

## DIRECTIVES

## COMMISSION DIRECTIVE 2009/84/EC

of 28 July 2009

**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**

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

the Standing Committee on Biocidal Products on 20 February 2009, in an assessment report.

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<sup>(1)</sup>, 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<sup>(2)</sup> 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) Commission Directive 2006/140/EC<sup>(3)</sup> included sulfuryl fluoride as an active substance in Annex I to Directive 98/8/EC for use in product-type 8, wood preservatives, as defined in Annex V to Directive 98/8/EC.
- (3) Pursuant to Regulation (EC) No 1451/2007, sulfuryl fluoride has now been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, as defined in Annex V to that Directive.
- (4) Sweden was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 19 June 2007 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

- (6) It appears from the examinations made that biocidal products used as insecticides and containing sulfuryl fluoride may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include sulfuryl fluoride in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as insecticides and containing sulfuryl fluoride can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.
- (7) In the light of the conclusions of the assessment report, it is appropriate to require that products containing sulfuryl fluoride and used as insecticides be authorised only for use by trained professionals in accordance with Article 10(2)(i)(e) of Directive 98/8/EC, and that specific risk mitigation measures are applied at product authorisation level to ensure the safety of operators and of bystanders.
- (8) In addition, it is appropriate to require continuous monitoring of sulfuryl fluoride in remote tropospheric air and to require results of such monitoring to be regularly reported to the Commission.
- (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 sulfuryl fluoride 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.

<sup>(1)</sup> OJ L 123, 24.4.1998, p. 1.

<sup>(2)</sup> OJ L 325, 11.12.2007, p. 3.

<sup>(3)</sup> OJ L 414, 30.12.2006, p. 78.

- (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 18 containing sulfuryl 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*

1. Member States shall adopt and publish, by 30 June 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 July 2011.

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, 28 July 2009.

*For the Commission*  
Stavros DIMAS  
*Member of the Commission*

## ANNEX

The following is added to entry 'No 1' 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 (*)
			'994 g/kg	1 July 2011	30 June 2013	30 June 2021	18	<p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(1) Products shall only be sold to and used by professionals trained to use them.</p> <p>(2) Appropriate measures to protect fumigators and bystanders during fumigation and venting of treated buildings or other enclosures must be taken.</p> <p>(3) Labels and/or safety-data sheets of products shall indicate that, prior to fumigation of any enclosure, all food items must be removed.</p> <p>(4) Concentrations of sulfuryl fluoride in remote tropospheric air are monitored.</p> <p>(5) Member States shall also ensure that reports of the monitoring referred to in point (4) are transmitted by authorisation holders directly to the Commission every fifth year, starting at the latest five years after the authorisation. The limit of detection for the analysis shall be at least 0,5 ppt (equivalent to 2,1 ng sulfuryl fluoride/m<sup>3</sup> of tropospheric air).'</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>