

COMMISSION DIRECTIVE 2012/15/EU

of 8 May 2012

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 margosa extract.

(2) Pursuant to Regulation (EC) No 1451/2007, margosa extract has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive. The evaluation concerned margosa extract from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents. Any possible other substances complying with the definition of margosa extract in the list of active substances to be assessed in Regulation (EC) No 1451/2007 have not been evaluated, and should therefore not be included in Annex I to Directive 98/8/EC based on this evaluation.

(3) Germany was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 26 November 2009 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 9 December 2011, in an assessment report.

(5) It appears from the evaluations that biocidal products used as insecticides, acaricides and products to control other arthropods and containing margosa extract may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include margosa extract in Annex I to that Directive.

(6) Not all potential uses have been evaluated at Union level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels.

(7) In view of the risks identified for surface water, sediment and non-target arthropods, it is appropriate to require that product authorisations are subject to appropriate risk mitigation measures.

(8) The provisions of this Directive should be applied at the same time in all Member States in order to ensure equal treatment on the Union market of biocidal products containing the active substance margosa extract 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 to Directive 98/8/EC, in order to permit Member States and 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.

(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,

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

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 April 2013 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 May 2014.

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, 8 May 2012.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the following entry is added:

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 (*)
'55	<i>margosa extract</i>	IUPAC name: Not applicable CAS-No: 84696-25-3 EC No: 283-644-7 Description: <i>margosa extract</i> from the kernels of <i>Azadirachta</i> <i>indica</i> extracted with water and further processed with organic solvents	1 000 g/kg	1 May 2014	30 April 2016	30 April 2024	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to appropriate risk mitigation measures for the protection of surface water, sediment and non-target arthropods.'

(*) 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>