Commission Directive 2013/7/EU of 21 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include Alkyl (C12-16) dimethylbenzyl ammonium chloride as an active substance in Annex I thereto (Text with EEA relevance)

COMMISSION DIRECTIVE 2013/7/EU

of 21 February 2013

amending Directive 98/8/EC of the European Parliament and of the Council to include Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride 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 Quaternary ammonium compounds, benzyl-C_{12-16}-alkyldimethyl, chlorides, which is synonymous with Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride.

(2) Pursuant to Regulation (EC) No 1451/2007, Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 8, wood preservatives, as defined in Annex V to that Directive.

(3) Italy was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 14 August 2007 in accordance with Article 10(5) and (7) of Commission Regulation (EC) No 2032/2003 of 4 November 2003 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, and amending Regulation (EC) No 1896/2000[(3)].

(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 21 September 2012, in an assessment report.

(5) It appears from the evaluations that biocidal products used as wood preservatives and containing Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride for use in product type 8 in Annex I to that Directive.

(6) Not all potential uses and exposure scenarios have been evaluated at Union level. For example, neither use by non-professionals, nor exposure of food or feeding stuff were assessed. 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.

(7) In view of the risks identified for human health, it is appropriate to require that safe operational procedures are established, that products are used with appropriate personal protective equipment, and that products are not applied on wood with which children may enter in direct contact, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.

(8) In view of the risks identified for the environment, it is appropriate to require that industrial or professional application is conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber is stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of products used as wood preservatives and containing Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride are collected for reuse or disposal.

(9) Unacceptable risks for the environment were identified for situations where wood treated with Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride was continually exposed to the weather or subject to frequent wetting (use class 3 as defined by OECD[(4)]), was used for outdoor constructions near or above water (the 'bridge' scenario in use class 3, as defined by OECD[(5)]) or was in contact with fresh water (use class 4b as defined by OECD[(6)]). It is therefore appropriate to require that products are not authorised for the treatment of wood intended for those uses, unless data is submitted demonstrating that the product will meet the requirements of both Article 5 of and Annex VI to Directive 98/8/EC, if necessary by the application of appropriate risk mitigation measures.

(10) 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 8 containing the active substance Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride and also to facilitate the proper operation of the biocidal products market in general.

(11) 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.

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

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

(14) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents[7], 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.

(15) 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 January 2014 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 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, 21 February 2013.

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 degree of purity of the active substance[a]	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies[b]	Expiry date of inclusion	Product type	Specific provisions[c]
'64	Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride; C_{12-16}-ADBAC	IUPAC name: Not applicable EC No: 270-325-2 CAS No: 68424-85-1	Dry weight: 940 g/kg	1 February 2015	31 January 2017	31 January 2025	8	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals and exposure of food or feed, were excluded. 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) For industrial

								or professional users safe operational procedures shall be established, 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)	Products shall not be used for treatment of wood with which

children may enter in direct contact, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.

(3) Labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable

								hard standing with bunding, and that freshly treated timber shall be stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
							(4)	Products shall not be authorised for treatment of wood that

								will be in contact with fresh water or used for outdoor constructions near or above water, continually exposed to the weather or subject to frequentwetting, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate mitigation measures.’

a	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.
b	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).
c	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 307, 24.11.2003, p. 1.

(**4**) *OECD Series on Emission Scenario Documents*, Number 2, 'Emission Scenario Document for Wood Preservatives, part 2', p. 64.

(**5**) Ibid.

(**6**) Ibid.

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