

DIRECTIVES

COMMISSION DIRECTIVE 2010/71/EU

of 4 November 2010

amending Directive 98/8/EC of the European Parliament and of the Council to include metofluthrin 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 Article 11(4) thereof,

Whereas:

- (1) The United Kingdom received on 23 December 2005 an application from Sumitomo Chemical (UK) Plc, in accordance with Article 11(1) of Directive 98/8/EC, for the inclusion of the active substance metofluthrin in its Annex I for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to Directive 98/8/EC. Metofluthrin was not on the market on the date referred to in Article 34(1) of Directive 98/8/EC as an active substance of a biocidal product.
- (2) After carrying out an evaluation, the United Kingdom submitted its evaluation report, together with a recommendation, to the Commission on 19 June 2008.
- (3) The report was reviewed by the Member States and the Commission within the Standing Committee on Biocidal Products on 27 May 2010, and the findings of the review were incorporated in an assessment report.
- (4) It appears from the examinations made that biocidal products used as insecticides, acaricides and products to control other arthropods and containing metofluthrin may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include metofluthrin in Annex I to that Directive.
- (5) Not all potential uses have been evaluated at the European level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to the compartments and populations that have not been representatively addressed in the European 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.

- (6) 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 metofluthrin and to facilitate the proper operation of the biocidal market in general.
- (7) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive.
- (8) Directive 98/8/EC should therefore be amended accordingly.
- (9) 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 30 April 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 May 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.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

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, 4 November 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the following entry for the substance metofluthrin 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 (*)
36	Metofluthrin	RTZ isomer: 2,3,5,6-tetrafluoro-4-(methoxy- methyl)benzyl-(1R,3R)-2,2-dimethyl-3- (Z)-(prop-1-enyl)cyclopropanecarboxylate EC No: n.a. CAS No: 240494-71-7 Sum of all isomers: 2,3,5,6-tetrafluoro-4-(methoxy- methyl)benzyl (EZ)-(1RS,3RS;1SR,3SR)- 2,2-dimethyl-3-prop-1-enylcyclopropane- carboxylate EC No: n.a. CAS No: 240494-70-6	The active substance shall comply with both the following minimum purities: RTZ isomer: 754 g/kg Sum of all isomers: 930 g/kg	1 May 2011	Not applicable	30 April 2021	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and popu- lations that have not been represen- tatively addressed in the European level risk assessment.

(*) 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>