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COMMISSION DIRECTIVE 2010/17/EU

of 9 March 2010

amending Council Directive 91/414/EEC to include malathion as active substance

(Text with EEA relevance)

(OJ L 60, 10.3.2010, p. 17)

Corrected by:

►**C1** Corrigendum, OJ L 113, 6.5.2010, p. 58 (2010/17/EU)

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COMMISSION DIRECTIVE 2010/17/EU

of 9 March 2010

amending Council Directive 91/414/EEC to include malathion as active substance

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ([1]), and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 451/2000 ([2]) and (EC) No 703/2001 ([3]) 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 included malathion. By Commission Decision 2007/389/EC ([4]) it was decided not to include malathion in Annex I to Directive 91/414/EEC.

(2) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier submitted a new application requesting the application of the accelerated procedure provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ([5]).

(3) The application was submitted to the United Kingdom, replacing Finland which had originally been designated rapporteur Member State by Regulation (EC) No 451/2000. The time period for the accelerated procedure was respected. The specification of the active substance is the same as was the subject of Decision 2007/389/EC while the initially supported use on apples has been replaced by strawberry and the application rate has been lowered. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(4) The United Kingdom evaluated the new information and data submitted by the notifier and prepared an additional report in February 2009.

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 55, 29.2.2000, p. 25.
([3]) OJ L 98, 7.4.2001, p. 6.
([4]) OJ L 146, 8.6.2007, p. 19.
([5]) OJ L 15, 18.1.2008, p. 5.

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(5) The additional report was peer reviewed by the Member States and the EFSA and presented to the Commission on 17 July 2009 in the format of the EFSA Scientific Report for malathion [1]. 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 22 January 2010 in the format of the Commission review report for malathion.

(6) The new assessment by the rapporteur Member State and the new conclusion by the EFSA concentrated on the concerns that lead to the non-inclusion. Those concerns were in particular the presence in the technical material of varying levels of isomalathion, an impurity that contributes significantly to the toxicity profile of malathion and the genotoxicity of which cannot be excluded. Because of this fact it was impossible to assess the risk to operators, workers and bystanders. Moreover, information on the effects of certain toxicologically relevant metabolites was insufficient, and it had, hence, not been demonstrated that the estimated exposure of consumers resulting from the acute and chronic intake of edible crops is acceptable.

(7) New data and information were submitted by the notifier in the new dossier and a new assessment was performed, as included in the additional report and in the EFSA conclusions. Those new data show that the genotoxicity of malathion containing not more than 2 g/kg isomalathion can be ruled out. It has therefore been possible to determine acceptable levels of exposure of operators, workers and bystanders. Use by non-professionals could, however, raise concerns, as it cannot be assumed that these have recourse to the adequate personal protective equipment. As a consequence, such use should not be authorised.

(8) Without prejudice to those conclusions, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EC provides that the inclusion of a substance in Annex I may be subject to conditions. Therefore it is appropriate to require that the notifier submit further information as regards consumer intakes, the acute and long-term risk assessment for insectivorous birds, and on the quantification of the different potency of malaoxon and malathion, before authorisations are granted. As regards the consumer exposure, the information currently available allows nonetheless to conclude that the risk is acceptable, given the large margin of safety that exists.

(9) Consequently, the additional data and information provided by the notifier permit to eliminate the specific concerns that led to the non-inclusion. No other open scientific questions have arisen.

[1] *EFSA Scientific Report (2009) 333 — Conclusion on pesticide peer review — peer review of the pesticide risk assessment of the active substance malathion (re-issued on 17 July 2009).*

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(10) It has appeared from the various examinations made that plant protection products containing malathion may be expected to satisfy, in general, the requirements laid down in Article 5(1) (a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include malathion in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance may be granted in accordance with the provisions of that Directive.

(11) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 September 2010 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on 1 May 2010.

Article 4

This Directive is addressed to the Member States.

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ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
	'Malathion CAS No: 121-75-5 CIPAC No: 12	*diethyl (dimethoxyphosphinothioylthio)succinate or S-1,2-bis(ethoxycarbonyl)ethyl O,O-dimethyl phosphorodithioate* racemate	≥ 950 g/kg Impurities: Isomalathion: not more than 2 g/kg	1 May 2010	►C1 30 April 2020 ◄	PART A Only uses as insecticide may be authorised. Authorisations shall be limited to professional users. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on malathion, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operator and worker safety: conditions of use shall prescribe the use of adequate personal protective equipment; — the protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones; — the protection of insectivorous birds and honey bees: conditions of authorisation shall include risk mitigation measures, where appropriate. As regards bees, the necessary indications shall be provided on the labelling and the accompanying instructions as to avoid exposure. Member States shall ensure that malathion-based formulations are accompanied by the necessary instructions to avoid any risk of formation of isomalathion in excess of the permitted maximum quantities during storage and transport. Where appropriate, conditions of authorisation shall include further risk mitigation measures. The Member States concerned shall ensure that the notifier presents to the Commission: — information confirming the consumer risk assessment and the acute and long-term risk assessment for insectivorous birds; — information on the quantification of the different potency of malaoxon and malathion.'

(1) Further details on identity and specification of active substance are provided in the review report.