

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

Review report for the active substance **dinoterb**.

Finalised in the Standing Committee on Plant Health at its meeting on 17 December 1997 in view of a decision to withdraw of the active substance dinoterb from the market.

1. Procedure followed for the re-evaluation process.

This review report has been established as a result of the re-evaluation of dinoterb, 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⁽¹⁾ 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) n° 1199/97⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Dinoterb is one of the 90 active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Rhone Poulenc notified to the Commission on 15 July 1993 of their wish to secure the inclusion of the active substance dinoterb 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⁽³⁾, as last amended by Regulation (EC) n° 2230/95⁽⁴⁾, designated France as rapporteur Member State to carry out the assessment of dinoterb on the basis of the dossier submitted by the notifier. In the same Regulation the Commission specified, furthermore, the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers **required under Article 6(2) of Regulation (EEC) n° 3600/92, as well as for other interested parties with regard to further technical or scientific information** ; for dinoterb this deadline was 30 April 1995.

¹ OJ No L 366, 15.12.1992, p. 10..

² O. J. N° L170, 28.6.1997, p.19

³ OJ No L 107, 28.4.1994, p. 8.

⁴ OJ No L 225, 22.9.1995, p.1.

Rhone Poulenc submitted a dossier to the rapporteur Member State for assessment on **24/4/1995**. Information has furthermore been submitted by third parties within the provisions of Regulation (EEC) No 3600/92.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, France submitted on 18 July 1996 to the Commission the report of its examination, based in particular on the dossier of the main data submitter, hereafter referred to as the monograph.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the monograph to all the Member States on **5 December 1996** as well as to Rhone Poulenc being the applicant on **9 December 1996**.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the monograph and the comments received thereon (peer review), in particular on each of the following disciplines :

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany from January to April 1997.

In accordance with the provisions of Article 5 (6) of Regulation 3600/92, Rhone Poulenc informed the rapporteur Member State and the Commission on 17 January 1997 that it wished to end its participation in the programme of works for this active substance.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the monograph and the peer review report were referred to the Standing Committee on Plant Health for final examination, with participation of representatives from the 15 Member States. This final examination took place from October to December 1997, and was finalised in the meeting of the Standing Committee on **17/12/1997**.

2. Purposes of this review report.

This review report has been developed and finalised in support of the Decision 98/269/EC concerning the withdrawal of dinoterb from the market.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, 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. Moreover the Commission will send a copy of this review report to all operators having notified for this active substance under Article 4(1) of this Regulation.

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

Based on the information available and the proposed conditions of use it was concluded from the evaluation that dinoterb cannot fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC and therefore a decision should be taken not to include this active substance in Annex I to the Directive. This conclusion has been reached primarily because the evaluation has identified **concerns with regard to the safety of this active substance, in particular for human health**. Additionally, the re-evaluation identified important data gaps which made it impossible to further investigate the human/animal health and environmental safety of this active substance in all its detailed aspects.