

COMMISSION DIRECTIVE 2005/72/EC**of 21 October 2005****amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

information was submitted on 3 October 2000, 29 November 2000 and 22 August 2000 respectively.

Having regard to the Treaty establishing the European Community,

- (3) The assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The reviews were finalised on 3 June 2005 in the format of the Commission review reports for chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb and metiram.

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 Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽²⁾, establishes 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 chlorpyrifos, chlorpyrifos-methyl (under the spelling chlorpyriphos and chlorpyriphos-methyl) mancozeb, maneb and metiram.

- (4) The reviews of chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb and metiram did not reveal any open question to be addressed by the Scientific Committee on Plants or the European Food Safety Authority (EFSA) which has taken over the role of that Committee.

(2) For those active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifiers. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the Rapporteur Member States for the implementation of Commission Regulation (EEC) No 3600/92 ⁽³⁾, the following Rapporteur Member States were designated, which submitted the relevant assessment reports and recommendations to the Commission in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92. For chlorpyrifos and chlorpyrifos-methyl the Rapporteur Member State was Spain, and all relevant information was submitted on 16 September 1997 and 7 May 1999. For mancozeb, maneb and metiram Italy was designated as Rapporteur Member State and all relevant

- (5) It has appeared from the various examinations made, that plant protection products containing chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb and metiram 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 these active substances in Annex I, in order to ensure that, in all Member States, the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of that Directive.

- (6) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore it is appropriate to require that chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb and metiram should be subjected to further testing for confirmation of the risk assessment for some non-target organisms and in case of maneb, and mancozeb also for developmental toxicity, and that such studies should be presented by the notifiers.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).

⁽²⁾ OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 10).

⁽³⁾ OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).

- (7) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

- (8) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb or metiram to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.
- (9) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I.
- (10) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (11) 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 adopt and publish by 31 December 2006 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 January 2007.

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

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb or metiram as active substances by 31 December 2006. By that date they shall in particular verify that the conditions in Annex I to that Directive relating to chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb and metiram are met, with the exception of those identified in part B of the entries concerning those active substances, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb or metiram as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 30 June 2006 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb and metiram respectively. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

- (a) in the case of a product containing chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb or metiram as the only active substance, where necessary, amend or withdraw the authorisation by 30 June 2010 at the latest; or
- (b) in the case of a product containing chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb or metiram as one of several active substances, where necessary, amend or withdraw the authorisation by 30 June 2010 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 July 2006.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 21 October 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

The following entries 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 (%)	Entry into force	Expiration of inclusion	Specific provisions
112	Chlorpyrifos CAS No 2921-88-2 CIPAC No 221	O,O-diethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate	≥ 970 g/kg The impurity O,O,O-tetraethyl dithiopyrophosphate (Sulfotep) was considered of toxicological concern and a maximum level of 3 g/Kg is established.	1 July 2006	30 June 2016	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on chlorpyrifos, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account. Member States must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones. Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals. They shall ensure that the notifiers at whose request chlorpyrifos has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
113	Chlorpyrifos-methyl CAS No 5598-13-0 CIPAC No 486	O,O-dimethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate	≥ 960 g/kg The impurities O,O,O-tetramethyl dithiopyrophosphate (Sulfotemp) and OOO-trimethyl-O-(3,5,6-trichloro-2-pyridinyl) diphosphorodithioate (Sulfotemp - ester) were considered of toxicological concern and a maximum level of 5 g/Kg is established for each impurity.	1 July 2006	30 June 2016	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on chlorpyrifos-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account.

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
114	Maneb CAS No 12427-38-2 CIPAC No 61	manganese ethylenebis (dithiocarbamate) (polymERIC)	≥ 860 g/kg The manufacturing impurity ethylene thiourea is considered to be of toxicological concern and must not exceed 0,5 % of the maneab content.	1 July 2006	30 June 2016	<p>Member States must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones.</p> <p>Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals in case of outdoor uses. They shall ensure that the notifiers at whose request chlorpyrifos-methyl has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.</p> <p>PART A Only uses as fungicide may be authorised.</p> <p>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on maneab, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account.</p> <p>Member States must pay particular attention to the potential for groundwater contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions.</p> <p>Member States must pay particular attention to the residues in food and evaluate the dietary exposure of consumers.</p> <p>Member States must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods and ensure that the conditions of authorisation include risk mitigation measures.</p>

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
115	Mancozeb CAS No 8018-01-7 (formerly 8065-67-5) CIPAC No 34	Manganese ethylenebis (dithiocarbamate) (polymERIC) complex with zinc salt	≥ 800 g/kg The manufacturing impurity ethylene thiourea is considered to be of toxico- logical concern and must not exceed 0,5 % of the mancozeb content.	1 July 2006	30 June 2016	<p>Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals and for developmental toxicity.</p> <p>They shall ensure that the notifiers at whose request maneb has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.</p> <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mancozeb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account.</p> <p>Member States must pay particular attention to the potential for groundwater contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions.</p> <p>Member States must pay particular attention to the residues in food and evaluate the dietary exposure of consumers.</p> <p>Member States must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods and ensure that the conditions of authorisation include risk mitigation measures.</p> <p>Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals and for developmental toxicity.</p>

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
116	Metiram CAS No 9006-42-2 CIPAC No 478	Zinc ammoniate ethylenebis(dithiocarbamate) — poly[ethylenebis(thiuramdisulfide)]	≥ 840 g/kg The manufacturing impurity ethylene thiourea is considered to be of toxicological concern and must not exceed 0,5 % of the metiram content.	1 July 2006	30 June 2016	<p>They shall ensure that the notifiers at whose request mancozeb has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.</p> <p>PART A Only uses as fungicide may be authorised.</p> <p>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metiram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account.</p> <p>Member States must pay particular attention to the potential for ground water contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions.</p> <p>Member States must pay particular attention to the residues in food and evaluate the dietary exposure of consumers.</p> <p>Member States must pay particular attention to the protection of birds, mammals, aquatic organisms and non target arthropods and must ensure that the conditions of authorisation include risk mitigation measures.</p> <p>Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals. They shall ensure that the notifiers at whose request metiram has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.</p>

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