COMMISSION DIRECTIVE 2011/11/EU

of 8 February 2011

amending Directive 98/8/EC of the European Parliament and of the Council to include (Z,E)-tetradeca-9,12-dienyl acetate as an active substance in Annexes I and IA 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 (Z,E)-tetradeca-9,12-dienyl acetate.

(2) Pursuant to Regulation (EC) No 1451/2007, (Z,E)-tetradeca-9,12-dienyl acetate has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 19, repellents and attractants, as defined in Annex V to that Directive.

(3) Austria was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 23 February 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 24 September 2010, in an assessment report.

(5) It appears from the evaluations that biocidal products used as attractants and containing (Z,E)-tetradeca-9,12-dienyl acetate may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include (Z,E)-tetradeca-9,12-dienyl acetate in Annex I to that Directive.

(6) It also appears from the evaluations that biocidal products used as attractants and containing (Z,E)-tetradeca-9,12-dienyl acetate may be expected to present only low risk to humans, animals and the environment and to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, in particular with regard to the use which was examined and detailed in the assessment report, i.e. in traps for indoor use containing a maximum of 2 mg of the active substance. It is therefore appropriate to include (Z,E)-tetradeca-9,12-dienyl acetate in Annex IA to Directive 98/8/EC.

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

(8) In the light of the assumptions made during the evaluation, it is appropriate to require that (Z,E)-tetradeca-9,12-dienyl acetate is not applied where food or feed is stored unless the food or feed packaging is closed or re-closed. Labels should therefore indicate that biocidal products containing (Z,E)-tetradeca-9,12-dienyl acetate are not to be used in spaces where un-packaged food or feed is kept.

(9) It is important that the provisions of this Directive be applied simultaneously in all Member States in order to ensure equal treatment of biocidal products on the market containing the active substance (Z,E)-tetradeca-9,12-dienyl acetate 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 to Directive 98/8/EC 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.

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

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

(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

Annexes I and IA to Directive 98/8/EC are amended in accordance with the Annex to this Directive.

Article 2

Transposition

1. Member States shall adopt and publish, by 31 January 2012 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2013.

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, 8 February 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

(1) 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 (*)
'39	(Z,E)-tetradeca-9, 12-dienyl acetate	(9Z,12E)-Tetradeca-9, 12-dien-1-yl acetate EC No: n.a. CAS No: 30507-70-1	977 g/kg	1 February 2013	31 January 2015	31 January 2023	19	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 environmental compartments and populations that have not been representatively addressed in Union level risk assessment. Member States shall ensure that authorisations are subject to the following condition: — Labels for biocidal products containing (Z,E)-tetradeca-9,12-dienyl acetate shall indicate that those products shall not be used in spaces where un-packaged food or feed is kept.',

(*) 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

(2) In Annex IA 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 (*)
'2	(Z,E)-tetradeca-9, 12-dienyl acetate	(9Z,12E)-tetradeca-9, 12-dien-1-yl acetate EC No: n.a. CAS No: 30507-70-1	977 g/kg	1 February 2013	31 January 2015	31 January 2023	19	Member States shall ensure that registrations are subject to the following conditions: — Only for traps containing a maximum of 2 mg of (Z,E)-Tetradeca-9,12-dienyl acetate for indoor use, — Labels for biocidal products containing (Z,E)-tetradeca-9,12-dienyl acetate shall indicate that those products shall only be used indoors, and shall not be used in spaces where un-packaged food or feed is kept.',

(*) 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