

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1950

of 14 October 2022

renewing the approval of creosote as an active substance for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 14(4), point (a), thereof,

Whereas:

- (1) The active substance creosote was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products of product-type 8 and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the conditions set out in Annex I to that Directive.
- (2) On 27 October 2016, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of creosote for use in biocidal products of product-type 8. That application was evaluated by the competent authority of the United Kingdom as the evaluating competent authority.
- (3) On 16 September 2019, the evaluating competent authority submitted a recommendation on the renewal of the approval of creosote to the European Chemicals Agency ('the Agency'). Due to the withdrawal of the United Kingdom from the Union, the competent authority of Poland has taken over the role of evaluating competent authority regarding the application on 30 January 2020.
- (4) In accordance with Article 14(3) of Regulation (EU) No 528/2012, on 4 December 2020 the Agency adopted an opinion ⁽³⁾ formulated by its Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ 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 (OJ L 123, 24.4.1998, p. 1).

⁽³⁾ Biocidal Products Committee (BPC) opinion on the application for renewal of the approval of the active substance: creosote, Product type: 8, ECHA/BPC/274/2020, adopted on 4 December 2020.

- (5) According to that opinion, creosote is classified as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁴⁾ and meets the criteria for being a persistent, bioaccumulative and toxic (PBT) substance and a very persistent and very bioaccumulative (vPvB) substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽⁵⁾. Creosote therefore meets the exclusion criteria set out in Article 5(1), points (a) and (e), of Regulation (EU) No 528/2012.
- (6) Pursuant to Article 12(1) of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed if the active substance still meets at least one of the conditions set out in Article 5(2) of that Regulation.
- (7) The Commission, with the support of the Agency, carried out a public consultation in order to gather information as to whether the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied.
- (8) The opinion of the Agency and the contributions to the public consultation were discussed with Member States in the Standing Committee on Biocidal Products. Member States were also requested to indicate whether they consider that at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 would be met in their respective territory, and to provide justifications.
- (9) From the information collected and the views expressed by Member States, it appears that creosote and wood treated with creosote are still needed in many Member States for railway sleepers and for utility poles for electricity and telecommunications.
- (10) Wood treated with products containing creosote is used to make wooden railway sleepers for various technical reasons (light weight compared to concrete sleepers and corresponding ease of maintenance, good resilience, high service life expectancy sought for railway infrastructures which are built to last several decades, sustainable material). Wooden railway sleepers have great flexibility in terms of where they can be used (such as inaccessible areas, switching points, tunnels, bridges, small radius curves). Moreover, the railway sleeper use class is a safety-critical application which may be subject to rail infrastructure type approval or certification requirements for reasons related to the safety of people (passengers, train operators, etc.) and railway equipment, namely trains and infrastructures. Good operation of train infrastructures is essential for the proper functioning of society and economic activities. Alternative biocidal products to treat wooden railway sleepers are under development and one product containing a mixture of copper hydroxide, DDA Carbonate and penflufen has recently been authorised in several Member States. However, time is needed to test and have a sufficient return on experience of those alternative products, and to ensure that they can meet the long service life expected of railway sleepers.
- (11) Alternative materials to wood for railway sleepers exist, including concrete, steel or composite materials such as fibre-reinforced foamed urethane, each presenting advantages (for example, similar mechanical properties and durability to creosote-treated wood railway sleepers) and disadvantages (for example, issues of maintenance of certain tracks in inaccessible areas, switching points, tunnels, secondary lines; cost; higher negative environmental footprint than wood; difficulty in track maintenance to mix wooden sleepers with sleepers made from other materials due to the different ballast requirements). A non-renewal of approval of creosote as an active substance for use in biocidal products for the treatment of wood to make railway sleepers would create serious technical and economic impacts on railway infrastructure operators in some Member States where substitution would be technically or economically difficult for the moment.

⁽⁴⁾ 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 (OJ L 353, 31.12.2008, p. 1).

⁽⁵⁾ 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 (OJ L 396, 30.12.2006, p. 1).

