apples	0.02*	No new proposal	The import tolerance request is not sufficiently supported by data regarding the storage stability of metabolite DMM and formation of degradation products under processing conditions. In addition, the data are not sufficient to conclude whether the toxicological reference values derived for malathion with a lower impurity concentration of isomalathion can be applied to assess the consumer risk related to apples treated with less pure malathion. Taking into account the uncertainties resulting from these data gaps and a potential long-term consumer exposure concerns identified, EFSA does not recommend raising the MRL for apples at the moment.
0130020	Pears	0.02*	No new proposal	In addition to the data gaps and uncertainties identified for apples, the number of residue trials on pears was not sufficient to support the import tolerance request.
0140040	Plums	0.02*	No new proposal	The import tolerance request is not sufficiently supported by data regarding the storage stability of metabolite DMM and formation of degradation products under processing conditions. In addition, the data are not sufficient to conclude whether the toxicological reference values derived for malathion with a lower impurity concentration of isomalathion can be applied to assess the consumer risk related to plums treated with less pure malathion. Taking into account the uncertainties resulting from these data gaps and a potential long-term consumer exposure concerns identified, EFSA does not recommend raising the MRL for plums at the moment.
0152000	Strawberries	0.02*	0.3 (provisional)	The MRL proposal is supported by residue data, but the applicant has to confirm that significant MoxDCA residues are not formed in processed strawberry products. Although a potential long-term consumer health risk could not be excluded at the moment, a provisional MRL setting might to be acceptable for risk managers, taking into account the low contribution of strawberries to the overall long-term exposure and high level of uncertainties of the risk assessment which were

Code number (a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
				compensated by using conservative assumptions leading to an overestimate the calculated dietary exposure.
0251020	Lettuce	0.02*	0.5 (provisional)	The MRL proposal is supported by residue data, but the applicant has to provide confirmation that the low DMM concentrations measured in residue trials are not due to inadequate storage of the samples. Although a potential long-term consumer health risk could not be excluded at the moment, a provisional MRL setting might be acceptable for risk managers, taking into account the low contribution of lettuce to the overall long-term exposure and high level of uncertainties of the risk assessment which were compensated by using conservative assumptions leading to an overestimate the calculated dietary exposure.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to set or to modify an MRL in accordance with the provisions of Article 7 of that Regulation.

Italy, hereafter referred to as the evaluating Member State (EMS), received an application from the company Cheminova[6] to modify the existing MRLs for the active substance malathion in citrus fruit, pome fruit, plum, strawberry and lettuce. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 3 September 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00782 and the following subject:

Malathion - Application to modify the existing MRLs in various crops.

The EMS Italy proposed to raise the existing MRLs for malathion from the limit of quantification (LOQ) of 0.02 mg/kg to 5 mg/kg in citrus fruit, 1 mg/kg in pome fruit and plums, 0.3 mg/kg in strawberries and 0.5 mg/kg in lettuce and other salad plants.

On 12 April 2013 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, partially addressing those data requirements, was submitted by the EMS on 16 May 2013. Following the assessment of the submitted data, EFSA came to a conclusion that a more detailed discussion is required and proposed that the following issues related to the toxicity of malathion and its metabolites are discussed in the EFSA Pesticides Peer Review Experts` Meeting 106 (hereafter-Experts` Meeting) held on 9-12 September 2013:

- the toxicity and AChE inhibition potential of MoxDCA and DM-MMCA;
- the toxicological impact of 0.4 % isomalathion content in the technical grade malathion on the toxicological reference values of malathion;
- the revision of the toxicity equivalence factors (TEF) for malaoxon.

The EMS was asked on 10 June 2013 to submit additional studies for the Pesticides Peer Review Experts` Meeting 106. Such studies were provided by the EMS on 3, 4 and 10 September 2013. The agreed position of the Pesticides Peer Review Meeting 106 which was summarised in the report of the meeting (EFSA, 2013) are taken into consideration by EFSA for finalization of this reasoned opinion.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

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

[5] 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

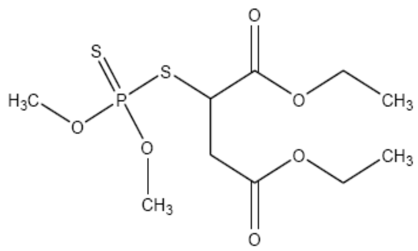
[6] Cheminova, PO Box 9, DK-7620, Lemvig, Denmark

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 19 September 2013.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Malathion is the ISO common name for diethyl (dimethoxyphosphinothioylthio)succinate or *S*-1,2-bis(ethoxycarbonyl)ethyl *O*,*O*-dimethyl phosphorodithioate (IUPAC). Malathion is a racemic mixture of two optical isomers (enantiomers). The chemical structure of the compound is herewith reported.



Molecular weight: 330.36

Malathion is an insecticide (acaricide) belonging to the organothiophosphate compounds group. After application malathion is absorbed either in the waxy plant cuticle or in the leaf apoplast, but it is not translocated to phloem. Malathion is acting as a cholinesterase inhibitor and it controls a wide range of pests including *Coleoptera*, *Diptera*, *Hemiptera* and *Lepidoptera*.

Malathion was evaluated according to Directive 91/414/EEC with Finland being the designated rapporteur Member State (RMS). Following the Commission Decision 2007/389/EC[7] concerning the non-inclusion of malathion in Annex I to Council Directive 91/414/EEC, the manufacturer made a resubmission application for the inclusion of malathion in Annex I in accordance with the provisions laid down in Commission Regulation (EC) No 33/2008[8]. Under the framework of the resubmission procedure the United Kingdom acted as the rapporteur Member State evaluating the new data and preparing an Additional Report. The representative uses evaluated under the resubmission process were indoor foliar applications on strawberries and ornamentals. Both Draft Assessment Report (DAR) (Finland, 2003) and Additional Report (United Kingdom, 2009) have been peer reviewed by EFSA (EFSA, 2009).

Malathion was included in Annex I of Directive 91/414/EEC by Directive 2010/17/EU[9] which entered into force on 1 May 2010 for uses as insecticide for professional users only. According to the inclusion Directive 2010/17/EC, Member States shall ensure that malathion based formulations are accompanied by the necessary instructions to avoid any risk of formation of isomalathion[10] in excess of the

[7] Commission Decision 2007/389/EC of 6 June 2007 concerning the non-inclusion of malathion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 146, 8.6.2007, p. 19.

[8] Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.01.2008, p. 5-12.

[9] Commission Directive 2010/17/EU of 9 March 2010 amending Council Directive 91/414/EEC to include malathion as active substance. OJ L 60, 10.3.2010, p. 17-19.

[10] diethyl (2RS)-2-{[methoxy(methylsulfanyl)phosphoryl]sulfanyl}butanedioate. See Appendix D.

permitted quantities during storage and transport. In addition, Member States shall ensure that the notifier presents to the Commission: 1) information conforming the consumer risk assessment and the acute and long-term risk assessment for insectivorous birds; 2) information on the quantification of the different potency of malaoxon and malathion. The maximum isomalathion content specified in the technical grade malathion, according to inclusion Directive 2010/17/EC, is 2 g/kg. Malathion is considered approved under Regulation (EC) No 1107/2009.

The EU MRLs for malathion are established in Annexes II and IIIA of Regulation (EC) No 396/2005 (Appendix C). The existing EU MRLs for malathion in the crops under consideration are set at the LOQ of 0.02 mg/kg. Codex Alimentarius has established CXL of 7 mg/kg in citrus fruits, 0.5 mg/kg in apple and 1 mg/kg in strawberry for the residue definition “malathion”. The review of malathion MRLs according to Article 12 of Regulation (EC) No 396/2005 is currently at an early stage and an issue of a reasoned opinion is not expected imminently.

The details of the intended uses of malathion on citrus fruits, strawberries and lettuce in the SEU and the authorised uses on plums and apples in New Zealand, Brazil and Argentina, are given in Appendix A. According to the information provided by the applicant, the purity of the technical grade malathion outside of Europe (except the USA) complies with the FAO technical specification (max. 0.4 % isomalathion); thus, the technical material used in third countries and malathion approved in the EU (max. 0.2 % isomalathion) are not equivalent.

ASSESSMENT

EFSA bases its assessment on the evaluation report and updated evaluation report submitted by the EMS (Italy, 2012; 2013), the Draft Assessment Report (DAR) and its addendum (Finland 2003, 2005), an Additional Report and its addendum prepared under Council Directive 91/414/EEC (United Kingdom, 2009a, 2009b), the conclusions on the peer review of the pesticide risk assessment of the active substance malathion (EFSA, 2009), the conclusions from a previous EFSA reasoned opinion on malathion (EFSA, 2011) and the Report of Pesticides Peer Review Meeting 106 on Mammalian Toxicology (EFSA, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[11] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

It should be noted that malathion and its metabolites consist of two optical isomers (enantiomers). There is no information available on the behaviour of each individual malathion enantiomer or enantiomers (EFSA, 2009). Therefore the data reported for malathion or isomalathion, malaoxon, DMM, MMCA, MDCA, DM-MMCA and MoxDCA in the framework of the peer review and in the current MRL application are not distinguished for the sum of two enantiomers.

1. Method of analysis

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

Analytical methods for the determination of malathion residues in plant commodities were assessed in the DAR and in the conclusion on the peer review under Directive 91/414/EEC (Finland, 2003; EFSA, 2009). A GC-FPD method is sufficiently validated at the LOQ of 0.001 mg/kg, respectively, for the individual determination of malathion and its metabolite malaoxon in high water (apple) and high acid (strawberry) content commodities and at the LOQ of 0.01 mg/kg in dry (alfalfa hay) and high fat content (cotton seed) commodities. The method is not enantiomer-selective. The peer review also stressed that cryogenic milling of samples has to be part of the analytical method for monitoring in order to avoid any degradation of malathion (EFSA, 2009).

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

Analytical methods for the determination of malathion residues in food of animal origin are not assessed in the current application, since no MRLs are proposed for malathion in the food commodities of animal origin.

2. Mammalian toxicology

2.1. Malathion

The toxicological profile of the active substance malathion was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2009). Four impurities in the technical malathion used in the toxicology studies were regarded as relevant of which isomalathion is of toxicological concern. One of the major uncertainties in the toxicological dossier was related to the impact of isomalathion on the toxicological profile of malathion. In the DAR several acute toxicity studies in rats were reported, which demonstrated that increasing amount of isomalathion increases the acute toxicity of malathion (EFSA, 2009). The concentration of isomalathion in the technical material used in the toxicological studies was 0.03 %, while the technical specification for the active substances assessed in the peer review specified a higher limit of this impurity (0.2 % isomalathion). To address this uncertainty an

[11] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

additional safety factor of 10 was applied to derive the ADI and the AOEL (EFSA, 2009). The derived toxicological reference values for malathion are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values for malathion

	Source	**Year**	**Value**	**Study relied upon**	**Safety factor**
Malathion[(a)]					
ADI	EFSA	2009	0.03 mg/kg bw/d	Rat, 2 years study	1000[(b)]
ARfD	EFSA	2009	0.3 mg/kg bw	Rabbit, teratology study	100[(c)]

(a): The toxicological reference values refer to the technical material complying with the EU specification (max. 0.2 % isomalathion

(b): An additional factor of 10 was added to the standard safety factor due to the uncertainties related to the impurity isomalathion, since the material tested in the animal test contained only 0.03 % of isomalathion.

(c): The study used for setting the ARfD had a high amount of isomalathion (0.14 %) considered to cover the uncertainties for the impurity.

In the framework of the current application, the applicant applied for the import tolerance on apples, pears and plums from New Zealand, Brazil and Argentina. The isomalathion content in the technical grade malathion used in these countries is max. 0.4 % (Italy, 2013). Thus, as the current toxicological reference values were derived for malathion complying with the EU specification (max. 0.2 % of isomalathion content), they cannot be used to assess the safety of residues resulting from a less pure technical malathion. The impact of higher isomalathion content on the toxicity of malathion was discussed in the Experts` Meeting organised in the framework of this MRL application (September 2013). However, the experts could not derive a conclusion since the supporting studies were submitted too late and have not been evaluated by the EMS (EFSA, 2013). EFSA is of the opinion that further guidance from risk managers is necessary to clarify the procedure for setting import tolerances, in particular, how to derive toxicological reference values for active substances which do not comply with the EU specifications.

2.2. Malaoxon

Malaoxon is a metabolite of malathion that was found to be more toxic than parent compound. During the peer review the toxicological potency of malaoxon compared to parent malathion was discussed controversially. Considering the NOAELs of the two long term toxicity studies a toxicological equivalence factor of 30 was calculated. The RMS United Kingdom proposed a factor of 7 which was derived from the ratio of two LOAELs from the two long term toxicity studies (United Kingdom, 2009a), but the data from the RMS were submitted too late to be peer reviewed. The peer review experts agreed on the TEF of 30 (EFSA, 2009). The TEF for malaoxon/malathion was discussed again in the Experts` Meeting in September 2013; the experts assessed the studies which were originally submitted by the United Kingdom in 2009. Since the results of different studies relevant for comparing the toxicological potency of malathion and its metabolites were not consistent and spread significantly, depending on the dose rates tested, the time points and dose spacing. The experts concluded not to follow the RMS proposal (EFSA, 2013). Thus the TEF of 30 is currently applicable to express malaoxon as malathion equivalents. EFSA calculated the resulting ADI and ARfD values for malaoxon which are resulting from this conclusion (Table 2-2).

