



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16.12.2002
COM(2002) 734 final

Proposal for a

COUNCIL DECISION

**concerning the non-inclusion of aldicarb in Annex I to Council Directive 91/414/EEC
and the withdrawal of authorisations for plant protection products containing this active
substance**

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Directive 91/414/EEC concerning the placing of plant protection products on the market sets up a harmonised framework for the authorisation and placing on the market of plant protection products.
2. Article 8(2) of this Directive provides a programme to be carried out over a period of 12 years for the gradual examination of the active substances contained in the pesticides, which are on the market for the inclusion in Annex I of the Directive.
3. Aldicarb is one of the 90 active substances covered by the first stage of this work programme.
4. On receipt of the report of the rapporteur Member State, the United Kingdom, the Commission undertook consultations with experts of the Member States and with the main notifier.
5. The Scientific Committee for Plants was also consulted. The Committee noted a risk to small birds and was not able to fully assess impact on other non-target organism on the basis of the available data. Therefore the Commission invited the notifier to complete its dossier by 31 December 2001 at the latest.
6. Assessments made on the basis of the information submitted have not demonstrated that, under the proposed conditions of use, it may be expected that plant protection products containing aldicarb satisfy the safety requirements of Directive 91/414/EEC, in particular for small birds and earthworms. Therefore it is not possible to include this active substance in Annex I to Directive 91/414/EEC
7. Any period of grace for disposal, storage, placing on the market and use of existing stocks of plant protection products containing aldicarb allowed by Member State, in accordance with the provisions of Article 4(6) of Directive 91/414/EEC should be limited to a period no longer than 12 months to allow existing stocks to be used in no more than one further growing season.
8. Under the procedure laid down in Article 19 of Council Directive 91/414/EEC, the Commission sought the opinion of the Standing Committee on the Food Chain and Animal Health on a draft Commission Decision concerning the non-inclusion of aldicarb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.
9. Owing to the fact that the Standing Committee on the Food Chain and Animal Health failed to deliver a favourable opinion on 18 October 2002, the Commission is required, under the above-mentioned Article, to refer the proposed measures to the Council. The Council will have 3 months to decide by qualified majority. If the Council fails to reach a decision, the Commission will adopt the measures.
10. The measure proposed by the Commission will have to be notified to WTO under the TBT arrangement before formal adoption is possible.
11. The proposed Decision will have no impact on the budget of the European Communities

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(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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 market¹, as last amended by Commission Directive 2002/81/EC², and in particular the fourth subparagraph of Article 8(2) thereof,

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 program of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market³, as last amended by Regulation (EC) No 2266/2000⁴, and in particular Article 7 (3A) (b) thereof,

Having regard to the proposal from the Commission⁵

Whereas:

- (1) Article 8(2) of Directive 91/414/EEC provided for the Commission to carry out a programme of work for the examination of the active substances used in plant protection products which were already on the market on 25 July 1993. Detailed rules for the carrying out of this programme were established in Regulation (EEC) No 3600/92.
- (2) 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 3600/92⁶, as last amended by Regulation (EC) No 2230/95⁷, designated the active substances which should be assessed in the framework of Regulation (EEC) No 3600/92, designated a Member State to act as rapporteur in respect of the assessment of each substance and

¹ OJ L 230, 19.8.1991, p.1.

² OJ L 276, 12.10.2002, p. 28.

³ OJ L 366, 15.12.1992, p.10.

⁴ OJ L 259, 13.10.2000, p.27.

⁵ OJ C [...], p. [...]

⁶ OJ L 107, 28.4.1994, p.8.

⁷ OJ L 225, 22.9.1995, p.1.

identified the producers of each active substance who submitted a notification in due time.

