

Commission Directive 2006/85/EC of 23 October 2006 amending
Council Directive 91/414/EEC to include fenamiphos and
ethephon as active substances (Text with EEA relevance)

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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 includes fenamiphos and ethephon.
- (2) For those active substances 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 fenamiphos the rapporteur Member State was the Netherlands and all relevant information was submitted on 27 November 2003. For ethephon the rapporteur Member State was the Netherlands and all relevant information was submitted on 21 April 2004.
- (3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 13 January 2006 for fenamiphos and on 24 April 2006 for ethephon in the format of the EFSA Scientific Reports⁽⁴⁾. These reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 14 July 2006 in the format of the Commission review reports for fenamiphos and ethephon.
- (4) It has appeared from the various examinations made that plant protection products containing fenamiphos and ethephon 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

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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.

- (5) 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.
- (6) 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 fenamiphos and ethephon 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 way of 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.
- (7) 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.
- (8) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (9) 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:

- (1) [OJ L 230, 19.8.1991, p. 1](#). Directive as last amended by Commission Directive 2006/75/EC ([OJ L 248, 12.9.2006, p. 3](#)).
- (2) [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](#)).
- (3) [OJ L 98, 7.4.2001, p. 6](#).
- (4) EFSA Scientific Report (2006) 62, 1-81, Conclusion regarding the peer review of the pesticide risk assessment of the active substance fenamiphos (finalised: 13 January 2006).
EFSA Scientific Report (2006) 67, 1-61, Conclusion regarding the peer review of the pesticide risk assessment of the active substance ethephon (finalised: 24 April 2006).