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and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto (Text with EEA relevance) (repealed)

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(Text with EEA relevance) (repealed)

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 Annex I, IA or IB to Directive 98/8/EC. That list includes sulfuryl fluoride.
- (2) Commission Directive 2006/140/EC⁽³⁾ 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 the Standing Committee on Biocidal Products on 20 February 2009, in an assessment report.
- (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.
- (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		n IUPAC	Minimu			e Expiry	Product	
	Name	Nameld	e ntificty tio		for	date of	type	provision
		Number		inclusion		ncienclusion		
			active		with			
			substanc	e	Article			
			in the		16(3)			
			biocidal		(except			
			product		for			
			as		products			
			placed		containi	ng		
			on the		more			
			market		than			
					one			
					active			
					substanc	e,		
					for			
					which			
					the			
					deadline			
					to			
					comply			
					with			
					Article			
					16(3)			
					shall			
					be the			
					one			
					set out			
					in the			
					last			
					of the			
					inclusior	1		
					decisions	5		
					relating			
					to its			
					active			
					substanc	es)		
			'994 g/	1 July	30 June	30 June	18	Member
				2011	2013	2021	10	States
			kg	2011	2013	2021		
								shall
								ensure
								that
								authorisati
								are
								subject
								to the

a 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

						following	
						condition	IS:
							Products
							shall
							only
							be
							sold
							to
							and
							used
							by
							professionals
							trained
							to
							use
							them.
							Appropriate
							measures
							to
							protect
							fumigators
							and
							bystanders
							during
							fumigation
							and
							venting
							of
							treated
							buildings
							or
							other
							enclosures
							must
							be
							taken.
							Labels
							and/
							or
							safety-
							data
							sheets
							of
							products
							shall
							indicate
							that,
							prior
							to
							fumigation
							of
of the comm	on principles c	of Annex VI, th	ne content and	conclusions of	assessment rej	ports are	

a 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

									any
									enclosure,
									all
									food
									items
									must
									be
									removed.
								(4)	Concentrations
									of
									sulfuryl
									fluoride
									in
									remote
									tropospheric
									air
									are
									monitored.
								(5)	Member
								(5)	
									States
									shall
									also
									ensure
									that
									reports
									of
									the
									monitoring
									referred
									to
									in
									point
									(4)
									(4)
									are
									transmitted
									by
									authorisation
									holders
									directly
									to
									the
									Commission
									every
									fifth
									year,
									starting
									at
									the
									latest
									five
									years
For the	implementatio	n of the comm	on principles o	of Annex VI, th	ne content and	conclusions of	f assessment re	ports are	

available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

a

 Stat	tus: This is the c	original versio	n (as it was ori	ginally adopted).	•	
						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^3
						of
						tropospheric
						air).'

7

Commission Directive 2009/84/EC of 28 July 2009 amending Directive 98/8/EC of the European...

a 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

- (**1**) OJ L 123, 24.4.1998, p. 1.
- (**2**) OJ L 325, 11.12.2007, p. 3.
- (**3**) OJ L 414, 30.12.2006, p. 78.