Commission Directive 2012/41/EU of 26 November 2012 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance nonanoic acid to product type 2 (Text with EEA relevance)

COMMISSION DIRECTIVE 2012/41/EU

of 26 November 2012

amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance nonanoic acid to product type 2

(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 nonanoic acid.

(2) Commission Directive 2011/13/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include nonanoic acid as an active substance in Annex I thereto[(3)] included nonanoic acid as an active substance in Annex I to Directive 98/8/EC for use in product type 19, repellents and attractants, as defined in Annex V to Directive 98/8/EC.

(3) Pursuant to Regulation (EC) No 1451/2007, nonanoic acid has now been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product type 2, private area and public health area disinfectants and other biocidal products, as defined in Annex V to that Directive.

(4) Austria was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 6 August 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 25 May 2012, in an assessment report.

(6) It appears from the evaluations that biocidal products used as private area and public health area disinfectants and other biocidal products as defined in Annex V to Directive 98/8/EC and containing nonanoic acid may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to extend the inclusion of nonanoic acid in Annex I to that Directive to product type 2.

(7) Not all potential uses 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 irritant properties of the substance, it is appropriate to require that exposure during non-professional use is minimised through the design of the packaging, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means.

(9) 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 2 containing the active substance nonanoic acid 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 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.

(13) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011[(4)], 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.

(14) 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 2013 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 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, 26 November 2012.

For the Commission

The President

José Manuel BARROSO

ANNEX

The following is added to entry ‘No 41’ in Annex I to Directive 98/8/EC:

No	**Common Name**	**IUPAC Name**	**Identity 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**[a]
					‘1 October 2014	30 September 2016	30 September 2024	2	When assessing the application for authorisation of a product in

a 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

								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 of products for non-professional use are subject to the packaging

a 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

								being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means.’

a 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

(**1**) OJ L 123, 24.4.1998, p. 1.

(**2**) OJ L 325, 11.12.2007, p. 3.

(**3**) OJ L 34, 9.2.2011, p. 52.

(**4**) OJ C 369, 17.12.2011, p. 14.