



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Phosalone  
SANCO/10020/2006 – rev. 2  
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*EU Limited*

**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY  
REPRESENT THE VIEWS OF THE COMMISSION SERVICES**

**DRAFT**

Review report for the active substance **phosalone**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting  
on 14 July 2006  
in support of a decision concerning the non-inclusion of phosalone 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 phosalone, 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. Phosalone 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, Aventis Crop Science GmbH notified to the Commission of their wish to secure the inclusion of the active substance phosalone in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated Austria as rapporteur Member State to carry out the assessment of phosalone on the basis of the dossiers submitted by the notifiers. In Regulation (EC) No

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<sup>1</sup> OJ No L 55, 29.02.2000, p.25.

<sup>2</sup> OJ No L 224, 21.8.2002, p.23.

703/2001<sup>3</sup> 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.

Aventis Crop Science GmbH submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Cheminova A/S took over on July 2003 and 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, Austria submitted on 6 July 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 phosalone 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 phosalone from Cheminova A/S, on 1 June 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 submitter, on 06 July 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 [Conclusions regarding the peer review of the pesticide risk assessment of the active substance phosalone (finalised: 13 January 2006)]<sup>4</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 8 (7) of Regulation (EC) No 451/2000, the Commission referred on 14 July 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 14 July 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 the Directive **2006/1010/EC** concerning the non-inclusion of phosalone in Annex I to Directive 91/414/EEC.

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<sup>3</sup> OJ No L 98, 7.4.2001, p. 6.

<sup>4</sup> *The EFSA Scientific Report* (2006) 60, 1-66

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.

### **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
  - consumers exposure
  - ecotoxicology
  
- **concerns were identified with regard to**
  - acute exposure of vulnerable groups of consumers
  - lack of toxicological characterisation of some metabolites and impurities
  - the risk to aquatic organisms
  - the risk to birds and mammals
  - the risk to 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.

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