- (12) Wood treated with products containing creosote is used to make utility poles for electricity and telecommunications for various technical reasons (for example, light weight compared to concrete poles and corresponding ease of maintenance, good resilience, high service life expectancy sought for electricity and telecommunication infrastructures which are built to last several decades, sustainable material). Alternative biocidal products to treat wooden poles are under development and a product containing a mixture of copper hydroxide, DDA Carbonate and penflufen has recently been authorised in several Member States. Some other biocidal products, based on copper compounds or quaternary ammonium compounds as active substances, have reached the final stage of authorisation procedure. However, time is needed to test and have a sufficient return on experience of those alternative products.
- (13) Alternatives to wood as a material for utility poles exist, including steel, concrete, fibreglass, composite materials or composite barrier sleeves installed around treated wooden utility poles. Each of these alternatives presents advantages (for example, rigidity; invariant physical characteristics; fire retardancy) and disadvantages (for example, the need for further testing; possible shorter service life or other technical concerns; more expensive when compared to wooden poles). Another alternative is the laying of transmission cables underground, in particular in urban and city environments, although this option may become more technically challenging depending on the natural terrain across which the network must traverse (for example, remote areas or mountains), and an installation and maintenance may appear more complex, costly and not feasible in all circumstances. A non-renewal of approval of creosote for use in wooden poles might create an economic impact on electricity and telecommunication infrastructure operators, and problems for the maintenance of certain transmission cables (for example, areas not easily accessible, rapid response in case of serious storms) in some Member States where substitution with other materials or underground transmission cables would be technically or economically difficult for the moment.
- (14) The Agency identified risks for human health arising from the use of biocidal products containing creosote for the treatment of railway sleepers and utility poles for the workers responsible for the treatment of wood, for the pole installers and the electricity pole installers, and for the exposure of the general public. Risk mitigation measures should be implemented to limit the exposure to creosote as far as possible, for example the recourse to mechanical or automated processes to avoid manual handling of treated wood, and the wearing of personal protective equipment by workers, and ensuring that treated wood is not accessible to the general public during storage. Risks for the environment have also been identified as creosote is PBT/vPvB, and risk mitigation measures should be implemented to limit the exposure of the environment to creosote as far as possible, for example providing that industrial application is to be conducted within a contained area or on impermeable hard standing with bunding; that freshly treated timber is to be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water; and that any losses from the application of the product are to be collected for reuse or disposal.
- (15) On the basis of the information collected, it is concluded that the non-approval of creosote as an active substance for use in biocidal products would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance for the treatment of wood used to make railway sleepers and utility poles for electricity and telecommunications. The condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is thus satisfied for those uses.
- (16) It is therefore appropriate to renew the approval of creosote for use in biocidal products of product-type 8, subject to compliance with certain conditions.
- (17) Creosote is a candidate for substitution in accordance with Article 10(1), points (a), (d) and (e), of Regulation (EU) No 528/2012 and therefore the period of renewal should not exceed 7 years, pursuant to Article 10(4) of that Regulation.
- (18) To keep exposure to humans and the environment to a minimum, biocidal products should only be authorised for the treatment by vacuum pressure impregnation of wood in industrial installations to make railway sleepers, or utility poles for electricity or telecommunications. Pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment should include an evaluation as to whether the conditions of Article 5(2) of that Regulation are satisfied. It should be provided that products may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied.

- (19) To ensure that products are only supplied for use in industrial installations, it should be allowed to place products on the market only in packaging of a capacity equal to or greater than 200 litres, and it should not be allowed to make products available on the market to the general public.
- (20) Furthermore, to ensure a high level of safety for human health, animal health and the environment, the placing on the market of wood treated with creosote should be subject to conditions. In particular, to ensure that wood treated with creosote is placed on the market only in Member States where the use of the biocidal products containing creosote could be authorised as the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied, lists of Member States where the placing on the market of railway sleepers or utility poles for electricity and telecommunication is allowed should be made publicly available. It should be possible for a Member State to ask to be removed from either of those lists so that wood treated for the concerned use(s) can no longer be placed on the market of that Member State. In addition, the person responsible for the placing on the market of wood treated with creosote should ensure that the label of that treated wood includes specific statements aiming to protect human health and the environment, avoid unauthorised use of the treated wood, and ensure that treated wood is placed on the market only in Member States included in such lists and in the Member States that have been removed from a list for a certain period of time.
- (21) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community ('Withdrawal Agreement'), and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, Regulation (EU) No 528/2012 as well as the Commission acts based on it, applies to and in the United Kingdom in respect of Northern Ireland after the end of the transition period provided for in the Withdrawal Agreement. For that reason the lists of states where treated wood may be placed on the market should also include the United Kingdom in respect of Northern Ireland, where necessary.
- (22) In respect of uses of creosote other than for the treatment of wood to make railway sleepers and utility poles for electricity and telecommunications referred to in the application for renewal of approval, it has not been demonstrated that any of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is met. In particular, as regards the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012, it has not been demonstrated that the non-renewal of creosote as an active substance for use in biocidal products for such uses will have a disproportionate negative impact on society compared to the risks of using creosote and wood treated with creosote. Suitable and sufficient alternatives exist and are already implemented in almost all Member States, and can be implemented in the entire Union. In order to allow sufficient time for economic operators to adapt to the requirements set down in this Implementing Regulation, a period of transition should be set after which that wood treated with biocidal products containing creosote is no longer placed on the market other than as railway sleepers and utility poles for electricity and telecommunications. The same period should apply to the placing on the market of railway sleepers and utility poles for electricity and telecommunications treated with creosote in Member States not included in the lists for the concerned uses.
- (23) By Commission Implementing Decision (EU) 2021/1839 ⁽⁶⁾, the expiry date of approval of creosote for use in biocidal products of product-type 8 was postponed to 31 October 2022. As the examination of the application for the renewal of that approval is now finalised, it is appropriate to repeal Implementing Decision (EU) 2021/1839.
- (24) Creosote, its compounds, and wood treated with them, are subject to restrictions laid down in Annex XVII to Regulation (EC) No 1907/2006. This Regulation does not affect the obligation to comply with those restrictions.
- (25) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽⁶⁾ Commission Implementing Decision (EU) 2021/1839 of 15 October 2021 postponing the expiry date of approval of creosote for use in biocidal products of product-type 8 (OJ L 372, 20.10.2021, p. 27).

