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EUROPEAN COMMISSION

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Draft

COMMISSION DIRECTIVE/.../EU

of [...]

amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance carbon dioxide to product type 18

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amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance carbon dioxide to product type 18

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 market¹, 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 market² 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 carbon dioxide.
- (2) Commission Directive 2008/75/EC of 24 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include carbon dioxide as an active substance in Annex I thereto³ included carbon dioxide as an active substance in Annex I to directive 98/8/EC for use in product type 14, rodenticides, as defined in Annex V to Directive 98/8/EC.
- (3) Pursuant to Regulation (EC) No 1451/2007, carbon dioxide has now been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive.
- (4) France was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on

¹ OJ L 123, 24.4.1998, p. 1.

² OJ L 325, 11.12.2007, p. 3.

³ OJ L 197, 25.7.2008, p. 54.

19 February 2008 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

- (5) 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 27 May 2010, in an assessment report.
- (6) It appears from the examinations made that biocidal products used as insecticides, acaricides and products to control other arthropods and containing carbon dioxide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to extend the inclusion of carbon dioxide in Annex I to that Directive to such products.
- (7) Not all potential uses have been evaluated at the European level. 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 European 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.
- (8) 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 carbon dioxide and used as insecticides, acaricides and products to control other arthropods to ensure that risks are reduced to an acceptable level in accordance with Article 5 of Directive 98/8/EC and Annex VI thereto. In particular, it is appropriate to require that products are only sold to and used by trained professionals, that appropriate measures to protect operators are taken to ensure minimum risk, including the availability of personal protective equipment if necessary, and that appropriate measures are taken to protect bystanders, such as exclusion from the treatment area during fumigation.
- (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 carbon dioxide 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.
- (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 October 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 November 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.

1. 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
The President
José Manuel BARROSO

ANNEX

The following is added to entry 'No. 7' 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 (*)
			"990 ml/l	1 November 2012	31 October 2014	31 October 2022	18	<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 European level risk assessment.</p> <p>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.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <ol style="list-style-type: none"> (1) Product shall only be sold to and used by professionals trained to use them. (2) Appropriate measures to protect operators shall be taken to ensure minimum risk, including the availability of personal protective equipment if necessary.

								(3) Appropriate measures shall be taken to protect bystanders, such as exclusion from the treatment area during fumigation."
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(*) 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>