Draft

COMMISSION DIRECTIVE .../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include etofenprox as an active substance in Annex I thereto

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/2000[2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes etofenprox.

(2) Pursuant to Regulation (EC) No 2032/2003, etofenprox has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 8, wood preservatives, as defined in Annex V to Directive 98/8/EC.

(3) Austria was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 11 October 2005 in accordance with Article 10(5) and (7) of Regulation (EC) No 2032/2003.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 21 June 2006, in an assessment report.

(5) The review of etofenprox did not reveal any open questions or concerns to be addressed by the Scientific Committee on Health and Environmental Risks.

[1] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2007/20/EC (OJ L 94, 04.04.2007, p. 23).

[2] OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1849/2006 (OJ L 355, 15.12.2006, p. 63).

(6) It appears from the examinations made that biocidal products used as wood preservatives and containing etofenprox may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. However, acceptable risks to human health were only identified for seasonal and intermittent (up to 3 months per year) use. It is therefore appropriate to include etofenprox in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing etofenprox can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC. Authorisations for products to be used year-round will require the submission of dermal absorption data in order to demonstrate that the products can be used without unacceptable risks to human health.

(7) In the light of the findings of the assessment report, and in particular of the risk identified for workers, it is appropriate to require that products containing etofenprox and intended for industrial use as wood preservatives be used with appropriate protective equipment.

(8) Not all potential uses have been evaluated at the Community level. It is therefore appropriate that Member States pay particular attention to the risks to the compartments and populations that have not been representatively addressed in the Community level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks to acceptable levels.

(9) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance etofenprox and also to facilitate the proper operation of the biocidal products market in general.

(10) 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 entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.

(11) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 8 containing etofenprox to ensure that they comply with Directive 98/8/EC.

(12) Directive 98/8/EC should therefore be amended accordingly.

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

Transposition

1. Member States shall adopt and publish, by 31 January 2009 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 February 2010.

   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.

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

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, […]

For the Commission
Stavros Dimas
Member of the Commission

ANNEX

The following entry 'No. 5' is inserted in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions[3]
"5	etofenprox	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether EC No: 407-980-2 CAS No: 80844-07-1	970 g/kg	1 February 2010	31 January 2012	31 January 2020	8	When assessing, in accordance with Article 5 and Annex VI, the application for authorisation of a product, Member States shall access those use and/or exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: In view of the risk identified for workers, products cannot be used year round unless

[3]

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions
								dermal absorption data is provided to demonstrate that there are no unacceptable risks from chronic exposure. In addition, products intended for industrial use must be used with appropriate personal protective equipment."

For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm