



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Malathion
SANCO/10018/2006 final
7 September 2007

Review report for the active substance **malathion**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 September 2006
in support of a decision concerning the non-inclusion of malathion in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance

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 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.

Commission Regulation (EC) No 451/2000⁽¹⁾ laying down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1490/2002⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Malathion is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EC) No 451/2000, Cheminova Agro A/S and Cequisa notified to the Commission of their wish to secure the inclusion of the active substance malathion in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated Finland as rapporteur Member State to carry out the assessment of malathion on the basis of the dossiers submitted by the notifiers. In Regulation (EC) No 703/2001³ the Commission specified furthermore that the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EC) No 451/2000, as well as for other parties with regard to further technical and scientific information was 30 April 2002.

¹ OJ No L 55, 29.02.2000, p.25.

² OJ No L 224, 21.8.2002, p.23.

³ OJ No L 98, 7.4.2001, p. 6.

Cheminova A/S submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Cheminova A/S was considered to be the main data submitter.

In accordance with the provisions of Article 8(1) of Regulation (EC) No 451/2000, Finland submitted on 02 February 2004 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of malathion in Annex I to the Directive. Moreover, in accordance with the provisions of Article 8(2) of Regulation (EC) 451/2000, the Commission and the Member States received also the summary dossier on malathion from Cheminova A/S, on 25 February 2004.

In accordance with the provisions of Article 8 of Regulation (EC) No 451/2000, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Cheminova A/S being the main data submitters, on 16 April 2004 by making it available.

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 8 (7) of Regulation 451/2000 the EFSA sent to the Commission its conclusion on the risk assessment regarding the peer review of the pesticide risk assessment of the active substance malathion (finalised: 13 January 2006)⁴. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 8 (7) of Regulation (EC) No 451/2000, the Commission referred on 28 September 2006 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 28 September 2006.

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 has been developed and finalised in support of Commission Decision 2007/389/EC concerning the non-inclusion of malathion in Annex I to Directive 91/414/EEC.

In accordance with the provisions of Article 8 of Regulation (EC) No 451/2000, as modified by Regulation (EC) No 1490/2002, the finalised review report, excluding any parts which refer to confidential information contained in the dossier and determined as such in accordance with Article 14 of the Directive shall be made available for public consultation.

⁴ *EFSA Scientific Report* (2006) 63, 1-87

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

The overall conclusion of this evaluation, based on the information available and the proposed conditions of use, is that:

- **the information available is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to
 - the presence in the technical material of isomalathion, the genotoxicity of which cannot be excluded,
 - the consumer exposure
 - the long term risk to mammals

- **concerns were identified with regard to**
 - the exposure of operators, workers and bystanders which cannot be concluded due to the presence of isomalathion in the technical material
 - the acute and chronic risk for consumers, due to the insufficient information on the effects of certain toxicologically relevant metabolites
 - the high risk to aquatic organisms, honey bees and non-target arthropods.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

Malathion should therefore not be included in Annex I to Directive 91/414/EEC.