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**SANCO/10341/2006 rev 4\_1**



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.9.2006  
SANCO/10341/2006 rev 4\_1

Draft

**COMMISSION DECISION**

**of**

**concerning the non-inclusion of malathion 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)**

Draft

**COMMISSION DECISION**

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**concerning the non-inclusion of malathion 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 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 malathion.

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<sup>1</sup> OJ L 230, 19.8.1991, p. 1. Directive as last amended by *[INSERT LAST AMENDMENT]*.

<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.

- (3) For malathion 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 malathion the rapporteur Member State was Finland and all relevant information was submitted on 2 February 2004.
- (4) The assessment report has been peer reviewed by the Member States and the EFSA within its Working Group Evaluation 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 malathion<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 29 September 2006 in the format of the Commission review report for malathion.
- (5) During the evaluation of this active substance, a number of concerns have been identified. Due to the presence of varying levels in the technical material of isomalathion, which is an impurity that contributes significantly to the toxicity profile of malathion and the genotoxicity of which cannot be excluded, the risk to operators, workers and bystanders could not be concluded. Moreover, based on the available information it has not been demonstrated that the estimated exposure of consumers resulting from the acute and chronic intake of edible crops is acceptable, due to the insufficient information on the effects of certain toxicologically relevant metabolites. Consequently, it was not possible to conclude on the basis of the information available that malathion met the criteria for inclusion in Annex I to Directive 91/414/EEC.
- (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 put forwards by the notifier, the concerns identified could not be eliminated, 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 malathion satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (7) Malathion 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 malathion 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 malathion should be limited to twelve months in order to allow existing stocks to be used in one further growing season.

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<sup>4</sup> EFSA Scientific Report (2006) 63, 1-87, Conclusion on the peer review of malathion.

- (10) This decision does not prejudice the submission of an application for malathion according to the provisions of Article 6 (2) of Directive 91/414/EEC in view of a possible inclusion in its Annex I.
- (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*

Malathion shall not be 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 malathion are withdrawn by *[INSERT DATE 6 MONTHS FROM THE DATE OF ADOPTION OF THIS DECISION]*;
- (b) no authorisations for plant protection products containing malathion 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 DATA 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*