COMMISSION DIRECTIVE 2004/62/EC

of 26 April 2004

amending Council Directive 91/414/EEC to include mepanipyrim 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) In accordance with Article 6(2) of Directive 91/414/EEC Italy received on 24 October 1997 an application from Kumiai Chemical Industry Co., Ltd for the inclusion of the active substance mepanipyrim (former name: KIF 3535) in Annex I to Directive 91/414/EEC. Commission Decision 98/676/EC ([2]) confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) For this active substance, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The designated rapporteur Member State submitted a draft assessment report concerning the substance to the Commission on 12 July 2000.

(3) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 30 March 2004 in the format of the Commission review report for mepanipyrim.

(4) The dossier and the information from the review were also submitted to the Scientific Panel on Plant Health, Plant Protection Products and their Residues. The report of this Panel was formally adopted on 23 October 2003 ([3]).

The Panel was asked to comment on the liver tumors found in rats and mice exposed to mepanipyrim and to give its opinion on the question whether a threshold of tumor formation can be assumed.

In its opinion the Panel concluded that mepanipyrim induces tumors in rats and mice by a mechanism which is currently unknown but nevertheless involves a threshold below which tumors are not expected to develop and that therefore a safe level of human exposure can be assigned.

The recommendations of the Scientific Panel were taken into account during the further review and in this Directive and in the Review Report. The evaluation within the Standing Committee concluded that there would be no unacceptable human exposure under the proposed conditions of use.

(5) It has appeared from the various examinations made that plant protection products containing the active substance concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1) (a) and (b) and Article 5(3) 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 mepanipyrim 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.

(6) After inclusion, Member States should be allowed a reasonable period to implement the provisions of Directive 91/414/EEC as regards plant protection products containing mepanipyrim and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of Directive 91/414/EEC.

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

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

([1]) OJ L 230, 19.08.1991, p. 1. Directive as last amended by Commission Directive 2004/30/EC (OJ L 77, 13.3.2004, p. 50).
([2]) OJ L 317, 26.11.1998, p. 47.
([3]) Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request from the European Commission related to the evaluation of mepanipyrim in the Context of Council Directive 91/414/EEC, The EFSA Journal (2003) 4, 1-14.

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

1. Member States shall adopt and publish by 31 March 2005 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 April 2005.

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

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

1. Member States shall review the authorisation for each plant protection product containing mepanipyrim to ensure that the conditions relating to this active substance set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw authorisations in accordance with Directive 91/414/EEC by 31 March 2005 at the latest.

2. For each authorised plant protection product containing mepanipyrim 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 September 2004 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. 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 mepanipyrim as the only active substance, where necessary, amend or withdraw the authorisation by 31 March 2006 at the latest; or

(b) in the case of a product containing mepanipyrim as one of several active substances, where necessary, amend or withdraw the authorisation by 31 March 2006 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 October 2004.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 26 April 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

In Annex I the following rows are added at the end of the table.

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'91	Mepanipyrim CAS No 110235-47-7 CIPAC No 611	N-(4-methyl-6-prop-1-ynyl-pyrimidin-2-yl)aniline	960 g/kg	1 October 2004	30 September 2014	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mepanipyrim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 30 March 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.

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