



Zineb  
SANCO/2225/2000-final  
06.10.2000

### Review report for the active substance **zineb**

Finalised in the Standing Committee on Plant Health at its meeting on 19.10.2000  
in support of a decision concerning the non-inclusion of zineb in Annex I to Directive  
91/414/EEC and 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 zineb, 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 (EEC) No 3600/92<sup>(1)</sup> laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1972/99<sup>(2)</sup>, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Zineb is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Topchem BV on 30 June 1993, LUXAN ON 21 JULY 1993, United Phosphorus Ltd on 26 July 1993, Bakelite Italia, on 13 July 1993, FMC foret SA on 23 July 1993, Elf Atochem on 26 July 1993, Helm AG on 23 July 1993 and Calliope SA on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance zineb in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94<sup>(3)</sup>, as last amended by Regulation (EC) No 2230/95<sup>(4)</sup>, designated Italy as rapporteur Member State to carry out the assessment of zineb on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the

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<sup>1</sup> OJ No L 366, 15.12.1992, p.10.

<sup>2</sup> OJ No L 244, 16.09.1999, p.41.

<sup>3</sup> OJ No L 107, 28.04.1994, p.8.

<sup>4</sup> OJ No L 225, 22.09.1995, p.1.

rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for zineb this deadline was 31 October 1995.

Elf Atochem on 21 April 1995 and Bakelite Italia on 31 August 1995 submitted a dossier to the rapporteur Member State. Information has furthermore been submitted by third parties. (

Elf Atochem and Bakelite submitted each a dossier to the rapporteur Member State. Elf Atochem was the main data submitter, with a dossier which did not contain substantial data gaps, taking into account the supported uses. Topchem BV, Luxan, and, FMC foret did not submit complete dossiers. United Phosphorus Ltd on 26 January 1995, Helm AG on 10 March 1995 and Calliope Sa on 24 April 1995 formally withdraw their support to Zineb. Information has furthermore been submitted by third parties.

## **2. Purposes of this review report**

This review report has been developed and finalised in support of Decision **2001/245/EC**<sup>5</sup> concerning the non-inclusion (at this stage) of zineb in Annex I to Directive 91/414/EEC.

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

Based on the information available in the framework of this evaluation and the proposed conditions of use it was concluded from the evaluation that plant protection products containing zineb have not been demonstrated to fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

In view of the fact that United Phosphorus on 26 January 1995, Helm AG on 10 March 1995, Calliope Sa on 24 April 1995, Elf Atochem on 8 May 2000 and Bakelite Italia on 31 May 2000 formally withdrew their support for zineb within the EU Peer Review Programme and, therefore, no engagements are made to produce the necessary supplementary data, an inclusion of this active substance in Annex I of Directive 91/414/EEC cannot be envisaged.

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<sup>5</sup> OJ N° L88, 28.3.01, p. 19