Table 2-2: Calculated toxicological reference values for malaoxon, based on malathion ADI/ARfD and TEF

	Source	Year	Value	Study relied upon	Safety factor
Malaoxon					
ADI			0.001 mg/kg bw/d	ADI of malathion/30 (TEF)	
ARfD			0.01 mg/kg bw	ARfD of malathion/30 (TEF)	

2.3. Other malathion metabolites observed in the plant metabolism and in processing studies

a) desmethyl-malathion (DMM)[12]

DMM was the major metabolite in the metabolism study in apples and was identified as the major degradation product in processing studies (standard hydrolysis studies). DMM has been identified in rat metabolism studies (in urine in low dose males). The peer review experts agreed that the metabolite should be considered less toxic than malathion, but toxicologically relevant because of its acetylcholinesterase inhibition activity. Since no toxicity studies have been performed with desmethyl-malathion which would allow deriving a TEF, the same toxicological reference values as for malathion are applicable (EFSA, 2009).

a) malathion dicarboxylic acid (MDCA)[13] and malathion monocarboxylic acid (MMCA)[14]

MDCA and MMCA were observed in significant concentrations in metabolism studies in alfalfa, lettuce and apples. No toxicity studies have been performed with MDCA or MMCA. Available metabolism data demonstrate that in rats and humans malathion is metabolized mainly to MMCA and MDCA which are rapidly excreted via urine. The experts therefore agreed that no further toxicological studies are needed. The available data gave some indications of a lower toxicity than malathion; however, lacking specific studies, the same toxicological reference values as for malathion are applicable (EFSA, 2009).

b) desmethyl malathion monocarboxylic acid (DM-MMCA)[15] and desmethyl malaoxon dicarboxylic acid (MoxDCA)[16]

According to hydrolysis studies submitted under the current application, desmethyl malathion monocarboxylic acid (DM-MMCA) and desmethyl malaoxon dicarboxylic acid (Mox-DCA) are the main degradation products of MMCA and MDCA, respectively, under processing conditions. The toxicity of these metabolites was investigated in the Experts` Meeting in September 2013 where it was concluded that for DM-MMCA a higher toxicity potential than malathion is unlikely to occur and the reference values of malathion can be applied in case a risk assessment is needed. With regard to MoxDCA, it was concluded that it is likely that its potential lies between malaoxon and malathion. If a risk assessment for consumer is needed the reference values of malathion cannot be applied. However, no alternative value could be derived (EFSA, 2013).

[12] desmethyl-malathion (DMM). See Appendix D.
[13] malathion dicarboxylic acid (MDCA). See Appendix D.
[14] malathion monocarboxylic acid (MMCA). See Appendix D.
[15] desmethyl malathion monocarboxylic acid (DM-MMCA). See Appendix D.
[16] desmethyl malaoxon dicarboxylic acid (MoxDCA). See Appendix D.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of malathion in primary crops (apples, lettuce, alfalfa, cotton, wheat) following foliar treatment was evaluated in the framework of the peer review under Directive 91/414/EEC (Finland, 2003, 2005; United Kingdom, 2009b). The details of the metabolism studies are compiled in the table below.

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

Group	Crop	Label position	Application details				
			Method, F or G[(a)]	Rate (kg a.s./ha)	No/ Interval	Sampling	Remarks
Fruits and fruiting vegetable	Apples	^{14}C-malathion labelled in 2[nd] and 3[rd] position of succinate moiety	Foliar spray, F	1.8	3/14	21 DALA	
Leafy vegetables	Lettuce		n.r.	3.5-4	6/5 to 14 days	14 DALA	Total appl. rate 22.8 kg a.s./ha
Pulses and oilseeds	Alfalfa		Foliar spray, F	2	2/43 days	18 h after last appl.	
	Cotton		Foliar spray, F	1.45-1.9	10/9 to 33 days	18 h after last appl.	
Cereals	Wheat		Foliar spray, F	1.7-1.8	3	8 DALA	

(a): Outdoor/field use (F) or glasshouse/protected crops/indoor application (G)
n.r.: not reported in the DAR

In **alfalfa** forage the majority of the radioactivity consisted of malathion (40.5 %; 56.72 mg/kg) with most abundant metabolite being MMCA (9.8 %; 13.77 mg/kg). Malaoxon and isomalathion were not present in forage, but were present at detectable levels in alfalfa hay (though less than 1 % TRR). The remaining identified metabolites both in forage and hay were individually below the 10 % of the total radioactivity.

In **wheat**, the TRR accounted for 53.7 mg eq./kg in forage, 10.37 mg eq./kg in grain and 133.9 mg eq./kg in straw. The major residue in various wheat fractions was malathion, accounting for 15 % TRR (8.11 mg/kg) in forage, 27 % TRR (2.8 mg/kg) in grain and 11 % TRR (14.7 mg/kg) in straw. No other metabolites individually exceeded 10 % TRR in wheat. The major metabolite was MMCA which was present up to 6 % (3.22 mg/kg) in forage and 7.3 % (9.8 mg/kg) in straw. Malaoxon was identified in grain (0.4 %; 0.04 mg/kg) and straw (0.1 %; 0.2 mg/kg) only.

In **lettuce**, the total radioactivity accounted for 437 mg eq./kg. The major components of the total radioactivity were malathion (36.8 %; 160.9 mg/kg) and MMCA (12.8 %; 56.12 mg/kg). Malaoxon accounted for 1.2 % TRR (5.25 mg/kg) and the remaining metabolites individually were present for less than 1 % TRR.

In **cotton**, the total radioactivity accounted for 2067.8 mg eq./kg in leaves, 149.8 mg eq./kg in seed, 55.58 mg eq./kg in immature bolls, 216.96 mg eq./kg in lint and 428.17 mg eq./kg in gin trash (seed pods). The major component of the total radioactivity was malathion (33 %; 49 mg/kg). Metabolite MMCA accounted for 2.6 % TRR (3.9 mg/kg). No other metabolite exceeded 0.5 % TRR. Malaoxon was identified at low levels (0.2 % TRR; 0.3 mg/kg).

In **apples** sampled immediately after application, the TRR accounted for 3.64 mg eq./kg and declined to 1.64 mg eq./kg at harvest 21 day later. The distribution of malathion and its metabolites in apples is given in the table below. During the peer review a discrepancy was noted regarding the residues of malaoxon in metabolism studies and in supervised field trials. Therefore the applicant was requested to re-analyse the samples from the original metabolism study (United Kingdom, 2009a). The results of this second analysis of the apple samples are also summarised in the Table 3-2.

Table 3-2: Comparative results of metabolism study in apples

	Sampled 7 days after last application, % (mg/kg)	**Sampled 14 days after the second application, % (mg/kg)**	**Sampled 21 days after the second application, %(mg/kg)**	
Results presented in the original metabolism study				
Malathion	9.87 (0.25)	20 (0.57)	0.66 (0.011)	
Malaoxon	7.67 (0.195)	1.07 (0.03)	1.2 (0.019)	
MMCA and MDCA	9.94 (0.25)	6.3 (0.178)	10.2 (0.167)	
DMM	24.8 (0.63)	29.9 (0.846)	48.8 (0.80)	
Results of metabolism study re-analysed after 2 years				
			Homogenized sample	Intact whole apple analyzed
Malathion	2.1 (0.05)	1.3 (0.007)	0.4 (<0.01)	3.8 (0.06)
Malaoxon	<0.1 (<0.001)	<0.1 (0.002)	<0.1 (<0.001)	<0.1 (<0.001)
MMCA	5.1 (0.12)	1.3 (0.03)	0.5 (0.008)	0.6 (0.01)
MDCA	6.0 (0.14)	3.4 (0.09)	0.6 (0.01)	3.4 (0.06)
DMM	0.4 (0.008)	0.2 (0.005)	0.4 (0.007)	<0.1 (<0.003)

A significant decline of the total residue was observed in all samples re-analysed after two years, compared to the initial analysis. The identification rate was low, and the proportions of the individual compounds were different from the first analysis, indicating that, apart from the residue levels, the composition of the residue has changed during the storage period. Hence, the peer review agreed that the re-analysis would only confirm the nature of the compounds already identified in previous metabolism studies. The new results are not reliable from a quantitative point of view and thus cannot be used to conclude on the relevance of metabolites or to derive reliable conversion factor for enforcement and risk assessment residue definition (EFSA, 2009).

In alfalfa, cotton, lettuce and wheat the main metabolic pathway proceeded via de-esterification of malathion to form malathion monocarboxylic and dicarboxylic acids and succinic acid[17]. The succinate was apparently incorporated into small organic acids and sugars via the citric acid cycle. In fruits the main route of metabolism seems to be the transformation of malathion to desmethyl-malathion. For enforcement purposes the residue was defined as "*sum of malathion and malaoxon expressed as malathion*" (EFSA, 2009). The current residue definition set in Regulation (EC) No 396/2005 is identical. The residue definition derived by the JMPR for enforcement and risk assessment is defined as parent malathion.

Considering the toxicological relevance of malathion metabolites as well as the occurrence of these compounds in the investigated crops, the residue definition for risk assessment was agreed by the peer review as: "*malathion and its metabolites malaoxon, desmethyl-malathion (DMM), malathion*

[17] See Appendix D.

monocarboxylic acid (MMCA) and malathion dicarboxcylic acid (MDCA) expressed as malathion toxic equivalents" (EFSA, 2009). The residue experts agreed to consider in the risk assessment the higher toxicity of malaoxon with a factor of 30 in order to adequately convert malaoxon residues into malathion toxicological equivalents (EFSA, 2009; EFSA, 2013).

For the uses on the crops under consideration EFSA concludes that the metabolism of malathion is sufficiently addressed. MRL proposals for the current enforcement residue definition will be derived. However, considering practical experiences in MRL enforcement, EFSA is of the opinion, that in future the residue definition for enforcement shall be set separately for malathion and malaoxon, considering their different toxicological profile.

For the risk assessment residue definition EFSA also recommends to split the risk assessment residue definition: residue definition (1) would cover all compounds with a similar toxicity of parent malathion, i.e, "the sum of malathion, DMM, MMCA and MDCA, expressed as malathion", whereas residue definition (2) would cover all compounds with a similar toxicity of malaoxon. In the final risk assessment a cumulative assessment, taking into account the TEF, should be performed. This approach would allow deriving unambiguous conversion factors for enforcement to risk assessment residue definition. EFSA proposes to discuss the proposal of setting of separate residue definitions in the framework of Article 12 of Regulation (EC) No 396/2005.

3.1.1.2. Magnitude of residues

The residue trial samples have been analysed separately for parent malathion, malaoxon, DMM, MMCA, MDCA. Residue values for the risk assessment were derived according to the two proposals for the residue definition (see 3.1.1.1.), which consider different toxicological properties of malathion and malaoxon: (1) "malathion, DMM, MMCA and MDCA expressed as malathion toxic equivalents"; (2) "malaoxon". The residues for the risk assessment residue definition (1) were expressed as malathion by applying the molecular weight conversion factors[18], of 1.09 for the MMCA 1.2 for MDCA and 1.04 for DMM.

a. Citrus fruits

GAP SEU (foliar spray): 2 -3 x 0.484 kg a.s./ha, 10 d interval, PHI 7 days.

The applicant submitted in total eight GAP compliant residue trials on **oranges** which were performed in Spain in 2010 and 2011. Residues of malaoxon, DMM and MMCA were in all trial samples below the LOQ of 0.01 mg/kg, residues of MDCA accounted for up to 0.04 mg/kg and malathion residues for up to 0.15 mg/kg. The samples of pulp were also analysed and did not contain residues above the LOQ of 0.01 mg/kg for any of the compounds.

The applicant also submitted eight GAP compliant residue trials on **mandarins**, which were performed in Spain in 2010 and 2011. Residues of malaoxon, DMM and MMCA were in all trial samples below the LOQ of 0.01 mg/kg (except one sample with MMCA at the LOQ), residues of MDCA accounted for up to 0.11 mg/kg and residues of malathion for up to 0.70 mg/kg. The samples of pulp were also analysed and did not contain residues above the LOQ of 0.01 mg/kg for any of the compounds. The MRL proposal derived for the foliar spray GAP in citrus is 0.9 mg/kg.

GAP: SEU: 2-3 x 0.24 kg a.s./ha (foliar spray with bait[19]); PHI 7 days

The applicant submitted in total eight GAP compliant residue trials on **oranges** which were performed in Spain in 2010 and 2011. In each trial two sampling procedures were applied- one sample was taken only from the treated part of the tree and one sample - from the whole tree. The results of analysis

[18] MW malathion=330.36; MW MMCA=302; MW MDCA=274; MW malaoxon=314.3; MW DMM=316.3

[19] The test substance was applied as a bait spray mixed with 0.6% protein bait on the tree`s side facing south at a rate of *ca.* 100 ml per tree. An area of approximately 1 m^2 was sprayed (Italy, 2013).

indicate that higher total residues are present in samples taken from the treated part of the tree and thus these results were used to derive MRL proposals and risk assessment values. Residues of malaoxon in all trial samples were below the LOQ of 0.01 mg/kg, whereas residues of DMM accounted for up to 0.03 mg/kg, MDCA for up to 0.06 mg/kg, MMCA for up to 0.02 mg/kg and malathion for up to 4.41 mg/kg. The samples of pulp were also analysed and did not contain residues above the LOQ of 0.01 mg/kg.

The applicant submitted in total eight GAP compliant residue trials on **mandarins** which were performed in Spain in 2010 and 2011. In each trial two sampling procedures were applied- one sample was taken only from the treated part of the tree and one sample - from the whole tree. The results of analysis indicate that higher total residues are present in samples taken from the treated part of the tree and thus these results were used to derive MRL proposals and risk assessment values. Residues of malaoxon in all trial samples were below the LOQ of 0.01 mg/kg, DMM residues accounted for up to 0.01 mg/kg, MDCA for 0.17 mg/kg, MMCA for 0.02 mg/kg and malathion for 1.38 mg/kg. The samples of pulp were also analysed and only residues of malathion were detected above the LOQ (up to 0.03 mg/kg in one sample).

The applicant proposes to extrapolate residue data on mandarins and oranges to the whole citrus fruit group. According to EU guidelines (EC, 2011), such an extrapolation is acceptable and sufficient number of residue trials has been submitted. The combined foliar and bait treatment results in a more critical residue situation. EFSA is of the opinion that the MRL proposal should be based on the residue trials with foliar spray plus bait, where the samples were taken form the whole tree. Thus, a MRL proposal of 2 mg/kg in citrus fruits is derived.

a. Apples and pears

GAP Argentina: 3 x 2.2 kg a.s./ha, BBCH 75-85, PHI 7 days

The applicant submitted in total eight GAP compliant residue trials on **apples** and four GAP compliant residue trials on **pears**. Trials were performed in 2009 in Argentina, Chile and South Africa. The residues of malaoxon, DMM and MMCA in apples accounted for up to 0.02 mg/kg, MDCA residues accounted for up to 0.26 mg/kg and residues of malathion for up to 0.72 mg/kg. In pears malaoxon was below the LOQ of 0.01 mg/kg in all samples, DMM accounted for up to 0.02 mg/kg, MDCA for 2.84 mg/kg, MMCA for 0.08 mg/kg and malathion for 0.25 mg/kg.

The EMS proposes to extrapolate the residue data from pears to the whole group of pome fruits. According to EC guidelines (EC, 2011), an extrapolation from apples or pears to the whole pome fruit group is acceptable, provided that at least four residue trials on apples are available. However, the residue situation in pears compared to apples is more critical with regard to total residues; in particular the metabolite MDCA was found in significantly higher concentrations in pears. Thus, a combination of residue trials on apples and pears might underestimate the actual residues in pears and the consumer exposure. Thus, EFSA did not accept the combination of apple and pear residue data for deriving a MRL proposal and risk assessment values in pears. An extrapolation of residue data in apples to the remaining crops of the pome fruit group (loquat, medlar, quinces) was not accepted as the notified GAPs refer to use of malathion on apples and pears only.

According to the EU guidance document, pear is a major crop in the world (EC, 2011) and thus at least eight GAP compliant residue trials on pears have to be performed. Since only four trials on pear are available, no MRL proposal was derived. For apples a MRL of 1 mg/kg was derived based on the submitted residue data.

According to the information provided by the EMS, the MRL set for apple and pears is 0.5 mg/kg in Argentina (enforcement residue definition not clear) and 8 mg/kg in New Zealand (for the enforcement residue definition malathion).

b. Plums

GAP Brazil, New Zealand: 3 x 2.6 kg a.s./ha, BBCH 75-85, PHI 7 days

The applicant submitted in total eight GAP compliant residue trials on plums, which were performed in South Africa, Argentina and Chile in 2009. In all samples residue of malaoxon were below the LOQ of 0.01 mg/kg, DMM accounted for up to 0.03 mg/kg, MMCA for up to 0.02 mg/kg, MDCA for up to 0.45 mg/kg and malathion for up to 0.36 mg/kg. Residue data are sufficient to derive a MRL proposal of 0.7 mg/kg for malathion in plums. According to the information provided by the EMS, the MRLs set for plums is 6 mg/kg in Brazil (enforcement residue definition not clear) and 8 mg/kg in New Zealand (for the enforcement residue definition malathion).

c. Strawberries

GAP SEU: 4 x 1.2 kg a.s./ha, BBCH 50-85, PHI 3 days

The applicant submitted in total thirteen residue trials on strawberries which were performed in Spain, Italy and Greece in 2007, 2008, 2010 and 2011. One trial was disregarded due to too high application rate. Eight residue trials have been already assessed by the peer review (EFSA, 2009); samples from four of these residue trials have been analysed for malathion, malaoxon and DMM and thus these data were appropriate for enforcement purposes only. The peer review concluded that the applicant has to provide additional four residue trials on strawberries in which residues at a longer PHI interval of 10 days would be determined in order to assess the possibility to establish a conversion factor (monitoring to risk assessment) for strawberries (EFSA, 2009).

The applicant in the framework of the current application submitted four trials which have been performed in Spain and Greece in 2010 and 2011 and in which samples were taken at 0, 3, 7 and 10 day PHI. Residues of malaoxon in all samples were below the LOQ of 0.01 mg/kg, except in one sample were it was detected at 0.01 mg/kg. Residues of malathion accounted for up to 0.16 mg/kg, DMM for up to 0.04 mg/kg, MDCA for up to 0.49 mg/kg and MMCA for 0.38 mg/kg. In two decline trials the residues of metabolites MMCA and MDCA increase with a longer PHI interval of 7 days, although parent malathion decreases.

The submitted residue data are sufficient to derive a MRL proposal of 0.3 mg/kg for malathion in strawberries.

d. Lettuce

GAP SEU: 3 x 1.1 kg a.s./ha, BBCH 15-45, PHI 14 days

The applicant submitted in total eight GAP compliant residue trials on head lettuce. Trials were performed in Spain, Italy and southern France in 2010 and 2011. The residues of malaoxon in all samples were below 0.01 mg/kg, malathion accounted for 0.27 mg/kg; DMM for 0.01 mg/kg, MDCA for 3 mg/kg and MMCA for 0.07 mg/kg. The EMS proposed to extrapolate residue data in lettuce to the whole group of lettuce and other salad plants. According to EC guidelines (EC, 2011), such an extrapolation is supported only from residue trials on an open leaf lettuce variety. Moreover, the applicant has not notified a GAP for the whole group of salad plants. Thus, a MRL proposal of 0.5 mg/kg is derived for malathion in lettuce only.

The results of the residue trials, the related risk assessment input values (highest residue, median residue, conversion factors) and the MRL proposals are summarised in Table 3-4.

The storage stability of malathion and malaoxon was investigated in the framework of the peer review of Directive 91/414/EEC in cotton seed, wheat grain, forage and straw, lettuce, potato and tomato as well as in the processed commodities of cotton, wheat and tomato (Finland, 2003). The peer review concluded that both substances are stable in these crops for at least 12 months when stored deep frozen (EFSA, 2009). In the Additional Report, the storage stability of malathion, malaoxon, DMM, MMCA and MDCA was investigated in strawberries stored frozen for up to 3 months (United Kingdom, 2009a). Results indicated that malathion, malaoxon and DMM are stable for up to 3 months, whereas MMCA and MDCA are stable for 2 months in strawberries (EFSA, 2009).

In the framework of the current application new studies investigating the storage stability of malathion, malaoxon, MMCA, MDCA and DMM in various crops (rape seed, orange, lemon, strawberry, plum and apples) and processed commodities (orange juice, plum puree, prunes, apple juice, apple dry pomace) were submitted (Italy, 2012; 2013). Samples were homogenized in the presence of ice.

An overview of the available storage stability data for high acid and high water content commodities and the storage intervals of the crops under consideration are compiled in Table 3-3.

Table 3-3: An overview of the storage stability studies in high water and high acid content commodities

Matrix	Commodity	Duration of the storage stability studies (months)	Demonstrated storage stability (months)					Residue trial sample storage (months)	Study
			Malathion	Malaoxon	MMCA	MDCA	DMM		
High acid content	Strawberry	12	-	-	12	12	9	4.7 (new trials); 3.6 - 12 (DAR trials)	Italy, 2012
		3	3	3	2	2	3		EFSA, 2009
	Orange	30	30	30	-	-	-	8.6 oranges; 5.9 mandarins	Italy, 2013
	Lemon	12	12	12	12	12	12		Italy, 2013
High water content	Plum fruit	13.5	-	-	13.5	13.5	1	13.5 plums	Italy, 2013
	Apples	20	-	-	20	20	<1	11 apples; 12.6 pears	Italy, 2013
	Lettuce	12	12	12	-	-	-	12.9 lettuce	EFSA, 2009
	Potatoes	12	12	12	-	-	-	-	EFSA, 2009
	Tomatoes	12	12	12	-	-	-	-	EFSA, 2009

– not investigated

From the available study results it can be concluded that malathion, malaoxon, MMCA, MDCA and DMM are stable in high acid content commodities for at least 12 months when stored deep frozen and when sample homogenization performed in the presence of ice. Malathion and malaoxon residues are stable for 12 months and MMCA and MDCA for 13 months in high water content matrices when samples are stored deep frozen. The storage stability of DMM has been demonstrated in one high water content matrix (plum) for 1 month. The EMS confirmed that residue trial samples (whole samples) were placed into frozen storage on the day of sampling and where shipped frozen to the analytical facility. The homogenization of samples prior to analysis was performed in the presence of dry ice (Italy, 2013).

The supervised residue trial samples of citrus fruits and strawberries have been stored under conditions for which integrity of samples was demonstrated for malathion and all relevant metabolites.

Residue data on apples, pears, plums and lettuce are considered valid with regard to the storage stability of malathion, malaoxon, MMCA and MDCA, but not with regard to the storage stability of metabolite DMM. The residue data in these crops are thus valid for the enforcement purposes, whereas for the risk assessment the total residues might be underestimated due to the degradation of DMM during the storage.

In lettuce, according to metabolism data (see 3.1.1.1) the formation of DMM is not the main route of malathion metabolism. Thus, low amounts of DMM present in lettuce can be explained by different metabolism of malathion rather than by degradation during storage. On January 2014 the applicant informed EFSA that a new study is ongoing where a storage stability of DMM is being investigated in lettuce over a storage period of 12 months. The results of this study will be assessed in the framework of the MRL review according to Article 12 of Regulation (EC) No 396/2005. In a meanwhile the applicant proposes to extrapolate storage stability data of DMM in oilseed rape plant (storage stability demonstrated for 12 months) to address the storage stability of DMM in lettuce. Pending new storage stability studies being submitted on lettuce, the MRL proposal for lettuce is derived on provisional basis.

With regard to residue data of DMM in apples, pears and plums, the EMS proposes to correct the residue data, assuming that 20 months after the storage only 32 % of residues were present in residue trial samples[20]. Such an approach is normally not used for compensating deficiencies in storage stability of residue trial samples. EFSA derived the risk assessment values without the correction factor, but notes that these values are affected by additional uncertainties which should be taken into account when interpreting the results of the risk assessment. The MRL proposals for apples and plums should therefore be also considered as provisional, pending the confirmation that DMM will not occur in these crops in higher concentrations that measured in the submitted residue trials.

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Italy, 2012).

[20] According to storage stability studies with apples, after 1, 8 and 20 months of storage 68%, 58% and 32%, respectively, of the initially spiked residues were recovered (Italy, 2013).

Table 3-4: Overview of the available residues trials data

Commodity	**Residue region (a)**	**Outdoor / Indoor**	**Individual trial results (mg/kg)**		**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**	**Median CF (d)**	**Comments (e)**
			Enforcement residue definition (the sum of malathion and malaoxon expressed as malathion)	**Risk assessment residue definition** **RD 1:** malathion, DMM, MMCA and MDCA expressed as malathion toxic equivalents; **RD 2:** malaoxon					
Oranges, mandarins → lemons, grapefruits, limes	SEU	Outdoor (foliar spray, overall treatment of the trees)	**Oranges:** 0.13; 0.14; 0.05[g]; 0.16[g]; 0.09; 0.04[h]; 0.13; <0.02 Pulp: 2 x <0.02 *Malathion: 0.12; 0.13; 0.04[g]; 0.15[g]; 0.08; 0.03[h]; 0.12; <0.01* *Malaoxon: 8 x <0.01* **Mandarins:** 0.18[h]; 0.12[h]; 0.24; 0.23; 0.30; 0.28[h]; 0.05[h]; 0.71 Pulp: 4 x <0.02 *Malathion: 0.17[h]; 0.11[h]; 0.23; 0.22; 0.29; 0.27[h]; 0.04[h]; 0.71* *Malaoxon: 8 x <0.01*	**Oranges:** **RD 1**: 0.16; 0.18; 0.07[g]; 0.18[g]; 0.13; 0.08[h]; 0.18; 0.06 Pulp: 2 x <0.04 *DMM: 8 x <0.01* *MDCA: 0.02; 0.03; 2 x <0.01; 2 x 0.03; 0.04; 0.03* *MMCA: 8 x <0.01* **RD 2:** 8 x <0.01 **Mandarins:** **RD 1:** 0.29[h]; 0.24[h]; 0.35; 0.31; 0.32; 0.31[h]; 0.08[h]; 0.73 Pulp: 4 x <0.04 *DMM: 8 x <0.01* *MDCA: 0.1[h]; 0.11[h]; 0.1; 0.07; 0.01; 0.02[h]; 0.03[h]; <0.01* *MMCA: 7 x <0.01; 0.01* **RD 2:** Malaoxon: 8 x <0.01	**RD 1**: 0.18 (pulp: 0.04) **RD 2**: <0.01	**RD 1**: 0.73 (pulp: 0.04) **RD 2**: <0.01	0.9	n.c.	R_{ber}= 0.475 R_{max}= 0.596 MRL_{OECD} =0.84/0.9

