DIRECTIVES

COMMISSION DIRECTIVE 2013/41/EU

of 18 July 2013

amending Directive 98/8/EC of the European Parliament and of the Council to include 1R-trans phenothrin 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 d-phenothrin.

(2) Pursuant to Regulation (EC) No 1451/2007, d-phenothrin 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.

(3) The data submitted for the purpse of the evaluation allowed conclusions to be drawn only regarding a certain form of d-phenothrin, i.e. a substance containing at least 89 % w/w of 1R-trans phenothrin. In accordance with current practice for naming of substances [3], that substance should be considered as mono-constituent and named 1R-trans phenothrin. The evaluation did not allow conclusions to be drawn regarding any other substance complying with the definition of d-phenothrin in the abovementioned list of active substances in Regulation (EC) No 1451/2007. Therefore, only 1R-trans phenothrin should be included in Annex I to Directive 98/8/EC based on the existing evaluation.

(4) Ireland was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 29 July 2010 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(5) 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 1 March 2013, in an assessment report.

(6) It appears from the evaluations that biocidal products used as insecticides, acaricides and products to control other arthropods and containing 1R-trans phenothrin may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include 1R-trans phenothrin for use in product-type 18 in Annex I to that Directive.

(7) Not all potential uses and exposure scenarios have been evaluated at Union level. It is therefore appropriate to require 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.

(8) In view of the risks identified for human health, it is appropriate to require that safe operational procedures are established for ultra low volume (ULV) application, and that products are used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means.

(9) In view of the risks identified for the environment, it is appropriate to require that product authorisations are subject to appropriate risk mitigation measures for the protection of honey bees.

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.
[3] See in particular *Guidance for identification and naming of substances under REACH and CLP*, ECHA-11-G-10.1-EN, p. 19 f.

(10) For products containing 1R-trans phenothrin that may lead to residues in food or feed, Member States should verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council [1] or Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC [2], and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

(11) The provisions of this Directive should be applied simultaneously in all Member States in order to ensure equal treatment on the Union market of biocidal products of product-type 18 containing the active substance 1R-trans phenothrin and also to facilitate the proper operation of the biocidal products market in general.

(12) 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.

(13) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.

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

(15) In accordance with the Joint Political Declaration of Member States and the Commission of 28 September 2011 on explanatory documents [3], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.

(16) 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 31 August 2014 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.

They shall apply those provisions from 1 September 2015.

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, 18 July 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 152, 16.6.2009, p. 11.
[2] OJ L 70, 16.3.2005, p. 1.
[3] OJ C 369, 17.12.2011, p. 14.

ANNEX

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

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
'66	1R-trans phenothrin	1R-trans phenothrin IUPAC name: 3-phenoxybenzyl(1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate EC No: 247-431-2 CAS No: 26046-85-5 Sum of all isomers: IUPAC name: (3-Phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropane-1-carboxylate EC No: 247-404-5 CAS No: 26002-80-2	89 % w/w of 1R-trans phenothrin 95,5 % w/w for the sum of all isomers	1 September 2015	31August 2017	31 August 2025	18	The Union level risk assessment did not address all potential uses and exposure scenarios. 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 the following conditions: (1) safe operational procedures shall be established for ultra low volume (ULV) application, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means; (2) for products containing 1R-trans phenothrin that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded; (3) where appropriate, measures shall be taken to protect honey bees.'

(*) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated substance.

(**) For products containing more than one active substance covered by Article 16(2), the deadline for compliance with Article 16(3) is that of the last of its active substances to be included in this Annex. For products for which the first authorisation has been granted later than 120 days before the deadline for compliance with Article 16(3) and a complete application has been submitted for mutual recognition in accordance with Article 4(1) within 60 days of the granting of the first authorisation, the deadline for compliance with Article 16(3) in relation to that application is extended to 120 days after the date of reception of the complete application for mutual recognition. For products for which a Member State has proposed to derogate from mutual recognition in accordance with Article 4(4), the deadline for compliance with Article 16(3) is extended to 30 days after the date of the Commission Decision adopted in accordance with the second subparagraph of Article 4(4).

(***) 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