COMMISSION DIRECTIVE 2008/78/EC

of 25 July 2008

amending Directive 98/8/EC of the European Parliament and of the Council to include propiconazole 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 1451/2007 of 4 December 2007 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 [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 propiconazole.

(2) Pursuant to Regulation (EC) No 1451/2007, propiconazole 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) Finland was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 5 April 2006 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 29 November 2007, in an assessment report.

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

(6) It appears from the examinations made that biocidal products used as wood preservatives and containing propiconazole may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include propiconazole in Annex I for product type 8, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing propiconazole can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC. However, unacceptable risks were identified for the *in situ* treatment of wood outdoors and for treated wood exposed to weathering. Authorisation of these uses will require the submission of data demonstrating that the products can be used without unacceptable risks to the environment.

(7) In the light of the findings of the assessment report, it is appropriate to require that products containing propiconazole and used as wood preservatives must be used with appropriate personal protective equipment, that risk mitigation measures are applied to protect the soil and aquatic compartments and that related instructions are provided, in accordance with Article 10(2)(i)(d) of Directive 98/8/EC.

(8) 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 propiconazole and also to facilitate the proper operation of the biocidal products market in general.

(9) 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.

(10) 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 propiconazole to ensure that they comply with Directive 98/8/EC.

[1] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2008/31/EC (OJ L 81, 20.3.2008, p. 57).
[2] OJ L 325, 11.12.2007, p. 3.

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

(12) 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 March 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 April 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 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 July 2008.

For the Commission

Stavros DIMAS

Member of the Commission

ANNEX

The following entry 'No 8' 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 (*)
'8	propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole EC No: 262-104-4 CAS No: 60207-90-1	930 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. In addition, products cannot be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.'

(*) 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