Commodity	**Residue region (a)**	**Outdoor / Indoor**	**Individual trial results (mg/kg)**		**Median residue (mg/kg) (b)**	**Highest residue (mg/kg) (c)**	**MRL proposal (mg/kg)**	**Median CF (d)**	**Comments (e)**
			Enforcement residue definition (the sum of malathion and malaoxon expressed as malathion)	**Risk assessment residue definition** **RD 1:** malathion, DMM, MMCA and MDCA expressed as malathion toxic equivalents; **RD 2:** malaoxon					
	SEU	Outdoor (foliar spray + bait, only part of the tree was treated)	Sample taken from the treated part of the tree: **Oranges**: 0.61; 0.09; 0.07; 0.33; 1.67; 0.08; 4.42; 0.38 Pulp: 4 x <0.02 Malathion: 0.60; 0.08; 0.06; 0.32; 1.66; 0.07; 4.41; 0.37 Malaoxon: 8 x <0.01 **Mandarins**: 0.33g; 0.19h; 0.88; 0.77; 0.32; 0.29; 0.16h; 1.39 Pulp: <0.02; 0.02; 0.04 Malathion: 0.32g; 0.18g; 0.87; 0.76; 0.31; 0.28; 0.15h; 1.38 Malaoxon: 8 x <0.01	Sample taken from the treated part of the tree: **Oranges:** **RD 1:** 0.64; 0.11; 0.09; 0.36; 1.71; 0.10; 4.51; 0.45 Pulp: 4 x <0.04 DMM: 4 x <0.01; 0.02; <0.01; 0.03; 0.02 MDCA: 0.02; 0.01; <0.01; 0.02; 0.02; <0.01; 0.06; 0.04 MMCA: 6 x <0.01; 0.01; 0.02 RD 2: 8 x <0.01 **Mandarins**: **RD 1**: 0.51g; 0.31h; 0.96; 0.88; 0.34; 0.34; 0.22h; 1.43 Pulp: <0.04; 0.04; 0.06 DMM: 0.01; <0.01; 4 x 0.01; <0.01; 0.01 MDCA: 0.17; 0.11; 0.07; 0.09; <0.01; 0.04; 0.05; 0.03 MMCA: 2 x <0.01; 0.01; 0.02; <0.01; 0.01; <0.01; 0.01 RD 2: 8 x <0.01	**RD 1:** 0.41 (pulp:0.04) **RD 2**: <0.01	**RD 1**: 4.51 (pulp: 0.06) **RD 2:** <0.01	5	n.c.	Rber= 1.71 Rmax= 3.49 MRLOECD = 5.1/5.0

Commodity	Residue region (a)	Outdoor / Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement residue definition (the sum of malathion and malaoxon expressed as malathion)	**Risk assessment residue definition** **RD 1:** malathion, DMM, MMCA and MDCA expressed as malathion toxic equivalents; **RD 2:** malaoxon					
			Sample taken from the whole tree: **Oranges:** 0.04[h]; 2 x 0.05; 0.05[g]; 0.96; 0.02; 1.66; 0.16 Pulp: 3 x <0.02 *Malathion: 0.03[h]; 2 x 0.04; 0.04[g]; 0.95; 0.01; 1.65; 0.15* *Malaoxon: 8 x <0.01* **Mandarins:** 0.24[g]; 0.06[h]; 0.28; 0.12[h]; 0.08; 0.07; 0.05; 0.27 Pulp: 3 x <0.02 *Malathion: 0.23[g]; 0.05[h]; 0.27; 0.11[h]; 0.07; 0.06; 0.04; 0.26* *Malaoxon: 8 x <0.01*	*Sample taken from the whole tree:* **Oranges:** **RD 1:** 0.06[h]; 0.07; 0.07; 0.07[g]; 0.99; 0.04; 1.70; 0.19 Pulp: 3 x <0.04 *DMM: 4 x <0.01; 0.02; <0.01; 0.01; <0.01* *MDCA: 4 x <0.01; 0.01; <0.01; 0.03; 0.02* *MMCA: 8 x <0.01* **RD 2:** 8 x <0.01 **Mandarins:** **RD 1:** 0.40[g]; 0.10[h]; 0.31; 0.21[h]; 0.10; 0.09; 0.07; 0.30 Pulp: 3 x <0.04 *DMM: 8 x <0.01* *MDCA: 0.15[g]; 0.03[h]; 0.02; 0.08[h]; 2 x <0.01; 0.01; 0.02* *MMCA: 0.01; 4 x <0.01; 0.01; <0.01; 0.01* **RD 2:** 8 x <0.01	**RD 1**: 0.10 (pulp:0.04) **RD 2**: <0.01	**RD 1**: 1.70 (pulp: 0.04) **RD 2**: <0.01	**2**	n.c.	R_{ber}= 0.53 R_{max}= 1.36 MRL_{OECD} = 2.01/2.0

Commodity	Residue region (a)	Outdoor / Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement residue definition (the sum of malathion and malaoxon expressed as malathion)	**Risk assessment residue definition** **RD 1:** malathion, DMM, MMCA and MDCA expressed as malathion toxic equivalents; **RD 2:** malaoxon					
Apples	Argentina, Chile, South Africa	Outdoor	0.20; 0.14; 0.12[h]; 0.22; 0.25; 0.73; 0.17; 0.19 *Malathion: 0.19; 0.13; 0.10[h]; 0.21; 0.24; 0.72; 0.16; 0.18* *Malaoxon: 2 x <0.01; 0.02[h]; <0.01; 0.01; 3 x <0.01*	**RD 1:** 0.30; 0.22; 0.14[h]; 0.32; 0.32; 0.92; 0.34; 0.46 **RD 2:** 2 x <0.01; 0.02[h]; <0.01; 0.01; 3 x <0.01 *DMM: 5 x <0.01; 0.02; 2 x <0.01* *MDCA: 0.09; 0.07; 0.02[h]; 0.09; 0.06; 0.16; 0.16; 0.26* *MMCA: 4 x <0.01; 0.01; 0.02; <0.01; 0.01*	**RD 1**: 0.32 **RD 2**: <0.01	**RD 1**: 0.92 **RD 2**: 0.02	**1** provisional	n.c.	Uncertainty regarding possible degradation of DMM during storage of samples. R_{ber}= 0.49 R_{max}= 0.88 MRL_{OECD} = 1.04/1.0
Pears	Argentina, Chile, South Africa	Outdoor	0.11; 0.15; 0.11; 0.26 *Malathion: 0.10; 0.14; 0.10; 0.25* *Malaoxon: 4 x <0.01*	**RD 1**: 1.14; 1.54; 1.43; 3.18 **RD 2:** 4 x <0.01 *DMM: 0.02; 2 x <0.01; 0.01* *MDCA: 0.97; 1.35; 1.26; 2.84* *MMCA: 0.05; 0.04; 0.06; 0.08*	Insufficient number of residue trials.				

Commodity	Residue region (a)	Outdoor / Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement residue definition (the sum of malathion and malaoxon expressed as malathion)	**Risk assessment residue definition** **RD 1:** malathion, DMM, MMCA and MDCA expressed as malathion toxic equivalents; **RD 2:** malaoxon					
Plums	Argentina, Chile, South Africa	Outdoor	0.11; 0.04; 0.07[g]; 0.30; 0.03[h]; 0.24; 0.19[g]; 0.37 *Malathion: 0.10; 0.03; 0.06[g]; 0.29; 0.02[h]; 0.23; 0.18[g]; 0.36* *Malaoxon: 8 x <0.01*	**RD 1:** 0.34; 0.51; 0.17[g]; 0.58; 0.21[h]; 0.27; 0.39[g]; 0.61 **RD 2:** 8 x <0.01 *DMM: 0.02; <0.01; <0.01[g]; 0.03; 0.01[h]; 0.02; 0.02[g]; 0.01* *MDCA: 0.21; 0.45; 0.09[g]; 0.25; 0.17[h]; <0.01; 0.18[g]; 0.23* *MMCA: <0.01; 0.02; <0.01[g]; 0.01; <0.01[h]; <0.01; 0.01[g]; 0.01*	**RD 1**: 0.37 **RD 2**: <0.01	**RD 1**: 0.61 **RD 2**: <0.01	**0.7** provisional	**n.c.**	Uncertainty regarding possible degradation of DMM during storage of samples. R_{ber}=0.57 R_{max}=0.57 MRL_{OECD} =0.68/0.7

Commodity	Residue region (a)	Outdoor / Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement residue definition (the sum of malathion and malaoxon expressed as malathion)	**Risk assessment residue definition** **RD 1:** malathion, DMM, MMCA and MDCA expressed as malathion toxic equivalents; **RD 2:** malaoxon					
Strawberries	SEU	Outdoor	0.04; 0.04; 0.04[f] (0.05 at 3 d PHI); 0.05[f] (0.10 at 3 d PHI) *Malathion: 0.03; 0.03; 0.03[f] (0.04 at 3 d PHI); 0.04[f] (0.09 at 3 d PHI)* *Malaoxon: 4 x <0.01* EFSA, 2009: 0.06[i]; 0.08[i]; 0.05[i]; 0.06[i]; 0.12; 0.17; 0.14; 0.14 *Malathion: 0.05; 0.07; 0.04; 0.05; 0.11; 0.16; 0.13; 0.13* *Malaoxon: 7 x <0.01; 0.01*	**RD 1:** 0.36; 0.47; 0.39[f] (0.27 at 3 d PHI); 0.49[f] (0.39 at 3 d PHI) **RD 2**: *0.03; 0.03; 0.03[f] (0.04 at 3 d PHI); 0.04[f] (0.09 at 3 d PHI* EFSA, 2009: **RD 1**: -; -; -; -; 1.01; 0.68; 0.68; 0.73 *DMM: 0.03; 0.03;0.02; 0.04* *MDCA: 0.49;0.28; 0.30; 0.38* *MMCA: 0.38; 0.21; 0.23; 0.18* **RD 2 :** 7 x <0.01; 0.01	**RD 1**: 0.59 **RD 2**: <0.01	**RD 1**: 1.01 **RD 2**: 0.01	**0.3**	n.c.	R_{ber}= 0.27 R_{max}= 0.21 MRL_{OECD} = 0.27/0.30

Commodity	Residue region (a)	Outdoor / Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement residue definition (the sum of malathion and malaoxon expressed as malathion)	**Risk assessment residue definition** **RD 1:** malathion, DMM, MMCA and MDCA expressed as malathion toxic equivalents; **RD 2:** malaoxon					
Lettuce	SEU	Outdoor	0.28; 0.12; 6 x 0.02 *Malathion: 0.27; 0.11; 0.01; 0.01; 4 x <0.01* *Malaoxon: 8 x <0.01*	**RD 1:** 3.35; 0.43; 2.47; 0.40; 0.05; 0.47; 0.38; 0.83 **RD 2:** 8 x <0.01 *DMM: 0.01; 2 x <0.01; 0.01; 3 x <0.01; 0.01* *MDCA: 3.0; 0.30; 2.43; 0.37; 0.02; 0.44; 0.35; 0.80* *MMCA: 0.07; 0.01; 0.02; 5 x <0.01*	**RD 1**: 0.45 **RD 2**: <0.01	**RD 1**: 3.35 **RD 2**: <0.01	**0.5** provisional	n.c.	Uncertainty regarding possible degradation of DMM during storage of samples. R_{ber}=0.19 R_{max}=0.36 MRL_{OECD} =0.44/0.50

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.
(e): Statistical estimation of MRLs according to the EU methodology (Rber, Rmax; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).
(f): Residue within a trial higher at a longer PHI interval of 7 days
(g): Residue within a trial higher at a longer PHI interval of 10 days
(h) Residue within a trial higher at a longer PHI interval of 14 days
(i): Samples analysed for malathion, malaoxon and DMM only.
n.c. Not calculated.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of **malathion** was investigated in the framework of the peer review in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (Finland, 2005). From the study results the peer review concluded that main residues in processed commodities are malathion and its metabolite DMM and that for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2009). However, EFSA concluded that further information is required on the fate of MMCA and MDCA upon processing (EFSA, 2009).

In the framework of the current application the applicant submitted hydrolysis studies where effects of processing on the nature of metabolites **MMCA** and **MDCA** were investigated in a standard hydrolysis study simulating pasteurisation, baking/brewing/boiling and sterilisation (Italy, 2012). The results indicate that metabolite MMCA is stable under baking/boiling conditions, but under pasteurization and sterilisation conditions degrades to desmethyl malathion monocarboxylic acid (DM-MMCA) (41.3 % and 71 % AR, respectively). No other metabolites were formed at levels above 10 % AR. Metabolite MDCA under baking/boiling conditions forms two metabolites: desmethyl malaoxon dicarboxylic acid (Mox DCA) (20.4 %) and mercaptosuccinic acid[21] (8.7 %). Under pasteurisation and sterilisation conditions MoxDCA accounted for 38.8 % and 10.7 % AR, respectively, and mercaptosuccinic acid for 39.4 % and 73.1 % AR, respectively.

Mercaptosuccinic acid was formed in rat metabolism of malathion and thus its toxicity is assumed to be covered by the toxicity of parent malathion. The toxicity of DM-MMCA and MoxDCA was investigated by the Experts` Meeting in September 2013 where it was concluded that for DM-MMCA the reference values of malathion can be applied. For MoxDCA, it was concluded that it is likely that its potential lies between malaoxon and malathion. If a risk assessment for consumer is needed, the reference values of malathion cannot be applied (EFSA, 2013). The available toxicity data and the results of the hydrolysis study indicate that metabolites DM-MMCA and MoxDCA have to be included in the risk assessment residue definition for processed commodities. The applicant has not provided studies on the magnitude of these metabolites in the processed crops under consideration. According to the residue trials data, the precursor compounds of these metabolites (MMCA and MDCA) are present at quantifiable levels in apples, pears, plums and strawberries and the formation of metabolites DM-MMCA and MoxDCA above 0.1 mg/kg cannot be excluded in the processed commodities of these crops. In citrus fruits formation of these metabolites during processing is considered not relevant due to reduction of residues by peeling.

EFSA concludes that for the current application on a provisional basis the enforcement residue definition in processed commodities is the same as in raw commodities ("malathion and malaoxon, expressed as malathion"); however, in future the residue definitions for processed commodities should be reconsidered (see 3.1.1.1). EFSA proposes that the risk assessment residue definition for processed commodities is split, considering different toxicological potencies of malathion and malaoxon:

(1) "malathion and DMM, MMCA, DM-MMCA and MDCA expressed as malathion toxic equivalents";

(2) "malaoxon and MoxDCA, expressed as malaoxon".

The enforcement and risk assessment residue definitions might be reconsidered in the framework of Article 12 of Regulation (EC) No 396/2005.

In the framework of the current application the applicant submitted studies investigating effects of processing on the magnitude of malathion residues in processed oranges (juice, wet pomace ad dry pomace), apples (apple juice, wet and dry pomace, apple sauce) and plums (pitted prunes, plum puree). Raw and processed commodities were analysed for parent malathion, malaoxon, DMM,

[21] Mercaptosuccinic acid. See Appendix D.

MMCA and MDCA. Due to uncertainties related to the storage stability of metabolite DMM in high water content matrices, the applicant proposes to correct residue data for DMM in apples, dry apple pomace, wet apple pomace, apple sauce and plums. Such approach is normally not used to compensate deficiencies of studies. Therefore the residue data are considered to be of limited validity as regards the magnitude of DMM residues.

Orange trees were treated three times with either a single application of 0.48 kg a.s./ha or 1.45 kg a.s./ha and mature oranges were harvested 7 DALA. Mature oranges were processed into pasteurized juice, wet and dry pomace. A reduction of residue concentration was observed in all processed commodities. From the submitted residue trials data on oranges and mandarins (see Table 3-4), a peeling factor of 0.15 was derived for the whole citrus fruit group. **Apple** trees were treated three times at an application rate of 2.2 kg a.s./ha and apples were harvested 7 DALA. Apples were processed into pasteurised juice, sauce, wet and dry pomace. A reduction of residues was observed both in juice and sauce whereas a concentration of residues was observed in wet and dry apple pomace. **Plum** trees were treated three times at an application rate of 2.6 kg a.s./ha and plums were harvested 7 DALA. Plums were pitted and processed into plum puree (sterilised). Results indicate a reduction of residues in all processed plum fractions.

Pending final decision to be taken on the residue definition for the risk assessment, EFSA derived processing factors (Table 3-5) only for the existing enforcement residue definition. A conversion factor, to take into account a possible degradation/conversion of parent compound to degradation products was not calculated, due to uncertainties of the available residue data. Thus, EFSA does not recommend using processing factors for a refined risk assessment.

Table 3-5: Overview of the available processing studies

Processed commodity	Number of studies	Median PF (a)	Median CF (b)	Comments
Enforcement residue definition (raw and processed commodity): Malathion and malaoxon, expressed as malathion				
Citrus fruit, peeled	19	<0.15	n.c.	In all pulp samples (except two samples with residues of malathion at 0.01 mg/kg and 0.03 mg/kg) residues were below the LOQ of 0.01 mg/kg.
Orange, pasteurised juice	4	<0.18	n.c.	In all juice samples all compounds below the LOQ of 0.01 mg/kg.
Orange, wet pomace	4	0.44	n.c.	
Orange, dry pomace	4	0.41	n.c.	
Apple, pasteurised juice	3	0.38	n.c.	The derived processing factors are driven by uncertainties regarding storage stability of metabolite DMM. Moreover, the magnitude of metabolites DM-MMCA and MoxDCA has not been investigated.
Apple, wet pomace	3	2.27	n.c.	
Apple, dry pomace	3	3.73	n.c.	
Apple, sauce	3	0.23	n.c.	
Plums, dried pitted	3	0.67	n.c.	
Plums, puree	3	0.90	n.c.	
Risk assessment residue definition (for dietary burden calculation): Malathion and malaoxon, DMM, MMCA and MDCA expressed as malathion				

Processed commodity	Number of studies	Median PF (a)	Median CF (b)	Comments
Oranges, wet pomace	4	0.57	n.r.	Rresidues in raw orange: 0.15; 0.09; 1.34; 0.24 Residues in wet pomace: 0.15; 0.05; 0.28; 0.14
Apples, wet pomace	3	1.84	n.r.	Residues in raw apple: 0.17; 0.18; 0.24 Residues in wet pomace: 0.21; 0.33; 0.45

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study. The processing factor reflects a ratio between enforcement residues (malathion and malaoxon, expressed as malathion) in a processed commodity and raw commodity. The potential conversion of malathion and/or malaoxon to other degradation products is not covered by the PF.
(b): The median conversion factor for enforcement to risk assessment.
n.c. Not calculated.
n.r. Not relevant.

Although the processed citrus fruit were not analysed for all compounds included in the proposed residue definition for processed commodities (DM-MMCA and MoxDCA), the available studies are considered sufficient to derive processing factors that can be recommended for inclusion in Annex VI of Regulation (EC) No 396/2005, as DM-MMCA and MoxDCA are not expected to occur at significant levels in processed citrus fruit commodities, The studies in citrus are also acceptable as regards the storage stability of malathion and all metabolites.

The processing factors for apple and plum commodities are associated by uncertainties related to storage stability of metabolite DMM and possible presence of metabolites MoxDCA and DM-MMCA and are thus not proposed to be included in Annex VI of Regulation (EC) No 396/2005.

The proposed processing factors for oranges (wet pomace) and apples (wet pomace) were derived to be used in an indicative dietary burden calculation for livestock. For these processing factors the transfer rate of the total measured residues of malathion, malaoxon, DMM, MMCA and MDCA to the processed commodities was calculated.

3.1.2. Rotational crops

Lettuce and strawberry can be grown in rotation with other plants and therefore the possible occurrence of residues in rotational/succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of malathion in soil is rapid with DT_{90lab} being less than 1 day; the $DT_{90field}$ value could not be calculated due to rapid degradation of malathion in the soil. The main soil metabolites are MMCA and MDCA which also degrade rapidly with DT_{90lab} values of 2.4 days and 17.8 days (EFSA, 2009). The $DT_{90field}$ for MDCA was also not calculated due to rapid degradation. Thus, according to the EU guidelines (EC, 1997c), further investigation of malathion residues in rotational/succeeding crops is not required. Nevertheless, a rotational crop study investigating the nature of malathion in rotational crops was submitted for the peer review and more details can be found in the DAR (Finland, 2005).

3.2. Nature and magnitude of residues in livestock

Since citrus fruit and pome fruit pomace can be used as livestock feed, the nature and magnitude of malathion residues in livestock has to be assessed in the framework of this application.

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (EC, 1996). The input values for the dietary burden calculation were selected according to the latest FAO recommendations[22] (FAO, 2009a) considering the livestock intake from the intended use on citrus fruits, apples and from the intake of cereals (wheat, rye, barley, oats, and maize) for which the existing EU MRL is set above the LOQ according to the Regulation (EC) No 396/2005. The input values for citrus and apple pomace were as derived from the submitted residue trials (see Table 3-4); to account for the concentration of residues in citrus and apple pomace, processing factors as derived in the framework of the current application (Table 3-5) were applied to the input values.

To refine the dietary burden calculations, EFSA used the risk assessment values as reported for wheat, barley, oat, rye and maize grain in the framework of setting of temporary MRLs of malathion (Finland, 2007). In order to account for the potential residue concentration in wheat and rye bran, a processing factor of 2.64 was applied as reported by the RMS Finland in the framework of setting temporary MRLs for malathion (Finland, 2007). Overall the dietary burden calculation should be considered as indicative only, since at the moment EFSA does not have a complete overview on all authorised uses.

The input values for the livestock dietary burden calculation are compiled in Table 3-6.

Table 3-6: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value** (mg/kg)	**Comment**
Risk assessment residue definition: Malathion and malaoxon, DMM, MMCA and MDCA expressed as malathion				
Citrus fruit pomace	0.24	Median residue [a] (SEU use (foliar and bait)) (Table 3-4) *PF (0.57) (Table 3-5)	0.24	Median residue [a] (SEU use (foliar and bait)) (Table 3-4) *PF (0.57) (Table 3-5)
Apple pomace	0.61	Median residue [a] (Table 3-4) *PF (1.84) (Table 3-5)	0.61	Median residue [a] (Table 3-4) *PF (1.84) (Table 3-5)
Wheat, rye, oat, barley, maize grain	2.48[b]	Median residue [c] (Finland, 2007)	2.48[b]	Median residue [c] (Finland, 2007)
Wheat, rye bran	6.55[b]	Median residue (grain) *PF (2.64) (Finland, 2007)	6.55[b]	Median residue (grain) *PF (2.64) (Finland, 2007)

(a): Median residue calculated as the sum of median residue for RD 1 and median residue for RD 2 (Table 3-4), multiplied by the molecular weight conversion factor of 1.05 to express malaoxon residues as malathion

(b): Post-harvest treatment; refers to the enforcement residue definition "malathion and malaoxon, expressed as malathion" (Finland, 2007). No information is available on the residues of DMM, MMCA and MDCA in cereals

(c): Since the existing MRL for cereals is set at the same level as for wheat (8 mg/kg), indicating a possible extrapolation of residue data from wheat to cereals, a median residue value reported for wheat was used as an input value also for other cereals

The results of the indicative dietary burden calculation are summarised in the following table.

[22] It is noted that for calculating the dietary burden the toxicological equivalence factors of malaoxon are not relevant. Thus, for the dietary exposure calculation of livestock EFSA used STMR values which reflect the sum of malathion and its metabolites without TEFs.

Table 3-7: Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw per d)	**Median dietary burden** (mg/kg bw per d)	**Highest contributing commodity**[(a)]	**Max dietary burden** (mg/kg DM)	**Trigger exceeded** (Y/N)
Risk assessment residue definition: Malathion and malaoxon, DMM, MMCA and MDCA expressed as malathion					
Dairy ruminants	0.063	0.063	Rye bran	1.74	Y
Meat ruminants	0.122	0.122	Wheat grain	2.84	Y
Poultry	0.127	0.127	Wheat grain	2.02	Y
Pigs	0.092	0.092	Wheat grain	2.31	Y

The calculated dietary burden indicates that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for all animal species and is driven solely by the existing uses of malathion on cereals. EFSA notes that the residue data on cereal straw and maize silage were not available and thus the dietary burden might underestimate the actual livestock exposure to malathion residues from the existing uses. It is also not known whether other uses on feed crops are authorized in Europe that could significantly contribute to the livestock dietary burden. In addition, no residue data on other malathion metabolites (DMM, MDCA and MMCA) in cereals are available.

According to the EFSA conclusion, livestock metabolism studies with lactating goats (dosed 3.3-3.8 mg/kg malathion bw/day; *ca.*1.3N the calculated dietary burden) and laying hens (dosed 2.5 mg/kg malathion bw/day; 1.2 N the calculated dietary burden) have been submitted but not fully peer reviewed because the representative uses considered under the peer review (strawberries and ornamentals) were not considered as important feed items (EFSA, 2009). Results of metabolism studies however indicate that in organs and edible tissues of both species TRR were highest in the excretory and metabolising organs liver and kidney. Neither malathion nor its immediate metabolites were present at levels exceeding the LOQ in edible tissues, milk and eggs, with the exception of goat kidney were metabolites MDCA and MMCA were found at levels above the LOQ. The peer review suggested that malathion is rapidly and completely metabolised and incorporated into naturally occurring biochemical compounds and neither malathion nor any toxicologically significant products arising from its immediate metabolism is expected to occur in edible animal matrices. Thus, the peer review did not propose residue definition for ruminants and hens (EFSA, 2009). It was noted, that the metabolism of DMM, MMCA and MDCA in livestock has not been investigated and potential residues of these compounds in animal products might be carried-over into food of animal origin and should therefore be considered in the final assessment of malathion related residues in food of animal origin.

For the new intended use on citrus fruits and the import tolerance on apples it is concluded that it will not raise significantly the existing dietary burden for livestock, which is mainly driven by cereal products and thus the nature and magnitude of malathion residues in livestock was further not assessed in the framework of this application.

The existing EU MRLs for the food commodities of animal origin are set at the LOQ of 0.02 mg/kg. EFSA proposes that a comprehensive assessment of the nature and magnitude of malathion residues in livestock and the potential carry-over of residues into food commodities of animal origin is performed in the framework of Article 12 of Regulation (EC) No 396/2006 when all authorised uses of malathion on feed crops and the residue data are known.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[23] (EFSA, 2007). In order to increase the transparency , EFSA performed the exposure calculation for the two separate risk assessment residue definitions derived by EFSA (see 3.1.1.1.) which were combined at the end in a cumulative assessment to estimate the overall exposure to all malathion related residues, taking into account the toxicological potency of the individual compounds.

In the long-term exposure assessment for **residue definition 1** (malathion, DMM, MMCA and MDCA expressed as malathion toxic equivalents) EFSA used the median residue values as derived from the residue trials on oranges, mandarins apples, plums, lettuce and strawberries (see Table 3-4). For citrus fruit no peeling factor was applied as data were available on residues in the pulp. For pears the existing MRL was used as an input value as no new MRL proposal was derived in the framework of the current application. For camomile the median residue value from the previously issued EFSA reasoned opinion (EFSA, 2011) was available to refine the calculation. For cereals the input value was as reported by the RMS Finland in the framework of the setting of temporary MRLs for malathion (Finland, 2007). For the remaining commodities of plant and animal origin for which the existing MRLs in Regulation (EC) No 396/2005 are set at the combined LOQ of 0.02 mg/kg for malathion and malaoxon, the input value was the enforcement LOQ for malathion (0.01 mg/kg). EFSA notes that data on the presence of other metabolites (DMM, MDCA and MMCA) in camomile and cereal grain are not available. The calculated exposure was then compared with the toxicological reference value derived for malathion (see Table 2-1). EFSA would like to reiterate that the application of the ADI/ARfD derived for the malathion with a maximum impurity of 0.2 % of isomalathion for the less pure active substance used in third countries on apples and plums may underestimate the risk for consumers. Further uncertainties of the assessment are summarised at the end of this section.