HAS ADOPTED THIS REGULATION:

Article 1

The approval of creosote as an active substance for use in biocidal products of product-type 8 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

Implementing Decision (EU) 2021/1839 is repealed.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (!)	Expiry date of approval	Product type	Specific conditions
Creosote	IUPAC Name: Creosote EC No: 232-287-5 CAS No: 8001-58-9	100 % (w/w) Creosote shall contain less than: — 0,005 % (w/w) of benzo[a]pyrene — 3 % (w/w) of water extractable phenols	31 October 2029	8	Creosote is considered a candidate for substitution in accordance with Article 10(1), points (a), (d) and (e), of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: (1) Products may only be authorised for the treatment by vacuum pressure impregnation of wood in industrial installations to make railway sleepers, or utility poles for electricity or telecommunications. (2) Pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied. (3) Products may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied. (4) Products may be placed on the market only in packaging of a capacity equal to or greater than 200 litres, and shall not be made available on the market to the general public. (5) The assessment of applications for product authorisation shall pay particular attention to: (a) professional users; (b) secondary exposure of the general public; (c) the soil and aquatic compartments; (d) the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

				<p>(6) Labels and, where provided, safety data sheets of products authorised, shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding; that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water; and that any losses from the application of the product shall be collected for reuse or disposal.</p> <p>The placing on the market of treated articles is subject to the following conditions:</p> <p>(1) By 31 January 2023, the Agency shall make publicly available on its website, based on the requests made by Member States:</p> <ol style="list-style-type: none"> (a) a list of Member States where railway sleepers treated with creosote may be placed on the market; (b) a list of Member States where utility poles for electricity and telecommunications treated with creosote may be placed on the market. <p>(2) As from 30 April 2023, only railway sleepers, or utility poles for electricity or telecommunications treated with creosote may be placed on the market in Member States included in the respective list referred to in this paragraph, point (1). A Member State may ask the Agency to be removed from the respective list at any time. When the Agency removes a Member State from either of the lists, the date of removal shall be indicated, and treated articles for the concerned use shall no longer be placed on the market of that Member State 180 days after the date of removal.</p> <p>(3) The person responsible for the placing on the market of a treated article shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.</p>
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					<p>(4) The person responsible for the placing on the market of a treated article shall ensure that the label of that treated article includes the statement: 'During storage, treated wood shall not be accessible to the general public. Measures shall be taken to prevent unauthorised access. Treated wood must be stored on impermeable hard standing or on absorptive material to prevent runoff to the environment, and under shelter or covered with a tarpaulin. Any spill or contaminated material must be collected on such sites and disposed as hazardous waste.'</p> <p>(5) As from 30 April 2023, the person responsible for the placing on the market of a treated article shall ensure that the label of that treated article includes the statement: 'Only allowed for use as a railway sleeper' or 'Only allowed for use as utility pole for electricity lines or for telecommunication lines', as appropriate.</p> <p>(6) As from 30 April 2023, the person responsible for the placing on the market of a treated article shall ensure that the label of that treated article includes the statement: 'The placing on the market is restricted to certain Member States of the European Union: verify on the website of the European Chemicals Agency where the placing on the market is allowed.'</p>
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(⁴) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.