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COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament
and the Council as regards creosote and creosote-related substances**

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

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amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and the Council as regards creosote and creosote-related substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard 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/EC¹, and in particular Article 68(1) thereof,

Whereas:

- (1) Entry 31 set out in the Table of Annex XVII to Regulation (EC) No 1907/2006 ('entry 31') prohibits the placing on the market and use of creosote and eight creosote-related substances, as substances or in mixtures, where the substance or mixture is intended for the treatment of wood, as well as the placing on the market of wood so treated. Under certain conditions, entry 31 provides for derogations from those prohibitions.
- (2) Creosote (EC No 232-287-5, CAS No 8001-58-9) is classified as carcinogen category 1B in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council² and considered a non-threshold carcinogen under Commission Directive 2011/71/EU³. Due to its classification as carcinogen category 1B, creosote is also covered by Directive 2004/37/EC of the European Parliament and of the Council⁴. Furthermore, creosote contains a mixture of polycyclic aromatic hydrocarbons (PAHs) and according to an opinion⁵ of the Biocidal Products Committee established by Article 75 of Regulation (EU) No 528/2012 of the European

¹ OJ L 396, 30.12.2006, p. 1, ELI: <https://data.europa.eu/eli/reg/2006/1907/oj>.

² 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 199/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008 p.1, ELI: <https://data.europa.eu/eli/reg/2008/1272/oj>).

³ 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 (OJ L 195, 27.7.2011, p. 46, ELI: <https://data.europa.eu/eli/dir/2011/71/oj>).

⁴ 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, mutagens or reprotoxic substances at work (OJ L 158, 30.4.2004, p. 50, ELI: <https://data.europa.eu/eli/dir/2004/37/2024-04-08>).

⁵ Biocidal Products Committee opinion on the application of the renewal of the approval of the active substance: creosote, Product type 8, ECHA/BPC/274/2020, adopted on 4 December 2020, <https://echa.europa.eu/documents/10162/fc41edcf-3732-2ba9-6a14-0fb9b423fd6c>.

Parliament and of the Council⁶ meets the criteria for being persistent, bioaccumulative and toxic as well as very persistent and very bioaccumulative in accordance with Annex XIII to Regulation (EU) No 1907/2006.

- (3) The following creosote-related substances as listed in entry 31 set out in the Table of Annex XVII to Regulation (EC) No 1907/2006 are also classified as carcinogen category 1B in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008: creosote oil; wash oil (EC No 263-047-8, CAS No 61789-28-4); creosote oil, acenaphthene fraction; wash oil (EC No 292-605-3, CAS No 90640-84-9); distillates (coal tar), upper; heavy anthracene oil (EC No 266-026-1, CAS No 65996-91-0); anthracene oil (EC No 292-602-7, CAS No 90640-80-5). Moreover, the following creosote-related substances are classified as carcinogen category 1B and mutagenic category 1B in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008: distillates (coal tar), naphthalene oils; naphthalene oil (EC No 283-484-8, CAS No 84650-04-4); tar acids, coal, crude; crude phenols (EC No 266-019-3, CAS No 65996-85-2); low temperature tar oil, alkaline; extract residues (coal), low temperature coal tar alkaline (EC No 310-191-5, CAS No 122384-78-5).
- (4) Creosote was approved as an active substance for use in biocidal products of product-type 8 (wood preservatives) by Directive 2011/71/EU. That approval was renewed by Commission Implementing Regulation 2022/1950⁷. The other eight substances listed in entry 31 set out in the Table of Annex XVII to Regulation (EC) No 1907/2006 have not been approved as active substances for use in biocidal products and, therefore, biocidal products containing them are not to be placed on the market or used in the Union. Similarly, wood which has been treated with, or intentionally incorporates, one or more biocidal products containing the other eight substances listed in entry 31 is not to be placed on the market for the first time.
- (5) On 25 February 2019, in accordance with the safeguard clause set out in Article 129(1) of Regulation (EC) No 1907/2006, the French Republic ('France') informed the Commission that it had adopted a provisional measure on 18 December 2018 to protect the environment from the risks arising for the aquatic and/or terrestrial environment compartment from wood treated with creosote and creosote-related substances ('creosote-treated wood'). In its information note to the Commission, France referred to its refusal to authorise the use of biocidal products containing creosote for wood treatment uses other than the treatment of railway sleepers, which the Commission deemed justified⁸. France pointed out that the current rules had some limitations. Specifically, neither entry 31 nor Regulation (EU) No 528/2012 precluded creosote-treated wood from being placed on the French market for the first time or installed in the French territory. Additionally, those rules did not prevent the placing on the French second-hand market of wood treated before 31 December 2002 for re-

⁶ 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 (OJ L 167, 27.6.2012, p. 1, ELI: <https://data.europa.eu/eli/reg/2012/528/oj>).

⁷ 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 (OJ L 269, 17.10.2022, p. 1, ELI: https://data.europa.eu/eli/reg_impl/2022/1950/oj).

⁸ Commission Implementing Decision (EU) 2018/1297 of 25 September 2018 on a derogation from mutual recognition of the authorisation of biocidal products containing creosote by France in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 243, 27.9.2018, p. 19, ELI: https://data.europa.eu/eli/dec_impl/2018/1297/oj).

use. On 5 March 2019, France informed the European Chemicals Agency ('the Agency') and the other Member States of the provisional measure.

