

## COMMISSION DECISION

of 22 December 2006

**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**

(notified under document number C(2006) 6897)

(Text with EEA relevance)

(2006/1010/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 <sup>(1)</sup>, 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 451/2000 <sup>(2)</sup> and (EC) No 703/2001 <sup>(3)</sup> 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.

- (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 phosalone <sup>(4)</sup>. 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.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/136/EC (OJ L 349, 12.12.2006, p. 42).

<sup>(2)</sup> 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).

<sup>(3)</sup> OJ L 98, 7.4.2001, p. 6.

<sup>(4)</sup> EFSA Scientific Report (2006) 60, 1-66, Conclusion regarding the peer review of pesticide risk assessment of phosalone.

(7) Phosalone should therefore not be included in Annex I to Directive 91/414/EEC.

HAS ADOPTED THIS DECISION:

*Article 1*

(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.

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

*Article 2*

Member States shall ensure that:

(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 12 months to allow existing stocks to be used in no more than one further growing season.

(a) authorisations for plant protection products containing phosalone are withdrawn by 22 June 2007;

(b) from 28 December 2006 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*

(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 substances <sup>(1)</sup>.

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 22 June 2008.

*Article 4*

(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.

This Decision is addressed to the Member States.

Done at Brussels, 22 December 2006.

(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,

*For the Commission*  
Markos KYPRIANOU  
*Member of the Commission*

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<sup>(1)</sup> OJ L 33, 8.2.1979, p. 36. Directive as last amended by Regulation (EC) No 850/2004 of the European Parliament and of the Council (OJ L 158, 30.4.2004, p. 7, corrected by OJ L 229, 29.6.2004, p. 5).