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Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

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

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 Article 16(2) second subparagraph thereof,

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 sulfuryl fluoride.
- (2) Pursuant to Regulation (EC) No 2032/2003, sulfuryl fluoride 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) In accordance with Article 5(2) of Regulation (EC) No 2032/2003, Sweden was designated as Rapporteur Member State. Sweden submitted the competent authority report, together with a recommendation, to the Commission on 19 April 2005 in accordance with Article 10(5) and (7) of that Regulation.
- (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 [date 2006], in an assessment report.

¹ OJ L 123, 24.4.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

² OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1048/2005 (OJ L 178, 9.7.2005, p.1).

- (5) The review of sulfuranyl fluoride did not reveal any open questions or concerns to be addressed by the Scientific Committee on Health and Environmental Risks (SCHER).
- (6) It appears from the various examinations made that biocidal products used as wood preservatives and containing sulfuranyl fluoride may be expected 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 sulfuranyl fluoride in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing sulfuranyl fluoride 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 sulfuranyl fluoride and also to facilitate the proper operation of the biocidal products market in general.
- (8) In the light of the findings of the assessment report, it is appropriate to require that such products be authorised only for use by trained professionals, in accordance with Article 10(2)(i)(e) of Directive 98/8/EC, and that risk mitigation measures are designed to ensure the safety of operators and bystanders, in accordance with Article 10(2)(i)(f) of Directive 98/8/EC.
- (9) In addition, it is appropriate to require continuous monitoring, as well as the provision of further information on certain specific points detailed in the assessment report, in accordance with Article 10(2)(i)(f) of Directive 98/8/EC.
- (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(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 8 containing sulfuranyl fluoride 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 December 2007 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 January ~~2008~~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’ shall be 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 ³
1	sulfuryl fluoride	sulfuryl difluoride EC No: 220-281-5 CAS No: 2699-79-8	≥994 g/kg	1 January 2009	31 December 2010	31 December 2018	8	<p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(1) the product may only be sold to and used by professionals trained to use it;</p> <p>(2) appropriate risk mitigation measures are included for operators and bystanders;</p> <p>(3) concentrations of sulfuryl fluoride in remote tropospheric air are monitored.</p> <p>Member States shall also ensure that reports of the monitoring referred to in point (3) are transmitted by marketing authorisation holders directly to the Commission every fifth year starting from 1 January 2009.</p>

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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>

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