COMMISSION DIRECTIVE 2005/57/EC

of 21 September 2005

amending Council Directive 91/414/EEC to include MCPA and MCPB as active substances

(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 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 MCPA and MCPB.

(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 State for the implementation of Regulation (EEC) No 3600/92 [3], Italy was designated as rapporteur Member State. On 5 April 2001 and 19 December 2001 Italy submitted the relevant assessment reports and recommendations to the Commission in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(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 15 April 2005 in the format of the Commission review reports for MCPA and MCPB.

(4) The reviews of MCPA and MCPB 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 the latter.

(5) It has appeared from the various examinations made that plant protection products containing MCPA or MCPB 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 reports. 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) 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.

(7) Without prejudice to the obligations defined by Directive 91/414 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 MCPA or MCPB 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.

(8) 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.

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[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).

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

(10) 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 October 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 November 2006.

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 MCPA or MCPB as active substances by 31 October 2006. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to MCPA and MCPB respectively are met, with the exception of those identified in part B of the entry 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 derogation from paragraph 1, for each authorised plant protection product containing MCPA or MCPB 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 April 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 MCPA and MCPB 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 MCPA or MCPB as the only active substance, where necessary, amend or withdraw the authorisation by 30 April 2010 at the latest; or

(b) in the case of a product containing MCPA or MCPB as one of several active substances, where necessary, amend or withdraw the authorisation by 30 April 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 May 2006.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 21 September 2005.

For the Commission
Markos KYPRIANOU
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
'108	MCPA CAS No 94-74-6 CIPAC No 2	4-chloro-o-tolyloxyacetic acid	≥ 930 g/kg	1 May 2006	30 April 2016	PART A Only uses as herbicide may be authorised PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on MCPA, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2005 shall be taken into account Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones
109	MCPB CAS No 94-81-5 CIPAC No 50	4-(4-chloro-o-tolyloxy)butyric acid	≥ 920 g/kg	1 May 2006	30 April 2016	PART A Only uses as herbicide may be authorised PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on MCPB, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2005 shall be taken into account Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones'

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