DIRECTIVES

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 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 Annexes I, IA or IB to Directive 98/8/EC. That list includes carbon dioxide.

(2) Pursuant to Regulation (EC) No 1451/2007, carbon dioxide has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC.

(3) France was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 15 May 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 21 June 2007, in an assessment report, with a proposal to include carbon dioxide in Annex IA to Directive 98/8/EC, only for use in ready-for-use gas canisters functioning together with a trapping device.

(5) An active substance listed in Annex IA should normally also be listed in Annex I. Inclusion in Annex I would cover those uses for which products may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, but not those of low-risk products. Such is the case of certain biocidal products used as rodenticides and containing carbon dioxide. It is therefore appropriate to include carbon dioxide in Annex I for product-type 14, in order to ensure that in all Member States authorisations for biocidal products used as rodenticides and containing carbon dioxide can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) The assessment report was modified accordingly, and was reviewed by the Standing Committee on Biocidal Products on 29 November 2007.

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

(8) The evaluation at the Community level was carried out for one specific use. In addition, in accordance with Article 8(5) of the Directive, some information was not submitted, and thus not assessed. It is therefore appropriate that Member States assess those 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 carbon dioxide and also to facilitate the proper operation of the biocidal products market in general.

[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.

(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 14 containing carbon dioxide 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 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 November 2009.

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, 24 July 2008.

For the Commission

Stavros DIMAS

Member of the Commission

ANNEX

The following entry 'No 7' 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 (*)
'7	carbon dioxide	carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	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, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. 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.'

(*) 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