DIRECTIVES

COMMISSION DIRECTIVE 2009/115/EC

of 31 August 2009

amending Council Directive 91/414/EEC to include methomyl as active 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 ([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 methomyl. By Commission Decision 2007/628/EC ([4]) it was decided not to include methomyl 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 Article 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, which had 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 and the supported uses are the same as were the subject of Decision 2007/628/EC. 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 on 15 May 2008.

(5) The additional report was peer reviewed by the Member States and the EFSA and presented to the Commission on 19 December 2008 in the format of the EFSA Scientific Report for methomyl ([6]). 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 12 June 2009 in the format of the Commission review report for methomyl.

(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 were the unacceptable operator exposure, the inconclusive nature of the exposure assessment for workers and bystanders and the high risk for birds, mammals, aquatic organisms, bees and other non-target arthropods.

(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 Scientific Report for methomyl. As a consequence, it was shown that acceptable levels of operator exposure can be achieved, if protective equipment, in addition to that referred to in the original dossier, is worn. As regards the risk to workers and bystanders, it has been clarified that no unacceptable risks are expected from the uses as supported in the resubmitted dossier. Finally, the risk to birds, mammals, aquatic organisms, bees and non-target arthropods may be considered as acceptable, provided that the lowest supported application rate is applied and that appropriate risk management measures are implemented.

([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 255, 29.9.2007, p. 40.
([5]) OJ L 15, 18.1.2008, p. 5.

([6]) *EFSA Scientific Report (2008) 222 — Conclusion regarding the peer review of the pesticide risk assessment of the active substance methomyl (re-issued on 19 December 2008).*

(8) 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.

(9) It has appeared from the various examinations made that plant protection products containing methomyl 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 methomyl 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.

(10) However, to exclude any risk of intentional or unintentional poisoning, it is appropriate to require repelling and/or emetic agents to be incorporated in plant protection products containing methomyl and to authorise use by professionals only.

(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 31 January 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 September 2009.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 31 August 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

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
	'Methomyl CAS No: 16752-77-50 CIPAC No: 264	S-methyl (EZ)-N-(methylcarbamoyloxy) thioacetimidate	≥ 980 g/kg	1 September 2009	31 August 2019	PART A Only uses as insecticide on vegetables may be authorised at rates not exceeding 0,25 kg active substance per hectare per application and for a maximum of 2 applications per season. 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 methomyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 June 2009 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operator safety: conditions of use shall prescribe the use of adequate personal protective equipment. Special attention shall be paid to the exposure of operators using knapsacks or other hand-held application equipment, — the protection of birds, — the protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as buffer zones, reduction of run-off and drift reduction nozzles, — the protection of non-target arthropods, in particular bees: risk mitigation measures to avoid all contact with bees shall be applied, Member States shall ensure that methomyl-based formulations contain effective repelling and/or emetic agents. Where appropriate, conditions of authorisation shall include further risk mitigation measures.'

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