COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18.3.2003
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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

A proposal was submitted to the Standing Committee on the Food Chain and Animal Health on 18 October 2002. It provided for the non-inclusion of the nematicide Aldicarb in Annex I to Directive 91/414/EEC. The decision to withdraw Aldicarb was based largely on its negative environmental impact. It obliged the 10 Member States that have authorisations to withdraw them within six months and permitted periods of grace for stock sell-out for up to another 12 months.

No qualified majority was obtained and as a result the proposal was referred to Council. The Council may react at any time until 18 March 2003. It will be discussed again at the Agriculture Council on 18 March.

Of the 800+ substances on the market, only 10 are nematicides and Member States are concerned about being left with no alternatives to manage these pests in the future.

A Presidency compromise text tabled at the meeting of the Group of attachés on 13 February 2003, proposes that Aldicarb would not be included in Annex I but provides for the possibility that for certain limited essential uses in certain Member States (specified in the Annex to the decision), authorisations may remain in place until 30 June 2007. In this proposal, Member States will have to take the responsibility upon themselves that authorisations are continued only where safety for humans, animals and the environment is not compromised and where the products are relabelled. Member States also have to commit to searching actively for alternatives.

Discussions have been proceeding with Member States on this compromise. The Commission has been pushing those Member States to limit to the minimum the essential uses of this nematicide. These discussions continued at Coreper on Monday 17 March and a qualified majority in support of this amendment was indicated. In view of the moves by Member States to limit the use of Aldicarb the Commission wishes to make a new proposal incorporating the amendments arrived at in Council.

Proposal for a

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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 market[1], as last amended by Commission Directive 2002/81/EC[2], and in particular the third and 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 market[3], as last amended by Regulation (EC) No 2266/2000[4], and in particular Article 7 (3A) (b) thereof,

Having regard to the proposal from the Commission[5]

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 3600/92[6], as last amended by Regulation (EC) N°2230/95[7], 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 identified the producers of each active substance who submitted a notification in due time.

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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.

(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) In the light of the information before the Council it appears that, in the absence of efficient alternatives for certain limited uses in certain Member States, there is a need for further use of the active substance so as to enable the development of alternatives. It is therefore justified in the present circumstances to prescribe under strict conditions aimed at minimising risk (for example stewardship programmes) a longer period for the withdrawal of existing authorisations for the limited uses considered as essential for which no efficient alternatives appear currently to be available for the control of harmful organisms.

(11) 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 short period to allow existing stocks to be used in no more than one further growing season.

(12) 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 substances[8], as last amended by the Act of Accession of Austria, Finland and Sweden.

(13) 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:

(1) authorisations for plant protection products containing aldicarb are withdrawn by .....[*];

(2) from ** 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.

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[8] OJ L 33, 8.2.1979, p. 36.

[*] Six months from the date of adoption of this Decision.

[**] the date of adoption of this Decision

(3) In relation to the uses listed in column B of the Annex, a Member State specified in column A may maintain in force authorisations for plant protection products containing aldicarb until 30 June 2007 provided that it:

(a) ensures that such plant protection products remaining on the market are relabelled in order to match the restricted use conditions,

(b) imposes all appropriate risk mitigation measures to reduce any possible risks and to ensure the protection of human and animal health and the environment, and

(c) ensures that alternative products or methods for such uses are being seriously sought, in particular, by means of action plans.

The Member State concerned shall inform the Commission on 31 December 2004 at the latest on the application of this paragraph and in particular on the actions taken pursuant to points (a) to (c) and provide on a yearly basis estimates of the amounts of aldicarb used for essential uses pursuant to this article.

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:

(a) for the uses for which the authorisation is to be withdrawn .....[*], shall expire not later than .....[**]

(b) for the uses for which the authorisation is to be withdrawn by 30 June 2007, shall expire not later than 31 December 2007.

Article 4

This Decision is addressed to the Member States.

Done at Brussels,

For the Council
The President

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[*] Six months from the date of adoption of this Decision.
[**] Eighteen months from the date of adoption of this Decision.

ANNEX

List of authorisations referred to in Article 2 (3)

Column A	**Column B**
Member State	Use
BELGIUM	BEET
FRANCE	BEET, VINEYARD
GREECE	POTATOES, TOBACCO,
NETHERLANDS	ORNAMENTALS SUGAR BEET POTATOES (seed and starch)
ITALY	SUGAR BEET TOBACCO NURSERIES
PORTUGAL	CITRUS, FLORICULTURE, VINE YARDS
SPAIN	COTTON, CITRUS (young plantations), WOODY NURSERIES
UNITED KINGDOM	POTATOES CARROTS (including parsnips) ONIONS ORNAMENTALS