# COMMISSION DIRECTIVE 2009/150/EC

## of 27 November 2009

## amending Directive 98/8/EC of the European Parliament and of the Council to include flocoumafen 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 [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 flocoumafen.

(2) Pursuant to Regulation (EC) No 1451/2007, flocoumafen 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) The Netherlands was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 4 October 2007 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 15 May 2009, in an assessment report.

(5) It appears from the examinations made that biocidal products used as rodenticides and containing flocoumafen may be expected not to present a risk to humans except for accidental incidents with children. A risk has been identified regarding non-target animals. However, flocoumafen is for the time being considered essential for reasons of public health and hygiene. It is therefore justified to include flocoumafen in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as rodenticides and containing flocoumafen can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) 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 flocoumafen 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. To this end, certain constraints such as the maximum concentration, the prohibition on marketing the active substance in products which are not ready to use and the use of aversive agents should be imposed across the board, while other conditions should be imposed by the Member States on a case-by-case basis.

(7) In view 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, flocoumafen 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.

(8) 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 flocoumafen and also to facilitate the proper operation of the biocidal products market in general.

(9) 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.

(10) 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 flocoumafen to ensure that they comply with Directive 98/8/EC.

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.

(11) Directive 98/8/EC should therefore be amended accordingly.

(12) 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 September 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 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, 27 November 2009.

*For the Commission*

Stavros DIMAS

*Member of the Commission*

*ANNEX*

The following entry 'No 31' 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 (*) |
|---|---|---|---|---|---|---|---|---|
| '31 | Flocoumafen | 4-hydroxy-3-[(1*RS*,3*RS*;1*RS*,3*RS*)-1,2,3,4-tetrahydro-3-[4-(4-trifluoromethyl-benzyloxy)phenyl]-1-naphthyl]coumarin<br>EC No 421-960-0<br>CAS No 90035-08-8 | 955 g/kg | 1 October 2011 | 30 September 2013 | 30 September 2016 | 14 | 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.<br>Member States shall ensure that authorisations are subject to the following conditions:<br>1. The nominal concentration of the active substance in products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised.<br>2. Products shall contain an aversive agent and, where appropriate, a dye.<br>3. Products shall not be used as tracking powder.<br>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. Those 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.' |

(*) 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