

COMMISSION DECISION
of 21 November 2001
concerning the decision on the possible inclusion of certain active substances into Annex I to
Directive 91/414/EEC

(notified under document number C(2001) 3685)

(Text with EEA relevance)

(2001/810/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 2001/49/EC ⁽²⁾,

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 Regulation (EC) No 2266/2000 ⁽⁴⁾, and in particular Article 7(3A)(d) and 7(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 933/94 of 27 April 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.
- (2) Article 7 of Regulation (EC) No 3600/92 provided that 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) The rapporteur Member States have submitted such reports and identified further data requirements in them. On receipt of the reports the Commission circulated them to the Member States for information 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 3600/92.

- (4) Article 7(4) of Regulation (EEC) No 3600/92 requires that all necessary data be submitted at the latest on 25 May 2002; in exceptional cases, where it was not possible for the rapporteur Member State and the Commission to identify such studies by 25 May 2001, an alternative date may be established. The setting of such an alternative, later date is justified, based on the duration and test conditions of the studies to be submitted, in relation to benalaxyl, chlorotoluron and dinocap and as regards long-term studies in relation to benomyl, cypermethrin and chlorotoluron. It is the responsibility of the notifier to ensure that their dossiers are completed such that all data requirements of Annex II and Annex III of Directive 91/414/EEC are satisfied for a limited range of representative uses. However, in order to assist the notifiers of these substances when preparing the necessary studies to complete their dossiers, the Commission, after consulting the Standing Committee on Plant Health, has identified certain studies and information which would be necessary to assess the safety and efficacy of the substances.

- (5) The information thus far submitted is not sufficient to determine whether or not, under the proposed conditions of use, plant protection products containing the active substances concerned would satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. Therefore it is not presently possible to decide whether to include such active substances in Annex I to Directive 91/414/EEC.
- (6) Article 8(3) of Directive 91/414/EEC provides that Member States 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 draft assessment reports referred to in recital 2 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 these active substances 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 of Directive 91/414/EEC.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 176, 29.6.2001, p. 61.

⁽³⁾ OJ L 366, 15.12.1992, p. 10.

⁽⁴⁾ OJ L 259, 13.10.2000, p. 27.

⁽⁵⁾ OJ L 107, 28.4.1994, p. 8.

⁽⁶⁾ OJ L 255, 22.9.1995, p. 1.

- (7) Following 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 as a minimum to determine whether the substances mentioned in recital 4 satisfy the requirements of Article 5 of Directive 91/414/EEC. 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.
- (8) To enable the Member States and the Commission to program 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.
- (9) 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 Directive 91/414/EEC, in accordance with the procedures under Article 6(2) of that Directive at a later date.
- (10) This decision is without prejudice to any action the Commission may undertake at a later stage relating to these active substances within the framework of Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances⁽¹⁾, as last amended by the Act of Accession of Austria, Finland and Sweden.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DECISION:

Article 1

The decision on the possible inclusion of the active substances referred to in the Annex hereto in Annex I to Directive 91/

414/EEC is postponed, pending receipt of the information referred to in Article 2 of this Decision.

Article 2

The rapporteur Member States shall inform the notifiers in relation to each active substance listed in the Annex of this Decision that they must complete their dossiers such that all data requirements of Annex II and Annex III of Directive 91/414/EEC are satisfied for a limited range of representative uses. The rapporteur Member States shall inform the notifiers that, without prejudice to further requirements which may be identified later, particular additional studies and information identified by the Commission after consulting the Standing Committee on Plant Health are required.

Each rapporteur Member State shall inform each notifier concerned that, if it wishes the rapporteur and Commission to continue the review process with a view to including the substance in Annex I to Directive 91/414/EEC, 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 to this Decision the requirements of Annexes II and III of Directive 91/414/EEC, and submit the studies and information referred to in the first paragraph as soon as possible and at the latest by the dates specified in the Annex to this Decision to the rapporteur.

Article 3

If for certain active substances the necessary information is not received by the dates specified in the Annex the rapporteur Member State shall inform the Commission as soon as possible and at the latest within two months.

Article 4

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

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 21 November 2001.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 33, 8.2.1979, p. 36.

ANNEX

	Latest date for the submission of studies	Latest date for the submission of specified long-term studies
Alachlor	25.5.2002	31.12.2002
Alpha-cypermethrin	25.5.2002	
Benalaxyl	31.1.2003	25.5.2003
Benomyl	25.5.2002	31.12.2003
Bromoxynil	25.5.2002	25.5.2003
Chlorothalonil	25.5.2002	25.5.2003
Chlorotoluron	30.11.2002	31.12.2003
Cypermethrin	25.5.2002	30.6.2003
Dinocap	31.12.2002	31.12.2003
Endosulfan	25.5.2002	31.5.2003
Ioxynil	25.5.2002	25.5.2003
Methamidophos	25.5.2002	25.5.2003