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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2006)

SANCO/10560/2006 Rev. 0

Draft

COMMISSION DECISION

of

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

(Text with EEA relevance)

(Memorandum from Mr M. KYPRIANOU)

Draft

COMMISSION DECISION

of

concerning the non-inclusion of oxydemeton-methyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance

(Text with EEA relevance)

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 market¹, and in particular the fourth subparagraph of Article 8(2) thereof,

Whereas:

- (1) Article 8(2) of Directive 91/414/EEC provides that a Member State may, during a period of 12 years following the notification of that Directive, authorise the placing on the market of plant protection products containing active substances not listed in Annex I of that Directive that are already on the market two years after the date of notification, while those substances are gradually being examined within the framework of a programme of work.
- (2) Commission Regulations (EC) No 451/2000² and (EC) No 703/2001³ lay down the detailed rules for the implementation of the second stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes oxydemeton-methyl.

¹ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/74/EC (OJ L 238, 30.8.2006, p.17).

² OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p. 32).

³ OJ L 98, 7.4.2001, p. 6.

- (3) For oxydemeton-methyl the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 703/2001 for a range of uses proposed by the notifier. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 8(1) of Regulation (EC) No 451/2000. For oxydemeton-methyl the rapporteur Member State was France and all relevant information was submitted on 3 May 2004.
- (4) The assessment report was peer reviewed by the Member States and the EFSA and presented to the Commission on 23 June 2006 in the format of the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance oxydemeton-methyl⁴. This report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 29 September 2006 in the format of the Commission review report for oxydemeton-methyl.
- (5) During the evaluation of this active substance, a number of concerns were identified. In particular based on the available data it has not been demonstrated that the consumer exposure is acceptable. The information available indicates concerns for metabolites which are at the same level of toxicity as the active substance, and their presence at levels which might be of toxicological concerns can not be excluded. Moreover concerns were identified with regard to operator, worker and bystander exposure.
- (6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments advanced, the above concerns remained unsolved, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing oxydemeton-methyl satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (7) Oxydemeton-methyl should therefore not be included in Annex I to Directive 91/414/EEC.
- (8) Measures should be taken to ensure that authorisations granted for plant protection products containing oxydemeton-methyl are withdrawn within a fixed period of time and are not renewed and that no new authorisations for such products are granted.
- (9) Any period of grace granted by a Member State for the disposal, storage, placing on the market and use of existing stocks of plant protection products containing oxydemeton-methyl, should be limited to twelve months in order to allow existing stocks to be used in one further growing season.
- (10) This decision does not prejudice the submission of an application for oxydemeton-methyl according to the provisions of Article 6 (2) of Directive 91/414/EEC in view of a possible inclusion in its Annex I.

⁴ EFSA Scientific Report (2006) 86, 1-96, Conclusion regarding the peer review of pesticide risk assessment of oxydemeton-methyl.

- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Oxydemeton-methyl shall not be included as an active substance in Annex I to Directive 91/414/EEC.

Article 2

Member States shall ensure that:

- (a) authorisations for plant protection products containing oxydemeton-methyl are withdrawn by [... *INSERT DATE 6 MONTHS FROM THE DATE OF ADOPTION OF THIS DECISION*];
- (b) no authorisations for plant protection products containing oxydemeton-methyl are granted or renewed from the date of publication of this Decision.

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 shall expire on [... *INSERT DATE 18 MONTHS FROM ADOPTION OF THIS DECISION*] at the latest.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, [...]

For the Commission
Markos KYPRIANOU
Member of the Commission