



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food chain  
**Chemicals, contaminants, pesticides**

SANCO/1336/08 final  
13 October 2009

**REVIEW REPORT FOR THE ACTIVE SUBSTANCE  
CHLOROTHAL-DIMETHYL  
FINALISED IN THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH  
AT ITS MEETING ON 12 JUNE 2009  
IN SUPPORT OF A DECISION CONCERNING THE NON-INCLUSION OF CHLOROTHAL-DIMETHYL 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 chlorthal-dimethyl, 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<sup>1</sup> 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<sup>2</sup>, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Chlorthal-dimethyl is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 10 of Regulation (EC) No 451/2000, AMVAC Chemical UK Limited notified to the Commission of their wish to secure the inclusion of the active substance chlorthal-dimethyl in Annex I to the Directive.

Under Annex I to Regulation (EC) No 1490/2002, Greece has been designated by the Commission as rapporteur Member State to carry out the assessment of chlorthal-dimethyl on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 1490/2002 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required under Article 7(1) of Regulation (EC) No 1490/2002, as well as for other parties with regard to further technical and scientific information was 30 November 2003.

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<sup>1</sup> OJ L 55, 29.2.2000

<sup>2</sup> OJ L 224, 21.8.2002

AMVAC Chemical UK Limited 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 AMVAC Chemical UK Limited was considered to be the sole data submitter.

In accordance with the provisions of Article 10(1) of Regulation 1490/2002, Greece submitted on 31 October 2006, later adding an addendum submitted on 3 April 2008, 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 chlorthal-dimethyl in Annex I to the Directive. Moreover, in accordance with the provisions of Article 10(2) of Regulation (EC) 1490/2002, the Commission and the Member States received also the summary dossier on chlorthal-dimethyl from AMVAC Chemical UK Limited.

In accordance with the provisions of Article 11c of Regulation (EC) No 1490/2002, the EFSA organised the focused consultation on specific points related to toxicology and risks to groundwater by all the Member States on 18 July 2008 by making it available. The notifier AMVAC Chemical UK Limited being the main notifier was asked by the rapporteur Member State to give its comments to the addendum by 15 September 2008. The Commission asked the EFSA to consider the comments from the notifier and amend the EFSA conclusion report if necessary by 30 November 2008.

In accordance with the provisions of Article 11c (1) of Regulation (EC) No 1490/2002, 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.

In accordance with the provisions of Article 11c of Regulation (EC) No 1490/2002, the EFSA sent to the Commission its conclusion on the risk assessment Conclusions regarding the focussed peer review of the pesticide risk assessment of the active substance chlorthal-dimethyl<sup>3</sup>. 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 12 of Regulation (EC) No 1490/2002, the Commission referred on 12 June 2009 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 12 June 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.

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<sup>4</sup> EFSA Scientific Report (2008) 202.

## 2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of the Decision 2009/715/EC concerning the non-inclusion of chlorthal-dimethyl in Annex I to Directive 91/414/EEC.

In accordance with the provisions of Article 13 of Regulation (EC) No 1490/2002, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

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

The overall conclusion of this examination, 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
  - leaching of metabolites to groundwater

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.

Chlorthal-dimethyl should therefore not be included in Annex I to Directive 91/414/EEC.