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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.07.2006
SANCO/10157/2006 rev. 2

COMMISSION DECISION (EC) No ...

[...]

**concerning the non-inclusion of phosalone 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)

COMMISSION DECISION (EC) No .

[...]

concerning the non-inclusion of phosalone 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 phosalone.
- (3) For phosalone 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 notifiers. 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 phosalone the Rapporteur Member State was Austria and all relevant information was submitted on 7 May 2004.

¹OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive xxxxxxxxxxxxxxxx (OJ L xxx, xx.xx.2004, p.).

²OJ 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).

³OJ L 98, 7.4.2001, p. 6.

- (4) The assessment report has been peer reviewed by the Member States and the EFSA and presented to the Commission on 13 January 2006 in the format of the EFSA Conclusion regarding the peer review of the pesticide risk assessment of the active substance phosalone⁴. This report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 14 July 2006 in the format of the Commission review report for phosalone.
- (5) During the evaluation of this active substance, a number of concerns have been identified. This was in particular the case concerning the risk for vulnerable groups of consumers, as estimated exposures to phosalone have not been demonstrated to be acceptable. Moreover, some of its metabolites and impurities need further toxicological characterisation and additional concerns have been identified concerning the risk for birds, mammals, aquatic organisms, bees and non target arthropods.
- (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 phosalone satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (7) Phosalone should therefore not be included in Annex I to Directive 91/414/EEC.
- (8) Measures should be taken to ensure that existing authorisations for plant protection products containing phosalone are withdrawn within a prescribed period and are not renewed and that no new authorisations for such products are granted.
- (9) Any period of grace for disposal, storage, placing on the market and use of existing stocks of plant protection products containing phosalone allowed by Member States, 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.
- (10) 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 substances⁵, as last amended by Regulation (EC) No 850/2004⁶.
- (11) This decision does not prejudice the submission of an application for phosalone 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) 60, 1-66, Conclusion regarding the peer review of pesticide risk assessment of phosalone.

⁵ OJ L 33, 8.2.1979, p.36.

⁶ OJ L 158, 30.4.2004, p. 7.

- (12) 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

Phosalone 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 phosalone are withdrawn by ^{*}
- (b) From ^{**} no authorisations for plant protection products containing phosalone 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 shall expire not later than ^{***}
...

Article 4

This Decision is addressed to the Member States.

Done at Brussels, [...]

For the Commission
Markos Kyprianou
Member of the Commission

* 6 months from the date of adoption of this Decision

** date of publication of the Decision

*** eighteen months from the date of adoption of this Decision

