

DIRECTIVES

COMMISSION DIRECTIVE 2010/50/EU

of 10 August 2010

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

the Standing Committee on Biocidal Products on 11 March 2010, in an assessment report.

Having regard to the Treaty on the Functioning of the European Union,

(5) It appears from the examinations made that biocidal products used as wood preservatives and containing dazomet may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include dazomet in Annex I to that Directive.

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,

(6) Not all potential uses have been evaluated at EU level. The EU level risk assessment addresses only professional use outdoors for the remedial treatment of wooden poles, such as transmission poles, by insertion of granules. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to the compartments and populations that have not been representatively addressed in the EU level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels.

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 dazomet.

(7) In the light of the findings of the assessment report, it is appropriate to require that risk mitigation measures are applied at product authorisation level to products containing dazomet and used as wood preservatives to ensure that risks are reduced to an acceptable level in accordance with Article 5 of Directive 98/8/EC and Annex VI thereto.

(2) Pursuant to Regulation (EC) No 1451/2007, dazomet 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 that Directive.

(3) Belgium was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission by 16 April 2007 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(8) In particular, it is appropriate to require that products intended for industrial or professional use be used with appropriate personal protective equipment, unless it can be demonstrated that risks for industrial or professional users can be reduced by other means.

(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

(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 dazomet and also to facilitate the proper operation of the biocidal products market in general.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

- (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.
- (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 July 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 August 2012.

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, 10 August 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the following entry for the substance dazomet is added:

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 (*)
'34	Dazomet	Tetrahydro-3,5-dimethyl- 1,3,5-thiadiazine-2-thione EC No: 208-576-7 CAS No: 533-74-4	960 g/kg	1 August 2012	31 July 2014	31 July 2022	8	<p>When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk assessment. In particular, where relevant, Member States shall assess any other use than professional use outdoors for the remedial treatment of wooden poles by insertion of granules.</p> <p>Member States shall ensure that authorisations are subject to the following condition:</p> <p>Products authorised for industrial and/or professional use shall 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 others means.'</p>

(*) 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>