



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants and pesticides

Malathion
SANCO/10668/2009 final
14 January 2010

Review report for the active substance **malathion**
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
22 January 2010
in view of the inclusion of malathion in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of malathion, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Malathion is a substance that was covered by the second stage of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

At the outcome of that evaluation, malathion was not included through Commission Decision 2007/389/EC¹ as, on the basis of the available information, it had not been demonstrated that the risk to operators, workers, bystanders and consumers in particular was acceptable. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/10018/2006 final of 7 September 2007).

In accordance with Article 13 of Regulation (EC) No 33/2008, Cheminova A/S, the sole data submitter presented, on 30 June 2008 a request to the United Kingdom, the rapporteur Member State that took over the dossier from Finland, for a new application aiming at Annex I inclusion of the substance.

The United Kingdom finalised in February 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was sent to the Commission and the European Food Safety Authority on 11 February 2009 and included a recommendation as to include malathion in Annex I for the supported uses.

In accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Cheminova A/S being the sole data submitter, on 17 March 2009 by making it available.

¹ OJ No L 146, 8.6.2007, p. 19.

The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance malathion (re-issued on 17 July 2009)²]. This conclusion refers to background document A (draft assessment report and additional report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 21 of Regulation (EC) No 33/2008, the Commission referred a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 27 November 2009

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Directive 2010/17/EU concerning the inclusion of malathion in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing malathion they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 22 of Regulation (EC) No 33/2008, this review report will be made available for public consultation by any interested parties.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

² *EFSA Scientific Report (2009) 333 – Conclusion on Pesticide peer review – Peer review of the pesticide risk assessment of the active substance malathion (re-issued on 17 July 2009).*

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing malathion will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each malathion containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI	0.03 mg/kg bw/day
ARfD	0.3 mg/kg bw/day
AOEL	0.03 mg/kg bw/day

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 70 kg adult is 1 % of the Acceptable Daily Intake (ADI), (WHO diet). Additional intake from water is not expected to give rise to intake problems.

Estimates of acute dietary exposure of adults and children revealed that the Acute Reference Dose (ARfD) would not be exceeded (According to the EFSA model (DE diet): less than 8% children)

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC.

4. Identity

The main identity of malathion is given in Appendix I.

The active substance shall comply with the FAO specification given in Appendix I of this report, with the exception of the level of the manufacturing impurity isomalathion which is of toxicological concern and must not exceed 2 g/kg.

The review has established that for the active substance notified by the data submitter the other manufacturing impurities are, on the basis of information currently available, of toxicological or environmental concern: malaaxon, MeOOSPS-triester and MeOOOPs-triester. These impurities must not exceed respectively 1 g/kg, 15 g/kg and 5 g/kg. as stated in the relevant FAO specification.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing malathion

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted:

Member States should pay particular attention to:

- the operator and worker safety: conditions of use shall prescribe the use of adequate personal protective equipment;
- the protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones;
- the protection of insectivorous birds and honey bees: conditions of authorisation shall include risk mitigation measures, where appropriate. As regards bees, the necessary indications shall be provided on the labelling and the accompanying instructions as to avoid exposure.

Member States shall ensure that malathion-based formulations are accompanied by the necessary instructions to avoid any risk of formation of isomalathion in excess of the permitted maximum quantities during storage and transport.

Where appropriate, conditions of authorisation shall include further risk mitigation measures.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of malathion in Annex I under the current inclusion conditions.

However, the concerned Member States shall request the submission of further information to confirm the consumer risk assessment and the risk assessment (acute and long-term) for insectivorous birds. In addition, information is to be submitted on the quantification of the different potency of malaaxon and malathion.

Some other endpoints may require the generation or submission of additional data to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for malathion in Annex I of the Directive.

APPENDIX I**Identity
MALATHION**

Common name (ISO)	Malathion
Chemical name (IUPAC)	<i>diethyl (dimethoxyphosphinothioylthio)succinate or S-1,2-bis(ethoxycarbonyl)ethyl O,O-dimethyl phosphorodithioate racemate</i>
Chemical name (CA)	butanedioic acid, [[dimethoxyphosphinothioyl]thio]-, diethyl ester racemate
CIPAC No	12
CAS No	121-75-5
EEC No	204-497-7 (EINECS)
FAO SPECIFICATION	12/TC (December 2004) min. 950 g/kg malathion impurities: max. 1 g/kg malaoxon max. 4 g/kg isomalathion max. 15 g/kg MeOOSPS-triester max. 5 g/kg MeOOOPS-triester
Minimum purity	950 g/kg (racemic mixture)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	max. 1 g/kg malaoxon max. 2 g/kg isomalathion max. 15 g/kg MeOOSPS-triester max. 5 g/kg MeOOOPS-triester
Molecular formula	C ₁₀ H ₁₉ O ₆ PS ₂
Molecular mass	330.36 g/mol
Structural formula	

APPENDIX II
List of uses supported by available data
MALATHION

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Strawberries	EU South	malathion	F	Lepidoptera Thrips Coleoptera Aphids	EW	440 g/l	foliar spray	ripening fruit	1 - 4	10 days	0.12	1000	1.2	3	
Ornamentals	EU North & South	malathion	G	Aphids, thrips, mealy bugs, whitefly, leaf hoppers	EW	440 g/l	hand held or gantry sprayers	when pests first seen	n/a	7-10 days	0.114	100	0.114	n/a	There is no maximum number of applications

Remarks:	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, <i>e.g.</i> overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(c)	<i>e.g.</i> biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	<i>e.g.</i> wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions