

Draft

COMMISSION DIRECTIVE .../.../EC

of [...]

amending Directive 98/8/EC of the European Parliament and of the Council to include carbon dioxide as an active substance in Annex IA 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 market¹, and in particular the second subparagraph of Article 16(2),

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 1896/2000² 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) Pursuant to Regulation (EC) No 2032/2003, 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 10(5) and (7) of Regulation (EC) No 2032/2003.
- (4) The competent authority report has been 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 2007, in an assessment report.

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).

- (5) 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.
- (6) It appears from the various examinations made that biocidal products used as rodenticides and containing carbon dioxide may be expected to present only low risk to humans, animals and the environment and to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, in particular with regard to the uses which were examined and detailed in the assessment report. It is therefore appropriate to include carbon dioxide in Annex IA, in order to ensure that in all Member States authorisations or registrations 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.
- (7) 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.
- (8) A reasonable period should be allowed to elapse before an active substance is included in Annex IA 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.
- (9) 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 or registrations of biocidal products in product-type 14 containing carbon dioxide to ensure that they comply with Directive 98/8/EC.
- (10) Directive 98/8/EC should therefore be amended accordingly.
- (11) 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 IA 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 2008 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, [...]

For the Commission
Stavros Dimas
Member of the Commission

ANNEX

The following table with entry 'No. 1' is inserted in Annex IA 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 *
1	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	Only for use in ready-for-use gas canisters functioning together with a trapping device.

* 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>“
