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EUROPEAN COMMISSION

Brussels, xxx
C(2010) yyy final
D008217/01
CA-May10-Doc.3.4

Draft

COMMISSION DIRECTIVE ../.../EU

of [...]

amending Directive 98/8/EC of the European Parliament and of the Council to include creosote as an active substance in Annex I thereto

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(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 market¹, 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 market² 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 creosote.
- (2) Pursuant to Regulation (EC) No 1451/2007, creosote 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) Sweden was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 31 October 2007 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.
- (4) A stakeholder consultation was launched on 30 April 2008. The outcome of the consultation was made public and discussed in the 30th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market. Most stakeholders considered that the use of creosote is vital in the areas of railway sleepers and poles in electricity transmission and telecommunications networks, and that a phasing out of creosote would have major practical and economical disadvantages. Many

¹ OJ L 123, 24.4.1998, p. 1.

² OJ L 325, 11.12.2007, p. 3.

stakeholders also warned that alternative technologies for these applications do not necessarily have a more favourable environmental impact.

- (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 27 May 2010, in an assessment report.
- (6) It appears from the examinations made that biocidal products used as wood preservatives and containing creosote may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include creosote in Annex I to that Directive.
- (7) Creosote is considered to be a non-threshold carcinogen and is classified as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006³. The substance, which is a mixture of hundreds of compounds, also contains constituents that are persistent, bioaccumulative and toxic (PBT). Creosote should therefore be included in Annex I for five years only and should be made subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in Annex I is renewed.
- (8) Not all potential uses of wood treated with creosote have been evaluated at the EU level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU 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.
- (9) Entry number 31 in Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC⁴ regulates the conditions for the use of creosote in wood treatment and for the placing on the market of wood treated with creosote. It is appropriate to require that product authorisations for biocidal products containing creosote are subject to compliance with those restrictions. Through Commission Decisions 1999/832/EC⁵, 2002/59/EC⁶, and 2002/884/EC⁷, the Commission has authorised the Netherlands to maintain existing and more stringent national provisions notified under the EC Treaty. By virtue of Article 67(3) of Regulation (EC) No 1907/2006, and as stated in the Communication from the Commission pursuant to

³ OJ L 353, 31.12.2008, p. 1.

⁴ OJ L 396, 30.12.2006, p. 1.

⁵ OJ L 329, 22.12.1999, p. 25.

⁶ OJ L 23, 25.1.2002, p. 37.

⁷ OJ L 308, 9.11.2002, p. 30.

Article 67(3) of Regulation (EC) No 1907/2006⁸, these restrictions may be maintained until 1 June 2013. They include a prohibition of the use of creosote-treated wood for applications involving contact with surface water or groundwater.

- (10) Unacceptable risks were identified during the in-service use of treated wood permanently exposed to salt water (use class 5 as defined by OECD⁹), including the scenario wharf. Unacceptable risks were also identified during in-service use of treated wood in contact with the ground or fresh water and thus permanently exposed to wetting (use class 4 as defined by OECD¹⁰), including the scenarios transmission pole, fence post, jetty in lake and sheet pilings in waterway. Risk assessments were also carried out for various scenarios representing in-service use of treated wood not under cover and not in contact with the ground, either continually exposed to the weather or protected from the weather but subject to wetting (use class 3 as defined by OECD¹¹). Within this use, unacceptable risks were identified for the specific scenario bridge over pond (on a foundation), but not for the scenarios house (on a foundation), fence (except posts in contact with the ground), railway sleepers (on a bed of ballast), or noise barriers (on a foundation). Due to the combination of these risks and the specific characteristics of creosote, in particular the non-threshold carcinogenicity and the PBT nature of some of its compounds, products containing creosote and used as wood preservatives should not be authorised for those uses where unacceptable risks were identified, unless data demonstrating that the products can be used without unacceptable risks for the environment is submitted in order to amend Annex I to this directive.
- (11) In the light of the findings of the assessment report, it is appropriate to require that risk mitigation measures are applied at product authorisation level to products containing creosote and used as wood preservatives. Due to the carcinogenic properties of creosote, it is appropriate to require that product authorisations for biocidal products containing the substance are subject to the requirement that all possible measures in accordance with Regulation (EC) No 1907/2006 and Directive 2004/37/EC be applied to protect workers, including down-stream users, from exposure during treatment and handling of treated wood. In the view of the risks identified for the soil and aquatic compartments, appropriate measures should be taken to protect those compartments. Instructions should therefore be provided to indicate that treated timber must be stored after treatment under shelter and/or on impermeable hard standing and that any losses must be collected for reuse or disposal.
- (12) 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 creosote and also to facilitate the proper operation of the biocidal products market in general.
- (13) A reasonable period should be allowed to elapse before an active substance is included in Annex I 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

⁸ OJ C 130, 9.6.2009 EN, p. 3.

⁹ OECD series on emission scenario documents, Number 2, Emission Scenario Document for Wood Preservatives, part 2, p. 64.

¹⁰ Ibid.

¹¹ Ibid.

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.

- (14) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.
- (15) Directive 98/8/EC should therefore be amended accordingly.
- (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

Transposition

1. Member States shall adopt and publish, by 31 October 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 November 2012.

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,

*For the Commission
The President*

José Manuel BARROSO

ANNEX

The following entry for the substance creosote is inserted in Annex I to Directive 98/8/EC:

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 (*)
(**) [OPOCE : please insert substance number]	Creosote	Creosote EC No: 232-287-5 CAS No: 8001-58-9	Grade B or Grade C creosote as specified in European Standard EN 13991:2003	1 November 2012	31 October 2014	31 October 2017	8	<p>The active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed.</p> <p>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, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the EU level risk assessment.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(1) Creosote may only be used under the conditions mentioned in point 2 of the second column of entry No 31 in Annex XVII to Regulation (EC) No 1907/2006.</p> <p>(2) Products containing creosote and used as wood preservatives shall not be authorised for the treatment of wood for those uses referred to in point 3 of the second column of entry No 31 in Annex XVII to Regulation (EC) No 1907/2006.</p> <p>(3) Without prejudice to paragraph 2, products containing creosote and used as wood preservatives shall not be authorised for the treatment of</p>

No	Comm on 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 (*)
								<ul style="list-style-type: none"> • wood permanently exposed to salt water • wood in contact with the ground or fresh water and thus permanently exposed to wetting, or • wood used for the specific scenario bridge over pond. <p>(4) Appropriate risk mitigation measures must be taken to protect workers, including down-stream users, from exposure during treatment and handling of treated wood in compliance with Regulation (EC) No 1907/2006 and Directive 2004/37/EC.</p> <p>(5) Appropriate risk mitigation measures must be taken to protect the soil and aquatic compartments. In particular, labels and/or safety data sheets of products authorised shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for re-use or disposal.</p> <ul style="list-style-type: none"> •

(*) 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>