

DIRECTIVES

COMMISSION DIRECTIVE 2011/71/EU

of 26 July 2011

amending Directive 98/8/EC of the European Parliament and of the Council to include creosote 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 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. It follows from the report that the evaluation only covers Grade B and Grade C creosote as specified in European Standard EN 13991:2003.

(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 Member States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market.

(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 17 December 2010 in an assessment report.

(6) It appears from the assessment report that wood preservatives containing creosote may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, when applied on wood in some of the scenarios evaluated. Furthermore, there were strong indications in the abovementioned stakeholder consultation that there are considerable socioeconomic benefits of using creosote in certain applications. Life cycle analyses submitted and published in the context of the consultation have suggested that, in certain cases, no appropriate alternatives to creosote exist, which are less damaging to the environment. It is therefore appropriate to include creosote in Annex I.

(7) However, for certain wood use scenarios presented in the assessment report, unacceptable risks for the environment were identified in the risk assessment.

(8) Furthermore, 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 1907/2006 ⁽³⁾.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

⁽³⁾ OJ L 353, 31.12.2008, p. 1.

- (9) Creosote, which is a mixture of hundreds of compounds, contains mainly polycyclic aromatic hydrocarbons (PAHs). Some of these have been considered by the Committee for Risk Assessment of the European Chemicals Agency as persistent, bioaccumulative and toxic (PBT; anthracene⁽¹⁾) or very persistent and very bioaccumulative (vPvB; fluoranthene, phenanthrene and pyrene⁽²⁾) in accordance with the criteria set out in Annex XIII 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/EC⁽³⁾.
- (10) PAHs are listed as substances subject to release reduction provisions in Annex III to the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (POPs) and in Annex III to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC⁽⁴⁾.
- (11) A guidance document adopted by Decision 2009/4 of the Executive Body to the 1979 Convention on Long-Range Transboundary Air Pollution lists best available techniques to control emissions of POPs from major stationary sources. Part E of Section V of that guidance document specifically addresses emissions of PAHs associated with the preservation of wood using coal tar derived products containing PAHs, such as creosote. The techniques relate to impregnation, storage, handling and use of the wood, and include using alternatives that minimise reliance on PAH-based products. It also recommends best available techniques to be applied if treated wood is burned.
- (12) According to the second subparagraph of Article 6(2) of Regulation (EC) No 850/2004 read in conjunction with Annex III to that Regulation, Member States are required to adopt action plans including measures to promote the development and, where they deem appropriate, require the use of substitute or modified materials, products and processes to prevent the formation and release of PAHs. Pursuant to Article 3(3) of Regulation (EC) No 850/2004, Member States and the Commission shall, within the assessment and authorisation schemes for existing chemicals and pesticides under the relevant Union legislation, take appropriate measures to control existing chemicals and pesticides which exhibit characteristics of POPs.
- (13) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy⁽⁵⁾ identifies PAHs as priority hazardous substances, from which pollution of surface waters through discharge, emission or loss must cease or be phased out.
- (14) It is therefore appropriate to limit the inclusion to 5 years only and to make it 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.
- (15) Furthermore, biocidal products containing creosote should be authorised only for applications where, all local and other circumstances taken into account, no appropriate alternatives are available. When an application is made for product authorisation or mutual recognition, the Member State receiving the application should therefore ask the applicant for an analysis regarding the technical and economic feasibility of substitution. Based on this analysis and any other information available to it, an authorising Member State should justify their conclusion that there are no appropriate alternatives and report the justification to the Commission at a stage when product authorisations can be expected to have been granted. In this context, to increase transparency, it is appropriate to require Member States to include in the report their information on how the development of alternatives is promoted in accordance with Article 6(2) of Regulation (EC) No 850/2004, either directly or by reference to a published action plan. To further increase transparency, it is appropriate to ensure that this information is made public.
- (16) Not all potential uses of wood treated with creosote have been evaluated at the Union 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 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.
- (17) Entry number 31 in Annex XVII to Regulation (EC) No 1907/2006 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

(1) Member State Committee support document for identification of anthracene as a substance of very high concern, adopted on 8 October 2008.

(2) Member State Committee support document for identification of anthracene oil, anthracene low as a substance of very high concern because of its CMR, PBT and vPvB properties, adopted on 4 December 2009.

(3) OJ L 396, 30.12.2006, p. 1.

(4) OJ L 158, 30.4.2004, p. 7.

(5) OJ L 327, 22.12.2000, p. 1.

require that product authorisations for biocidal products containing creosote are subject to compliance with those restrictions. Through Commission Decisions 1999/832/EC of 26 October 1999 concerning the national provisions notified by the Kingdom of the Netherlands concerning the limitations of the marketing and use of creosote ⁽¹⁾, 2002/59/EC of 23 January 2002 concerning draft national provisions notified by the Kingdom of the Netherlands under Article 95(5) of the EC Treaty on limitations on the marketing and use of creosote-treated wood ⁽²⁾, and 2002/884/EC of 31 October 2002 concerning national provisions on restrictions on the marketing and use of creosote-treated wood notified by the Netherlands under Article 95(4) and (5) of the EC Treaty ⁽³⁾, 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 Article 67(3) of Regulation (EC) No 1907/2006 ⁽⁴⁾, 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.

- (18) 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 of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) ⁽⁵⁾ 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 freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, and that any losses must be collected for reuse or disposal.

- (19) 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.

⁽¹⁾ OJ L 329, 22.12.1999, p. 25.

⁽²⁾ OJ L 23, 25.1.2002, p. 37.

⁽³⁾ OJ L 308, 9.11.2002, p. 30.

⁽⁴⁾ OJ C 130, 9.6.2009, p. 3.

⁽⁵⁾ OJ L 158, 30.4.2004, p. 50.

- (20) 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 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.
- (21) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.
- (22) Directive 98/8/EC should therefore be amended accordingly.
- (23) The Committee established by Article 28(1) of Directive 98/8/EC has not delivered an opinion on the measures provided for in this Directive and the Commission therefore submitted to the Council a proposal relating to the measures and forwarded it to the European Parliament. The Council did not act within the 2-month period provided for by Article 5a of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽⁶⁾, and the Commission therefore submitted the proposal to the European Parliament without delay. The European Parliament did not oppose the measure within 4 months from the abovementioned forwarding,

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 30 April 2012 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 May 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.

⁽⁶⁾ OJ L 184, 17.7.1999, p. 23.

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, 26 July 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

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

45	Creosote	<p>Creosote</p> <p>EC No: 232-287-5</p> <p>CAS No: 8001-58-9</p>	<p>Grade B or Grade C creosote as specified in European Standard EN 13991:2003</p>	1 May 2013	30 April 2015	30 April 2018	8	<p>Biocidal products containing creosote may only be authorised for uses where the authorising Member State, based on an analysis regarding the technical and economic feasibility of substitution which it shall request from the applicant, as well as on any other information available to it, concludes that no appropriate alternatives are available. Those Member States authorising such products in their territory shall no later than 31 July 2016 submit a report to the Commission justifying their conclusion that there are no appropriate alternatives and indicating how the development of alternatives is promoted. The Commission will make these reports publicly available.</p> <p>The active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) 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, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed at the Union 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 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/EC ⁽¹⁾.</p> <p>(2) Creosote shall not be used for the treatment of wood intended 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>
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								<p>(3) Appropriate risk mitigation measures shall 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 of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) ⁽²⁾.</p> <p>(4) Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.</p>
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⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ OJ L 158, 30.4.2004, p. 50.