

## DIRECTIVES

## COMMISSION DIRECTIVE 2008/81/EC

of 29 July 2008

**amending Directive 98/8/EC of the European Parliament and of the Council to include difenacoum 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<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 difenacoum.
- (2) Pursuant to Regulation (EC) No 1451/2007, difenacoum 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) Finland was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 21 March 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 29 November 2007, in an assessment report.
- (5) The review of difenacoum 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 examinations made that biocidal products used as rodenticides and containing difenacoum may be expected not to present a risk to humans except for accidental incidents with children. Regarding non-target animals and the environment a risk has been identified. However, the target rodents are vermin and thus constitute a danger to public health. Moreover, it has not yet been established that adequate alternatives to difenacoum exist, which are both equally effective and less damaging to the environment. It is therefore justified to include difenacoum in Annex I for a limited period, in order to ensure that in all Member States authorisations for biocidal products used as rodenticides and containing difenacoum can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.
- (7) In the light of the findings of the assessment report, it is appropriate to require that specific risk mitigation measures are applied at product authorisation level to products containing difenacoum and used as rodenticides. Such measures should be aimed at limiting the risk of primary and secondary exposure of humans and non-target animals as well as the long-term effects of the substance on the environment.
- (8) Because of the identified risks and its characteristics, which render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate difenacoum should be included in Annex I for five years only and should be made subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in Annex I is renewed.
- (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 difenacoum and also to facilitate the proper operation of the biocidal products market in general.

<sup>(1)</sup> 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).

<sup>(2)</sup> 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 difenacoum 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 April 2010.

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, 29 July 2008.

*For the Commission*

Stavros DIMAS

*Member of the Commission*

## ANNEX

The following entry 'No 9' 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 (*)
'9	Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4- tetrahydro-1-naphthyl)-4- hydroxycoumarin EC No: 259-978-4 CAS No: 56073-07-5	960 g/kg	1 April 2010	31 March 2012	31 March 2015	14	<p>In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised.</p> <p>(2) Products shall contain an aversive agent and, where appropriate, a dye.</p> <p>(3) Products shall not be used as tracking powder.</p> <p>(4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.'</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>