# COMMISSION

## **COMMISSION DECISION**

of 14 February 2001

concerning the decision on the possible inclusion of certain active substances into Annex I to Council Directive 91/414/EEC

(notified under document number C(2001) 374)

(Text with EEA relevance)

(2001/134/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant-protection products on the market (1), as last amended by Commission Directive 2000/ 80/EC (2) (hereinafter referred to as 'the Directive'),

Having regard to Commission Regulation (EEC) No 3600/92 of 11 December 1992 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 concerning the placing of plant-protection products on the market (3), as last amended by Commission Regulation (EC) No 2266/2000 (4), and in particular Article 7(3A)(d) and 7(4) thereof.

#### Whereas:

- Commission Regulation (EC) No 933/94 of 27 April (1)1994 laying down the active substances of plant-protection products and designating the rapporteur Member States for the implementation of Commission Regulation (EEC) No 3600/92 (5), as last amended by Regulation (EC) No 2230/95 (6), identified the rapporteur Member States and notifiers for each active substance.
- Article 7 of Regulation (EEC) No 3600/92 provided that (2) for each active substance for which it has been designated rapporteur, a Member State should examine the dossiers and submit to the Commission the report of its assessment of the information submitted by the notifiers in accordance with the provisions of Article 6(1) of that Regulation.
- (3) In accordance with the above Article, on receipt of the reports of the rapporteur Member States, the Commission circulated them to the Member States for informa-

tion and undertook consultations with experts of the Member States as well as with the main notifiers as provided for in Article 7(3) of Regulation (EEC) No 3600/92.

- (4) It appears from the assessments made on a number of active substances that the submitted information is not sufficient to determine whether or not, under the proposed conditions of use, plant-protection products containing the active substance concerned would satisfy in general the requirements laid down in Article 5(1)(a)and (b) of the Directive. Therefore it is not presently possible to decide whether to include such active substances in Annex I to the Directive.
- Article 8(3) of the Directive provides that Member States (5) should apply the requirements of Article 4(1)(b)(i) to (v), and (c) to (f) in accordance with national provisions concerning the data to be provided. The assessments referred to in recital 4 did not identify concerns which can not be mitigated by appropriate risk-management measures at Member State level. Therefore it is not appropriate at this stage to suspend plant-protection products containing the active substances mentioned before the additional required information has been submitted and evaluated. Therefore a decision should be taken to postpone a decision on the possible inclusion of such active substances into Annex I to the Directive.
- (6) Following detailed discussions in the Standing Committee on Plant Health, and in accordance with the opinion of that Committee, the Commission has determined the further data required to determine whether the substances mentioned in recital 4 satisfy the requirements of Article 5 of the Directive. The rapporteur Member States should therefore inform the notifiers in detail about all additional studies and information which would be required to demonstrate that these requirements are satisfied.

OJ
 L
 230,
 19.8.1991,
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 1.

- (7) To enable the Member States and the Commission to programme their work, an unconditional undertaking to submit the additional required information should be provided by the notifier wishing the rapporteur Member State and the Commission to continue the review process. To enable the Commission to complete its work on the programme established by Regulation (EEC) No 3600/92 within a reasonable time, a deadline should be established within which notifiers of these substances must complete their files. This deadline should be as short as possible taking into account the time needed to perform the necessary studies.
- (8) If, for a particular active substance, the requirements of the present Decision concerning submission of the necessary information are not satisfied, interested parties are not prevented from seeking inclusion of that substance in Annex I to the Directive, in accordance with the procedures under its Article 6(2) at a later date.
- (9) This Decision does not prejudice any action the Commission may undertake at a later stage relating to these active substances within the framework of Council Directive 79/117/EEC (<sup>1</sup>), as last amended by Commission Directive 91/188/EEC (<sup>2</sup>),

HAS ADOPTED THIS DECISION:

#### Article 1

For the active substances referred to in the Annex hereto, the decision on their possible inclusion in Annex I to Directive 91/414/EEC is postponed, pending receipt of the information referred to in Article 2 below.

### Article 2

The rapporteur Member States shall inform the notifiers in relation to each active substance listed in the Annex to this Decision, of the additional studies and information identified by the Commission after consulting the Standing Committee on Plant Health as being required in order to complete their dossier such that all data requirements of Annex II and Annex III to the Directive are satisfied for a limited range of representative uses.

Each rapporteur Member State shall inform each notifier concerned that, if it wishes the rapporteur and the Commission to continue the review process with a view to including the substance in Annex I to the Directive, it must communicate to the rapporteur and to the Commission, within three months of the date of publication of this Decision, an undertaking to ensure that its dossier will satisfy, at the latest by the dates specified in the Annex hereto, the requirements of Annexes II and III to the Directive, and submit the studies and information referred to in the previous paragraph as soon as possible and at the latest by the dates specified in the Annex.

#### Article 3

If for certain active substances the necessary information is not received within the time limit referred to in Article 2 the rapporteur Member State shall inform the Commission as soon as possible and at the latest within two months.

### Article 4

This Decision is addressed to the Member States. The rapporteur Member States shall immediately inform the notifiers for the active substances referred to in Article 1 about the present Decision.

Done at Brussels, 14 February 2001.

For the Commission David BYRNE Member of the Commission

<sup>(&</sup>lt;sup>1</sup>) OJ L 33, 8.2.1979, p. 36. (<sup>2</sup>) OJ L 92, 13.4.1991, p. 42.

EN

	Date for the submission of studies	Date for the submission of specified long- term studies
2,4-DB	31.10.2001	
Acephate	31.3.2001	
Amitraz	31.8.2001	
Chlorpropham	31.12.2001	
Chlorpyrifos	30.4.2002	
Chlorpyrifos-methyl	30.4.2002	
Daminozide	31.12.2001	
Deltamethrin	31.1.2002	
Linuron		31.3.2002
Месоргор	31.12.2001	
Mecoprop-P	31.12.2001	
Molinate	31.3.2001	31.3.2002
Pendimethalin	30.6.2001	
Propiconazole	31.10.2001	
Propyzamide	31.12.2001	
Thiram	31.12.2001	
Ziram	31.12.2001	

## ANNEX