The long-term exposure for **residue definition 2** (malaoxon) was calculated separately, considering that this metabolite is 30 times more toxic than parent malathion. For the calculation of the chronic exposure, EFSA used the median residue values for malaoxon as derived from the residue trials on oranges, mandarins, apples, plums and strawberries (see Table 3-4). For citrus fruit no peeling factor was applied as data were available on residues in the pulp. According to the previous EFSA reasoned opinion (EFSA, 2011), malaoxon is not relevant metabolite in camomile and thus the input value for camomile was the LOQ of malaoxon. For cereals the median residue values are based on the post-harvest treatment of cereals (Finland, 2007). According to residue trials submitted for the JMPR evaluation 2008, the residues of malaoxon in wheat following post-harvest treatment (leading to a CXL proposal of 10 mg/kg) are below the LOQ of 0.01 mg/kg (FAO, 2009b). Thus, for cereals, the input value was the LOQ of malaoxon (0.01 mg/kg). For the remaining commodities of plant and animal origin for which the existing MRLs in Regulation (EC) No 396/2005 are set at the combined LOQ of 0.02 mg/kg for malathion and malaoxon, the input value was the enforcement LOQ for malaoxon (0.01 mg/kg). The calculated exposure was then compared to a toxicological reference value for malaoxon (see Table 2-2). The uncertainties related to the exposure assessment for malaoxon are discussed at the end of the section.

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

[23] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

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

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition (1): Malathion and DMM, MMCA and MDCA expressed as malathion toxic equivalents				
Citrus fruits	0.04	Median residue (pulp) (SEU foliar and bait treatment) (Table 3-4)	0.06	Highest residue(pulp) (SEU foliar and bait treatment) (Table 3-4)
Apples	0.32	Median residue (Table 3-4)	0.92	Highest residue (Table 3-4)
Plums	0.37	Median residue (Table 3-4)	0.61	Highest residue (Table 3-4)
Strawberries	0.59	Median residue (Table 3-4)	1.01	Highest residue (Table 3-4)
Lettuce	0.45	Median residue (Table 3-4)	3.35	Highest residue (Table 3-4)
Camomile	0.19	Median residue (EFSA, 2011)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Tea	0.5	MRL		
Wheat grain	1.64	Median residue *PF (0.66 whole meal flour) (Finland, 2007)		
Cereal grain[a] (except wheat)	2.48	Median residue (extrapolation form wheat) (Finland, 2007)		
Other commodities of plant and animal origin	0.01 (1/2 MRL =LOQ of malathion)	See Appendix C		
Risk assessment residue definition (2): Malaoxon				
Citrus fruits	0.01	Median residue (pulp) (SEU foliar and bait treatment) (Table 3-4)	0.01	Highest residue (pulp) (SEU foliar and bait treatment) (Table 3-4)
Apples	0.01	Median residue (Table 3-4)	0.02	Highest residue (Table 3-4)
Plums	0.01	Median residue (Table 3-4)	0.01	Highest residue (Table 3-4)
Strawberries	0.01	Median residue (Table 3-4)	0.01	Highest residue (Table 3-4)
Lettuce	0.01	Median residue (Table 3-4)	0.01	Highest residue (Table 3-4)
Camomile	0.01	LOQ	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Tea	0.5	MRL		
Cereal grain	0.01	LOQ		

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other commodities of plant and animal origin	0.01 (1/2 MRL =LOQ of malaoxon)	See Appendix C		

(a): The existing MRL for cereal grain is set at 8 mg/kg, indicating a possible extrapolation of residue data from wheat to cereals and therefore the median residue value reported for wheat was used as an input value for all cereal grain. The residue data reflect post-harvest treatment of cereals and refer to the sum of malathion and malaoxon residues.

The results of the intake calculation are presented in Appendix B to this reasoned opinion.

Residue definition 1. The long-term consumer exposure as accounted for up to 77 % of the ADI derived for malathion (WHO Cluster diet B). The individual contribution of residues in the crops under consideration to the total consumer exposure (in the percentage of the ADI) accounted for a maximum of 12.9 % for apples (DE child diet), 1.2 % for strawberries (FR toddler diet), 0.8 % for lettuce (ES adult diet), 0.53 % for oranges (maximum of citrus fruit group; DE child diet) and 0.4 % for plums (IE adult diet). The acute exposure to the total malathion residues in the crops under consideration accounted for 30 % for lettuce and apples, respectively, 7 % for plums, 5 % for strawberries, 3 % for oranges and was below for other crops under consideration (all results expressed in percentage of the ARfD of malathion)

Residue definition 2. The total calculated intake for malaoxon accounted for up to 71 % of the ADI for malaoxon (UK Infant diet). The contribution of residues in the crops under consideration to the total consumer exposure (in the percentage of the ADI) accounted for a maximum of 12.1 % for apples (DE child diet), 3.8 % for oranges (highest from all citrus fruits group; DE child diet), 0.6 % for strawberries (FR toddler diet), 0.5 % for lettuce (ES adult diet) and 0.3 % for plums (IE adult diet). The calculated maximum exposure (in percentage of the ARfD) accounted for 20 % for apples, 13 % for oranges, 9 % for grapefruit, 6 % for mandarins and was below 5 % for other crops under consideration.

In the combined long-term exposure (combining the exposure calculated for the two separate residue definitions expressed in malathion equivalents), the calculated exposure exceeded the ADI for 5 diets (125 % for WHO cluster diet, 116 % Danish child, 111 % for Dutch child, 105 % for UK infant and 103 % for German child). EFSA notes, that exclusion of the crops under consideration for MRL setting (citrus, apples, plums, strawberries and lettuce) from the exposure calculation does not have a significant effect on the overall dietary exposure (malathion 75 % of the malathion ADI; malaoxon 71 % of the malaoxon ADI; combined exposure: exceedance of the toxicological reference value for 4 diets (WHO Cluster diet B (124 %), DK child diet (113 %), UK infant (104 %), NL child diet (104 %)).
EFSA concludes that based on the current information, taking into account the existing MRLs and the lack of detailed information on the actual approved uses of malathion a potential long-term consumer health risk cannot be excluded. Risk managers should consider the following uncertainties in the assessment which may have lead to an over- or underestimation of the long-term exposure:

- a lower ADI might be required for the assessment of the long-term consumer exposure to malathion residues from the intake of apples and plums, considering that in the third countries for which the import tolerances are requested on these fruits, malathion with higher isomalathion content (0.4 %) is used (see section 2.1.);

- the residue data in plums, apples and lettuce are affected by uncertainties regarding storage stability of metabolite DMM; thus, the results of residue trials may underestimate the actual dietary burden for consumers;

- the possible formation of DM-MMCA and, in particular, the formation of the more toxic degradation product MoxDCA in processed commodities (relevant for apples, plums, strawberries under current application) may lead to an underestimation of the risk for consumers resulting from the consumption of processed products;

- the lack of detailed information on the authorized uses of malathion in Europe and third countries. In the dietary exposure assessment for all crops except the crops under consideration EFSA assumed that they contribute to the dietary burden with residues at the LOQ of malathion and malaoxon, respectively. These “background” levels are accounting for the major part of the calculated long-term exposure. Thus, the calculations are considered to be conservative with regard to these crops, leading to a possible overestimation of the calculated exposure;

- The lack of detailed information on the authorised uses may also lead to an underestimation of the actual exposure, in particular related to the residues in cereals, where EFSA assumed that only post-harvest uses are approved which are not expected to lead to malaoxon residues. In case foliar treatments are approved, the malaoxon residues might occur in concentrations relevant for consumer exposure.

For a combined short-term exposure assessment for all malathion related compounds (malathion, malaoxon, DMM, MMCA and MDCA, expressed as malathion toxic equivalents), no consumer health concern was identified for the crops under consideration. The maximum short-term exposure for apples accounted for 50 % of the toxicological reference value for malathion; 33 % for lettuce, 16 % for oranges, 11 % for grapefruit, 10 % for plums, 7 % for strawberries and mandarins, respectively, 4 % for lemons and 2 % for limes. Also the short-term exposure assessment is affected by uncertainties as regards the applicability of the toxicological reference values derived for the active substance with a higher purity. Also the possible degradation of DMM in supervised field trials for plums, apples and lettuce due to the storage period of samples which exceeded the period for which integrity of the samples was demonstrated may lead to an underestimation. The same is true for the lack of knowledge regarding the possible formation of MoxDCA in processed apples, plums and strawberries.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of malathion was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.03 mg/kg bw per day and an ARfD of 0.3 mg/kg bw. These toxicological reference values are applicable for malathion containing maximum 0.2 % of isomalathion. According to the EMS, the isomalathion content in malathion used in the third countries for which the import tolerance is requested now for apples, pears and plums, is 0.4 %. The impact of higher isomalathion content on the toxicity of malathion was discussed by the Experts` Meeting, but no conclusion could be derived. Thus, using the toxicological reference values mentioned above for the current MRL application leads to an additional uncertainty in the risk assessment, in particular for the risk related to malathion residues on imported apples, pears and plums. The metabolite malaoxon was found to be more toxic than the parent compound. On the basis of the toxicological studies a toxicity equivalence factor (TEF) of 30 was derived.

The metabolism of malathion in primary crops was investigated in four crop groups and the peer review derived the residue definition for risk assessment as “malathion and its metabolites malaoxon, desmethyl-malathion (DMM), malathion monocarboxylic acid (MMCA) and malathion dicarboxylic acid (MDCA) expressed as malathion toxic equivalents”. For enforcement the residue was defined as “the sum of malathion and malaoxon, expressed as malathion”. The current residue definition set in Regulation (EC) No 396/2005 is identical. For the uses on the crops under consideration, EFSA concludes that the metabolism of malathion is sufficiently addressed. However, EFSA is of the opinion, that the residue definition for enforcement shall be set separately for malathion and malaoxon, considering their different toxicological profile. For reasons of transparency, EFSA also recommends two separate residue definitions for the exposure assessment where residue definition (1) would cover all compounds with a similar toxicity of malathion (“malathion and DMM, MMCA and MDCA, expressed as malathion”) and residue definition (2) would refer to all compounds with a similar toxicity of malaoxon; in the final risk assessment the combined exposure for the two residue definitions should be calculated. EFSA proposes to discuss this proposal in the framework of Article 12 of Regulation (EC) No 396/2005.

EFSA considers that the submitted supervised residue trials are sufficient to derive MRL proposals for citrus fruits, apples, plums, strawberries and lettuce. Residue data were not sufficient to derive a MRL proposal for pears. An extrapolation of residue data from lettuce to the whole group of salad plants is not appropriate since no data are available for open leaf varieties of lettuce. The derived risk assessment values for apples, plums and lettuce are driven by uncertainties related to the storage stability of metabolite DMM. The applicant has to investigate the magnitude of metabolite DMM in high water content matrices during freezer storage. Adequate analytical enforcement methods are available to control the residues of malathion and malaoxon in the crops under consideration.

Studies investigating the nature of malathion residues in processed commodities were assessed in the peer review and indicated that relevant residues are malathion and desmethyl-malathion (DMM). Under current application new studies were submitted on the nature of MMCA and MDCA in processed commodities. MMCA under pasteurization and sterilisation degrades to desmethyl malathion monocarboxylic acid (DM-MMCA), whereas MDCA under all processing conditions degrades to desmethyl malaoxon dicarboxylic acid (MoxDCA). The toxicity of these metabolites was investigated in the Experts` Meeting where it was concluded that for DM-MMCA the reference values of malathion can be applied; the toxicity potential of MoxDCA lies between malaoxon and malathion, but lacking data no TEF could be derived. According to a theoretical estimation, residues of both metabolites can be formed above 0.1 mg/kg in strawberries, apples, pears and plums under various processing conditions and therefore these metabolites should be included in the risk assessment residue definition of processed commodities. EFSA concludes that for the current application on a provisional basis the enforcement residue definition in processed commodities is the same as in raw commodities; however, in future the residue definition for processed commodities should be reconsidered. The applicant has to submit adequate processing studies investigating the magnitude of metabolites DM-MMCA and MoxDCA in the processed commodities. EFSA proposes that the risk assessment residue definition for processed commodities is split, considering different toxicological potencies of malathion and malaoxon and including relevant metabolites formed during processing.

The applicant submitted processing studies with apples, plums and oranges. A reduction of residues (sum of malathion and malaoxon, expressed as malathion) was observed in all processed commodities, except in wet and dry apple pomace. Although the processed citrus fruit were not analysed for metabolites DM-MMCA and MoxDCA, the available studies are considered sufficient to derive processing factors that can be recommended for inclusion in Annex VI of Regulation (EC) No 396/2005, as these metabolites are not expected to occur at significant levels in processed citrus fruit commodities. The processing factors for apple and plum commodities are associated by uncertainties related to storage stability of metabolite DMM and possible presence of metabolites MoxDCA and DM-MMCA and are thus not proposed for inclusion in Annex VI of the above mentioned Regulation. The proposed processing factors are:

- Citrus fruit, peeled: <0.15
- Oranges, pasteurized juice: <0.18
- Oranges, wet pomace: 0.44

- Oranges, dry pomace: 0.41

Lettuce and strawberries can be grown in rotation with other plants. However, malathion and its soil metabolites MMCA and MDCA degrades rapidly in the soil and thus further investigation of malathion residues in rotational/succeeding crops is not required.

The contribution of malathion residues in citrus and pome fruit pomace to the current livestock dietary burden from the intended and authorized uses was also assessed. The calculated livestock dietary burdens exceeded the trigger value of 0.1 mg/kg (dry matter) for all animal species and were driven by the existing uses on cereals. Thus, the nature and magnitude of malathion residues in livestock was not further assessed in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). The consumer exposure calculation was performed for the two separate risk assessment residue definitions proposed by EFSA ((1): “malathion, DMM, MMCA and MDCA, expressed as malathion”; (2): “malaoxon”), which were combined at the end in a cumulative assessment to estimate the overall exposure to all malathion related residues, taking into account the toxicological potency of the individual compounds.