- (3) Aldicarb is one of the 89 active substances designated in Regulation (EC) No 933/94.
- (4) In accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92, the United Kingdom, being the designated rapporteur Member State, submitted on 30 April 1996 to the Commission the report of its assessment of the information submitted by the notifiers in accordance with Article 6 (1) of that Regulation.
- (5) On receipt of the report of the rapporteur Member State, the Commission undertook consultations with experts of the Member States as well as with the main notifier (Rhône-Poulenc, now Bayer CropScience) as provided for in Article 7(3) of Regulation (EEC) No 3600/92.
- (6) The assessment report prepared by the United Kingdom has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. It appeared that the information submitted was 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 Directive 91/414/EEC. The dossier and the information from the review were also submitted to the Scientific Committee for Plants. The Committee was asked to comment on the ecotoxicological risk assessment, including the risk to small birds. The Committee noted that the risk assessment for the exposure of small birds to granules critically depends on the assumption that more than 99% of the granules are incorporated into the soil. Whilst this may be achieved under ideal conditions, the Committee believed that this high degree of incorporation is not consistently achievable under normal agricultural use conditions and therefore advised that a re-assessment is necessary. In relation to other non-target organisms the Committee is not able to assess from the data available whether the use of aldicarb should continue pending the generation, submission and evaluation of further data. Therefore the Commission invited the notifier to complete its dossier by 31 December 2001 at the latest for a limited range of representative uses. Upon receipt of the additional information, the review was finalised on 18 October 2002 in the format of the Commission review report for aldicarb, in accordance with Article 7(6) of Regulation (EEC) No 3600/92.
- (7) Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing aldicarb satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to its possible impact on non-target organisms. It is appropriate to take this decision in view of the high risk of aldicarb in its present granular formulation in particular to small birds. Data submitted by the notifier for the proposed representative uses indicate that granules will remain on the soil surface after treatment. The possibility of a lethal intake of granules by small birds cannot be excluded. A probabilistic risk assessment was prepared by the notifier and evaluated by the rapporteur Member State who concluded that effects on national populations would not be expected although some local impact might occur. It must be taken into consideration that agreed criteria for the interpretation of such a probabilistic risk assessment are not yet consolidated and it would not be appropriate, in view of the possible risks, to delay decision making further until such criteria are agreed.

Moreover, the review has identified a risk to earthworms, and the available information from field studies is still insufficient to fully resolve these concerns.

- (8) Aldicarb should therefore not be included in Annex I to Directive 91/414/EEC.
- (9) Measures should be taken to ensure that existing authorisations for plant protection products containing aldicarb are withdrawn within a prescribed period and will not be renewed and that no new authorisations for such products are granted.
- (10) Any period of grace for disposal, storage, placing on the market and use of existing stocks of plant protection products containing aldicarb allowed by Member States, in accordance with Article 4(6) of Directive 91/414/EEC should be limited to a period no longer than twelve months to allow existing stocks to be used in no more than one further growing season.
- (11) This Decision does not prejudice any action the Commission may undertake at a later stage for this active substance 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 substances⁸, as last amended by the Act of Accession of Austria, Finland and Sweden.
- (12) In the absence of a favourable opinion of the Standing Committee on the Food Chain and Animal Health, the Commission has been unable to adopt the provisions it envisaged under the procedure laid down in Article 19 of Council Directive 91/414/EEC,

HAS ADOPTED THIS DECISION:

Article 1

Aldicarb is not included as active substance in Annex I to Directive 91/414/EEC.

Article 2

Member States shall ensure that:

- (a) authorisations for plant protection products containing aldicarb are withdrawn within a period of six months from the date of adoption of this Decision;
- (b) from the date of adoption of this Decision no authorisations for plant protection products containing aldicarb are granted or renewed under the derogation provided for in Article 8 (2) of Directive 91/414/EEC.

Article 3

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC, shall be as short as possible and not longer than 18 months from the date of adoption of this Decision.

⁸ OJ L 33, 8.2.1979, p.36.

Article 4

This Decision is addressed to the Member States.

Done at Brussels,

For the Council

The President