In the long-term exposure calculation EFSA used the median residue values as derived from the residue trials on oranges, mandarins, apples, plums, lettuce and strawberries. For citrus fruit no peeling factor was applied as data were available on residues in the pulp. For pears the existing MRL was used as an input value as no MRL proposal was derived in the framework of the current application. For camomile and cereals the risk assessment values for malathion and malaoxon were available to refine the calculation. For the remaining commodities of plant and animal origin for which the existing MRLs in Regulation (EC) No 396/2005 are set at the combined LOQ of 0.02 mg/kg for malathion and malaoxon, the input value was the enforcement LOQ for each of these compounds (0.01 mg/kg), depending on the exposure calculation scenario.

The calculated exposure for residue definition (1) was then compared with the toxicological reference value derived for malathion; the calculated exposure for residue definition (2) was compared with a toxicological reference value derived for malaoxon which was 30 times lower than the ADI for parent malathion, to take into account the TEF. The acute exposure assessment was performed only with regard to the commodities under consideration. Also in this case the short term exposure was calculated separately for the two residue definitions.

For the residue definition (1) the long-term consumer exposure accounted for up to 77 % of the ADI (WHO Cluster diet B). The individual contribution of residues in the crops under consideration to the total consumer exposure (in the percentage of the ADI) accounted for a maximum of 12.9 % for apples (DE child diet), 1.2 % for strawberries (FR toddler diet), 0.8 % for lettuce (ES adult diet), 0.53 % for oranges (maximum of citrus fruit group; DE child diet) and 0.4 % for plums (IE adult diet). The acute exposure to the total malathion residues in the crops under consideration accounted for 30 % for lettuce and apples, respectively, 7 % for plums, 5 % for strawberries, 3 % for oranges and was below for other crops under consideration.

For the residue definition (2) the total calculated intake for malaoxon accounted for up to 71 % of the ADI (UK Infant diet). The contribution of residues in the crops under consideration to the total consumer exposure (in the percentage of the ADI) accounted for a maximum of 12.1 % for apples (DE child diet), 3.8 % for oranges (highest from all citrus fruits group; DE child diet), 0.6 % for strawberries (FR toddler diet), 0.5 % for lettuce (ES adult diet) and 0.3 % for plums (IE adult diet). The calculated maximum exposure (in percentage of the ARfD) accounted for 20 % for apples, 13 % for oranges, 9 % for grapefruit, 6 % for mandarins and was below 5 % for other crops under consideration.

The **combined long-term exposure** exceeded the ADI for five diets (**125 %** for WHO cluster diet B, **116 %** Danish child, **111 %** for Dutch child, **105 %** for UK infant and **103 %** for German child). Excluding the crops under consideration for MRL setting (citrus, apples, plums, strawberries and lettuce) from the exposure calculation does not have a significant effect on the overall dietary exposure (malathion 75 % of the malathion ADI; malaoxon 71 % of the malaoxon ADI, combined exposure: exceedance of the toxicological reference value for 4 diets (WHO Cluster diet B (124 %), DK child diet (113 %), UK infant (104 %), NL child diet (104 %)).

EFSA concludes that, based on the currently available information for the crops under consideration, taking into account the existing MRLs and the lack of detailed information on the actual approved uses of malathion, a potential long-term consumer health risk cannot be excluded. Risk managers should consider the following uncertainties in the assessment which may have lead to an over- or underestimation of the long-term exposure:

- a lower ADI might be required for the assessment of the long-term consumer exposure to malathion residues from the intake of apples and plums, considering that in the third countries for which the import tolerances are requested on these fruits, malathion with higher isomalathion content (0.4 %) is used;

- the residue data in plums, apples and lettuce are affected by uncertainties regarding storage stability of metabolite DMM; thus, the results of residue trials may underestimate the actual dietary burden for consumers;

- the possible formation of DM-MMCA and, in particular, the formation of a more toxic degradation product MoxDCA in processed commodities (relevant for apples, plums, strawberries) may lead to an underestimation of the risk for consumers resulting from the consumption of processed products;

- the lack of detailed information on the authorized uses of malathion in Europe and third countries. In the dietary exposure assessment for all crops except the crops under consideration EFSA assumed that they contribute to the dietary burden with residues at the LOQ of malathion and malaoxon, respectively. This “background” levels are accounting for the major part of the calculated long-term exposure. Thus, the calculations are considered to be conservative with regard to these crops, leading to a possible overestimation of the calculated exposure;

- The lack of detailed information on the authorised uses may also lead to an underestimation of the actual exposure, in particular related to the residues in cereals, where EFSA assumed that only post-harvest uses are approved which are not expected to lead to malaoxon residues. In case foliar treatments are approved, the malaoxon residues might occur in concentrations relevant for consumer exposure.

In the **combined short-term exposure** assessment for the malathion related compounds (malathion, malaoxon, DMM, MMCA and MDCA, expressed as malathion toxic equivalents), no consumer health concern was identified for the crops under consideration. The maximum short-term exposure for apples accounted for 50 % of the toxicological reference value for malathion; 33 % for lettuce, 16 % for oranges, 11 % for grapefruit, 10 % for plums, 7 % for strawberries and mandarins, respectively, 4 % for lemons and 2 % for limes. Also the short-term exposure assessment is affected by the above-mentioned uncertainties.

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Malathion and malaoxon, expressed as malathion				
0110000	Citrus fruits	0.02*	2 (provisional)	The MRL proposal is sufficiently supported by residue data. Although a long-term consumer health risk could not be excluded, setting a MRL on provisional basis might be acceptable for risk managers, taking into account the low contribution of citrus fruits to the overall long-term exposure and the high level of uncertainties of the risk assessment which were compensated by using conservative assumptions leading to an overestimation of the calculated dietary exposure.
0130010	Apples	0.02*	No new proposal	The import tolerance request is not sufficiently supported by data regarding the storage stability of metabolite DMM and formation of degradation products under processing conditions. In addition, the data are not sufficient to conclude whether the toxicological reference values derived for malathion with a lower impurity concentration of isomalathion can be applied to assess the consumer risk related to apples treated with less pure malathion. Taking into account the uncertainties resulting from these data gaps and a potential long-term consumer exposure concerns identified, EFSA does not recommend to raise the MRL for apples at the moment.
0130020	Pears	0.02*	No new proposal	In addition to the data gaps and uncertainties identified for apples, the number of residue trials on pears was not sufficient to support the import tolerance request.
0140040	Plums	0.02*	No new proposal	The import tolerance request is not sufficiently supported by data regarding the storage stability of metabolite DMM and formation of degradation products under processing conditions. In addition, the data are not sufficient to conclude whether the toxicological reference values derived for malathion with a lower impurity concentration of isomalathion can be applied to assess the consumer risk related to plums treated with less pure malathion. Taking into account the uncertainties resulting from these data gaps and a potential long-term consumer exposure concerns identified, EFSA does not recommend to raise the MRL for plums at the moment.

Code number[(a)]	**Commodity**	**Existing EU MRL (mg/kg)**	**Proposed EU MRL (mg/kg)**	**Justification for the proposal**
0152000	Strawberries	0.02*	0.3 (provisional)	The MRL proposal is supported by residue data, but the applicant has to confirm that significant MoxDCA residues are not formed in processed strawberry products. Although a potential long-term consumer health risk could not be excluded at the moment, a provisional MRL setting might to be acceptable for risk managers, taking into account the low contribution of strawberries to the overall long-term exposure and the high level of uncertainties of the risk assessment which were compensated by using conservative assumptions leading to an overestimate the calculated dietary exposure.
0251020	Lettuce	0.02*	0.5 (provisional)	The MRL proposal is supported by residue data, but the applicant has to provide confirmation that the low DMM concentrations measured in residue trials are not due to inadequate storage of the samples. Although a potential long-term consumer health risk could not be excluded at the moment, a provisional MRL setting might be acceptable for risk managers, taking into account the low contribution of lettuce to the overall long-term exposure and the high level of uncertainties of the risk assessment which were compensated by using conservative assumptions leading to an overestimate the calculated dietary exposure.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Citrus fruit	SEU	F	Ceratitis capitata	EW	440	Low volume spray in tank mix with bait	BBCH 75-85	2-3	10 days	0.3	80	0.24	7	
						Low volume overall spray	BBCH 75-85	2-3	10 days	0.07-0.1	500-700	0.484	7	
Apple, pear	New Zealand, Argentina	F	Thrips, aphids, *Ceratitis capitata*	EW	440	Overall spray	BBCH 75-85	3	7 days	0.18-0.29	750-1250	2.2	7	
Plum	New Zealand, Brazil	F	Thrips, aphids, *Ceratitis capitata*	EW	440	Overall spray	BBCH 75-85	3	7 days	0.21-0.35	750-1250	2.6	7	
Strawberries	SEU	F	Thrips	EW	440	Overall spray	BBCH 50-85	4	10 days	0.11-0.12	1000-1100	1.2	3	
Lettuce	SEU	F	Thrips	EW	440	Overall spray	BBCH 15-45	3	10 days	0.11	1000	1.1	14	

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

B. Pesticide Residues Intake Model (PRIMo)

Scenario 1

Malathion			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,03	ARfD (mg/kg bw):	0,3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2009	Year of evaluation:	2009

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum: 3 – 77

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
77	WHO Cluster diet B	47	Wheat	20	Maize	4	Rice	1,0
75	DK child	37	Rye	30	Wheat	3	Oats	0,9
53	WHO cluster diet D	35	Wheat	5	Rice	4	Maize	0,6
53	IT kids/toddler	36	Wheat	12	Other cereal	2	Rice	0,2
52	IE adult	19	Maize	13	Wheat	10	Barley	0,9
50	DE child	22	Wheat	13	Apples	7	Rye	1,0
43	NL child	26	Wheat	7	Apples	3	Rice	1,7
41	WHO cluster diet E	22	Wheat	7	Barley	5	Maize	0,7
37	WHO Cluster diet F	20	Wheat	6	Rye	5	Barley	0,6
35	PT General population	21	Wheat	6	Rice	4	Maize	0,4
34	UK Infant	14	Wheat	8	Maize	5	Rice	2,0
34	ES child	24	Wheat	4	Rice	2	Maize	0,9
32	IT adult	23	Wheat	6	Other cereal	1	Rice	0,2
31	UK Toddler	21	Wheat	5	Rice	2	Apples	1,8
26	SE general population 90th percentile	17	Wheat	3	Rice	2	Rye	0,9
25	WHO regional European diet	16	Wheat	3	Barley	2	Rice	0,7
24	FR toddler	14	Wheat	3	Rice	3	Apples	2,0
22	LT adult	9	Rye	6	Wheat	2	Apples	0,4
22	ES adult	13	Wheat	4	Barley	2	Rice	0,5
20	FR all population	18	Wheat	1	Rice	1	Apples	0,5
20	DK adult	11	Wheat	6	Rye	1	Oats	0,4
20	NL general	11	Wheat	3	Barley	1	Rice	0,6
17	UK vegetarian	11	Wheat	3	Rice	1	Apples	0,4
14	FI adult	6	Rye	5	Wheat	1	Rice	0,4
14	UK Adult	9	Wheat	3	Rice	0	Apples	0,4
10	FR infant	5	Wheat	3	Apples	1	Strawberries	1,3
3	PL general population	2	Apples	0	Plums	0	Potatoes	0,2

Conclusion:

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

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

The acute risk assessment is based on the ARfD.

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

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a 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)
30	Lettuce	3,35 / -	22	Apples	0,92 / -	12	Lettuce	3,35 / -	7	Lettuce	3,35 / -
30	Apples	0,92 / -	18	Lettuce	3,35 / -	7	Apples	0,92 / -	6	Apples	0,92 / -
7	Plums	0,61 / -	5	Plums	0,61 / -	2	Plums	0,61 / -	2	Strawberries	1,01 / -
5	Strawberries	1,01 / -	5	Strawberries	1,01 / -	2	Strawberries	1,01 / -	2	Plums	0,61 / -
3	Oranges	0,06 / -	2	Oranges	0,06 / -	1	Oranges	0,06 / -	0	Oranges	0,06 / -
2	Grapefruit	0,06 / -	2	Grapefruit	0,06 / -	0	Grapefruit	0,06 / -	0	Grapefruit	0,06 / -
1	Mandarins	0,06 / -	1	Mandarins	0,06 / -	0,3	Mandarins	0,06 / -	0,2	Mandarins	0,06 / -
0,7	Lemons	0,06 / -	0,5	Lemons	0,06 / -	0,1	Lemons	0,06 / -	0,1	Lemons	0,06 / -
0,4	Limes	0,06 / -	0,3	Limes	0,06 / -	0,1	Limes	0,06 / -	0,1	Limes	0,06 / -
0,0	Other citrus fruit	0,06 / -	0,0	Other citrus fruit	0,06 / -						
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)

*) 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 Malathion 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.

Scenario 2

Malaoxon			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,001	ARfD (mg/kg bw):	0,01
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
10 71

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
71	UK Infant	39	Milk and cream,	10	Sugar beet (root)	3	Potatoes	68
68	NL child	29	Milk and cream,	6	Apples	6	Potatoes	67
67	FR toddler	40	Milk and cream,	5	Potatoes	3	Apples	67
64	UK Toddler	23	Sugar beet (root)	21	Milk and cream,	4	Wheat	63
53	DE child	14	Milk and cream,	12	Apples	4	Wheat	53
48	WHO Cluster diet B	9	Wheat	3	Milk and cream,	3	Tomatoes	46
44	FR infant	26	Milk and cream,	4	Potatoes	3	Carrots	44
44	IE adult	7	Tea (dried leaves and stalks,	4	Sweet potatoes	3	Milk and cream,	38
41	DK child	13	Milk and cream,	6	Wheat	4	Rye	41
35	ES child	13	Milk and cream,	4	Wheat	2	Oranges	35
32	SE general population 90th percentile	12	Milk and cream,	4	Potatoes	3	Wheat	32
31	WHO cluster diet E	4	Wheat	4	Potatoes	3	Milk and cream,	29
30	WHO cluster diet D	7	Wheat	5	Milk and cream,	4	Potatoes	28
29	WHO regional European diet	5	Milk and cream,	4	Potatoes	3	Wheat	27
26	WHO Cluster diet F	4	Milk and cream,	4	Wheat	3	Potatoes	25
23	NL general	7	Milk and cream,	3	Potatoes	2	Wheat	23
21	PT General population	5	Potatoes	4	Wheat	2	Wine grapes	21
20	UK vegetarian	4	Sugar beet (root)	3	Milk and cream,	2	Tea (dried leaves and stalks,	18
20	ES adult	5	Milk and cream,	2	Wheat	1	Oranges	20
19	UK Adult	4	Sugar beet (root)	3	Milk and cream,	3	Tea (dried leaves and stalks,	16
19	FR all population	4	Wine grapes	3	Wheat	3	Milk and cream,	18
18	DK adult	5	Milk and cream,	2	Wheat	1	Potatoes	17
16	IT kids/toddler	7	Wheat	2	Other cereal	1	Tomatoes	16
16	LT adult	4	Milk and cream,	3	Potatoes	2	Apples	16
15	FI adult	6	Milk and cream,	1	Potatoes	1	Wheat	14
12	IT adult	4	Wheat	1	Tomatoes	1	Apples	12
10	PL general population	3	Potatoes	2	Apples	1	Tomatoes	10

Conclusion:

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

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

The acute risk assessment is based on the ARfD.

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

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a 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)
20	Apples	0,02 / -	14	Apples	0,02 / -	4	Apples	0,02 / -	4	Apples	0,02 / -
13	Oranges	0,01 / -	10	Oranges	0,01 / -	3	Oranges	0,01 / -	2	Oranges	0,01 / -
9	Grapefruit	0,01 / -	9	Grapefruit	0,01 / -	2	Grapefruit	0,01 / -	1	Grapefruit	0,01 / -
6	Mandarins	0,01 / -	4	Mandarins	0,01 / -	1	Mandarins	0,01 / -	1	Mandarins	0,01 / -
3	Lemons	0,01 / -	3	Plums	0,01 / -	1	Lettuce	0,01 / -	1	Plums	0,01 / -
3	Plums	0,01 / -	3	Lemons	0,01 / -	1	Plums	0,01 / -	1	Lettuce	0,01 / -
3	Lettuce	0,01 / -	2	Lettuce	0,01 / -	0,7	Lemons	0,01 / -	0,5	Strawberries	0,01 / -
2	Limes	0,01 / -	1,6	Strawberries	0,01 / -	0,6	Limes	0,01 / -	0,5	Lemons	0,01 / -
2	Strawberries	0,01 / -	1,4	Limes	0,01 / -	0,5	Strawberries	0,01 / -	0,5	Limes	0,01 / -
0	Other citrus fruit	0,01 / -	0,0	Other citrus fruit	0,01 / -						
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)

*) 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 Malaoxon 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.

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 27/02/2013 16:24))

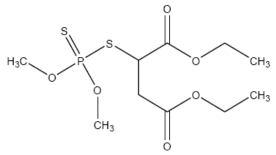
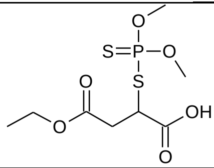
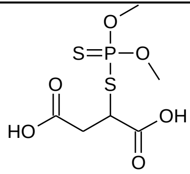
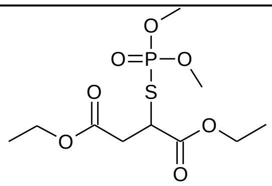
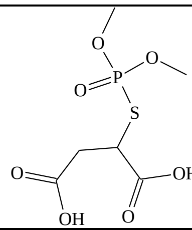
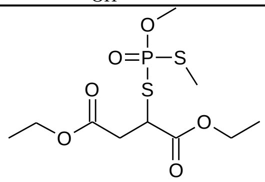
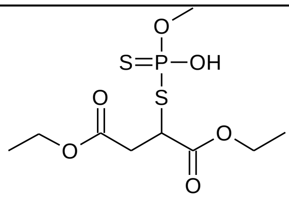
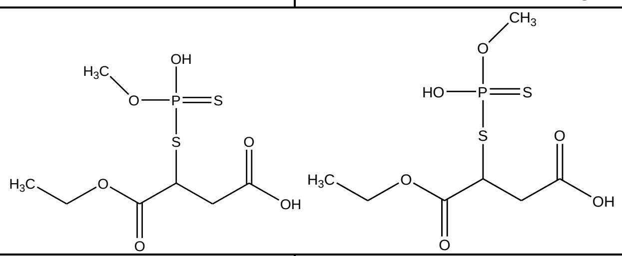
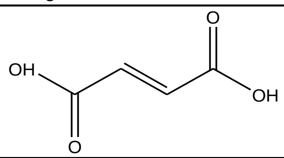
Code number	Groups and examples of individual products to which the MRLs apply	Malathion (sum of malathion and malaoxon expressed as malathion)
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,02*
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
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)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	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	0,02*
140010	Apricots	0,02*
140020	Cherries (sweet cherries, sour cherries)	0,02*
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	0,02*
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
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*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	0,02*
210000	(i) Root and tuber vegetables	0,02*
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	0,02*
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,02*
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	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	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*

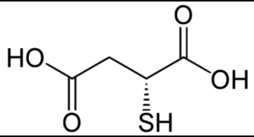
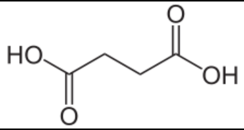
Code number	Groups and examples of individual products to which the MRLs apply	Malathion (sum of malathion and malaoxon expressed as malathion)
232020	Gherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson))	0,02*
232990	Others	0,02*
233000	(c) Cucurbits-inedible peel	0,02*
233010	Melons (Kiwano)	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*
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	0,02*
401000	(i) Oilseeds	0,02*
401010	Linseed	0,02*
401020	Peanuts	0,02*
401030	Poppy seed	0,02*
401040	Sesame seed	0,02*
401050	Sunflower seed	0,02*
401060	Rape seed (Bird rapeseed, turnip rape)	0,02*
401070	Soya bean	0,02*
401080	Mustard seed	0,02*
401090	Cotton seed	0,02*
401100	Pumpkin seeds	0,02*
401110	Safflower	0,02*
401120	Borage	0,02*
401130	Gold of pleasure	0,02*
401140	Hempseed	0,02*
401150	Castor bean	0,02*
401990	Others	0,02*
402000	(ii) Oilfruits	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	8
500010	Barley	8
500020	Buckwheat	8
500030	Maize	8
500040	Millet (Foxtail millet, teff)	8
500050	Oats	8
500060	Rice	8
500070	Rye	8
500080	Sorghum	8
500090	Wheat (Spelt Triticale)	8
500990	Others	8
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,5
620000	(ii) Coffee beans	0,02*
630000	(iii) Herbal infusions (dried)	
631000	(a) Flowers	
631010	Camomille flowers	1,5
631020	Hybiscus flowers	0,02*
631030	Rose petals	0,02*
631040	Jasmine flowers	0,02*
631050	Lime (linden)	0,02*
631990	Others	0,02*
632000	(b) Leaves	0,02*
632010	Strawberry leaves	0,02*
632020	Rooibos leaves	0,02*
632030	Maté	0,02*
632990	Others	0,02*
633000	(c) Roots	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Malathion (sum of malathion and malaoxon expressed as malathion)
633010	Valerian root	0,02*
633020	Ginseng root	0,02*
633990	Others	0,02*
639000	(d) Other herbal infusions	0,02*
640000	(iv) Cocoa (fermented beans)	0,02*
650000	(v) Carob (st johns bread)	0,02*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,02*
800000	8. SPICES	0,02*
810000	(i) Seeds	0,02*
810010	Anise	0,02*
810020	Black caraway	0,02*
810030	Celery seed (Lovage seed)	0,02*
810040	Coriander seed	0,02*
810050	Cumin seed	0,02*
810060	Dill seed	0,02*
810070	Fennel seed	0,02*
810080	Fenugreek	0,02*
810090	Nutmeg	0,02*
810990	Others	0,02*
820000	(ii) Fruits and berries	0,02*
820010	Allspice	0,02*
820020	Anise pepper (Japan pepper)	0,02*
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*
820070	Vanilla pods	0,02*
820080	Tamarind	0,02*
820990	Others	0,02*
830000	(iii) Bark	0,02*
830010	Cinnamon (Cassia)	0,02*
830990	Others	0,02*
840000	(iv) Roots or rhizome	0,02*
840010	Liquorice	0,02*
840020	Ginger	0,02*
840030	Turmeric (Curcuma)	0,02*
840040	Horseradish	0,02*
840990	Others	0,02*
850000	(v) Buds	0,02*
850010	Cloves	0,02*
850020	Capers	0,02*
850990	Others	0,02*
860000	(vi) Flower stigma	0,02*
860010	Saffron	0,02*
860990	Others	0,02*
870000	(vii) Aril	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,02*
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	0,02*
1011000	(a) Swine	0,02*
1011010	Meat	0,02*
1011020	Fat free of lean meat	0,02*
1011030	Liver	0,02*
1011040	Kidney	0,02*
1011050	Edible offal	0,02*
1011990	Others	0,02*
1012000	(b) Bovine	0,02*
1012010	Meat	0,02*
1012020	Fat	0,02*
1012030	Liver	0,02*
1012040	Kidney	0,02*
1012050	Edible offal	0,02*
1012990	Others	0,02*
1013000	(c) Sheep	0,02*
1013010	Meat	0,02*
1013020	Fat	0,02*
1013030	Liver	0,02*
1013040	Kidney	0,02*
1013050	Edible offal	0,02*
1013990	Others	0,02*
1014000	(d) Goat	0,02*
1014010	Meat	0,02*
1014020	Fat	0,02*
1014030	Liver	0,02*
1014040	Kidney	0,02*
1014050	Edible offal	0,02*
1014990	Others	0,02*
1015000	(e) Horses, asses, mules or hinnies	0,02*
1015010	Meat	0,02*
1015020	Fat	0,02*
1015030	Liver	0,02*
1015040	Kidney	0,02*
1015050	Edible offal	0,02*
1015990	Others	0,02*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,02*
1016010	Meat	0,02*
1016020	Fat	0,02*
1016030	Liver	0,02*
1016040	Kidney	0,02*
1016050	Edible offal	0,02*
1016990	Others	0,02*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,02*
1017010	Meat	0,02*
1017020	Fat	0,02*
1017030	Liver	0,02*
1017040	Kidney	0,02*
1017050	Edible offal	0,02*
1017990	Others	0,02*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,02*
1020010	Cattle	0,02*
1020020	Sheep	0,02*
1020030	Goat	0,02*
1020040	Horse	0,02*
1020990	Others	0,02*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,02*
1030010	Chicken	0,02*
1030020	Duck	0,02*
1030030	Goose	0,02*
1030040	Quail	0,02*
1030990	Others	0,02*
1040000	(iv) Honey (Royal jelly, pollen)	0,02*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,02*
1060000	(vi) Snails	0,02*
1070000	(vii) Other terrestrial animal products	0,02*

(*) Indicates lower limit of analytical determination

D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structure
Malathion	diethyl (dimethoxyphosphinothioylthio)succinate or *S*-1,2-bis(ethoxycarbonyl)ethyl *O*,*O*-dimethyl phosphorodithioate	
MMCA malathion monocarboxylic acid	(2*RS*)-2-[(dimethoxyphosphorothioyl)sulfanyl]-4-ethoxy-4-oxobutanoic acid	
MDCA malathion dicarboxylic acid	(2*RS*)-2-[(dimethoxyphosphorothioyl)sulfanyl]butanedioic acid	
malaoxon	diethyl (2*RS*)-2-[(dimethoxyphosphoryl)sulfanyl]butanedioate	
MoxDCA (desmethyl malaoxon dicarboxylic acid)	(2*RS*)-2-[(dimethoxyphosphoryl)sulfanyl]butanedioic acid	
isomalathion	diethyl (2*RS*)-2-{[methoxy(methylsulfanyl)phosphoryl]sulfanyl}butanedioate	
DMM desmethyl-malathion	diethyl (2*RS*)-2-{[hydroxy(methoxy)phosphorothioyl]sulfanyl}butanedioate	
DM-MMCA desmethyl malathion monocarboxylic acid (pair 1 and pair 2)		
Fumaric acid		

Mercaptosuccinic acid		
Succinic acid	Butanedioic acid	

ABBREVIATIONS

ADI	acceptable daily intake
AIR	Annex I Renewal
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DM	dry matter
DE	Germany
DK	Danmark
$DT_{90field/lab}$	period required for 90 % dissipation (field/laboratory)
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
ES	Spain
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
EW	Emulsion, oil in water
FAO	Food and Agriculture Organization of the United Nations
FR	France
GAP	good agricultural practice
GC-FPD	gas chromatography with flame photometric detector
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre

IE	Ireland
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NOAEL	no observed adverse effect level
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RD	residue definition
RMS	rapporteur Member State
SEU	Southern European Union
TEF	toxicity equivalence factor
TRR	total radioactive residue