- (6) On 7 June 2019, by Commission Implementing Decision (EU) 2019/961⁹, the Commission authorised the provisional measure taken by France until 7 September 2021. The authorisation was extended until 7 May 2024 by Commission Implementing Decision (EU) 2022/326¹⁰.
- (7) In accordance with Article 129(3) of Regulation (EC) No 1907/2006, France, as the 'Dossier Submitter', initiated the restriction procedure by submitting to the Agency a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier') on 7 October 2022.
- (8) The Annex XV dossier¹¹ considered that Regulation (EU) No 528/2012 governs the approval of active substances for use in biocidal products, the authorisation of biocidal products and the placing on the market for the first time of treated articles. It proposed to amend column 2 of entry 31 of the Table set out in Annex XVII to Regulation (EC) No 1907/2006 to reduce the human health and environmental risks associated with reuse, for the same purpose as the original use ('reuse'), and use for other purposes other than the original use, of creosote-treated wood. The Annex XV dossier demonstrated that action on a Union-wide basis was necessary to address the risk due to emissions to the environment and exposure of the general public to creosote-treated wood.
- (9) The Dossier Submitter proposed to prohibit the placing on the market, except under the conditions set out in Regulation (EU) No 528/2012, the placing on the second-hand market, of creosote-treated wood, as well as to prohibit its use for other purposes other than the original use. The Dossier Submitter also proposed to limit the reuse of creosote-treated wood to the original user in the same Member State under the same conditions and for the same uses in accordance with Regulation (EU) No 528/2012.
- (10) The prohibition proposed by the Dossier Submitter aimed to increase the protection of human health and the environment by greatly decreasing the reuse of creosote-treated wood by non-professionals and by prohibiting the placing on the second-hand market and the use of creosote-treated wood by other users than the original user and for other purposes than the original use. The Dossier Submitter proposed to specify that creosote-treated wood must be placed on the market under the conditions and derogations laid down by Regulation (EU) No 528/2012 and that, once considered waste, creosote-treated wood must be handled as hazardous waste.

⁹ Commission Implementing Decision (EU) 2019/961 of 7 June 2019 authorising a provisional measure taken by the French Republic in accordance with Article 129 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) to restrict the use and the placing on the market of certain wood treated with creosote and other creosote-related substances (OJ L 154, 12.6.2019, p. 44, ELI: https://data.europa.eu/eli/dec_impl/2019/961/oj).

¹⁰ Commission Implementing Decision (EU) 2022/326 of 24 February 2022 amending Implementing Decision (EU) 2019/961 authorising a provisional measure taken by the French Republic in accordance with Article 129 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) to restrict the use and the placing on the market of certain wood treated with creosote and other creosote-related substances (OJ L 55, 28.2.2022, p. 76, ELI: http://data.europa.eu/eli/dec_impl/2022/326/oj).

¹¹ <https://echa.europa.eu/documents/10162/8c86e241-dd35-1812-6a4e-52e90ec1d320>

- (11) On 14 September 2023, the Agency’s Committee for Risk Assessment (‘RAC’) adopted its opinion¹² concluding that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks arising from the placing on the market, reuse and use for other purposes than the original use of creosote-treated wood.
- (12) RAC concluded that the risk management measures and the operational conditions associated with the derogations are appropriate and effective for professional users of creosote-treated wood as the restriction prohibits only any reuse and use by the general public. RAC supported allowing the placing on the second-hand market and the reuse of wood treated with creosote by professional users (both the original professional user and other professional users), provided that the same conditions and risk management measures (as identified pursuant to Regulation (EU) No 528/2012 for the first placing on the market and use) are applied, that the reuse is for the same use, and that it takes place in the same Member State as the first use. RAC also concluded that in order for enforcement to be more effective, it should be required to keep documentation of the purchase, sales and disposal of creosote-treated wood until its end of life.
- (13) RAC concluded that “creosote, wood” (EC No 232-419-1, CAS No 8021-39-4), which is one of the creosote-related substances listed in column 1 of entry 31, does not share the same hazardous properties of the other substances since it has not been classified as carcinogenic nor fulfils the PBT and/or vPvB criteria. “Creosote, wood” does not contain PAH and has likely never been used in the Union. Therefore, RAC recommended not to retain “creosote, wood” in column 1 of entry 31.
- (14) RAC acknowledged that Implementing Regulation (EU) 2022/1950 renewed the approval of creosote as an active substance in accordance with Regulation (EU) No 528/2012. RAC further acknowledged that the approval sets out specific conditions for creosote-treated wood, namely it only allows railway sleepers and utility poles for electricity or telecommunications treated with creosote to be placed on the market for the first time in certain Member States. RAC noted that the Member States concerned are included in a list made publicly available by the Agency¹³. RAC also noted that, once creosote-treated wood has been placed on the market for the first time in the listed Member States in accordance with Regulation (EU) No 528/2012, it could be further distributed in other, non-listed Member States, and took the view that such situations should be addressed in accordance with Regulation (EC) No 1907/2006.
- (15) On 1 December 2023, the Agency’s Committee for Socio-Economic Analysis (‘SEAC’) adopted its opinion¹⁴, concluding that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks, taking into account its socio-economic benefits and costs. SEAC agreed with RAC that the placing on the second-hand market and reuse of creosote-treated wood by professional users, whether the original professional users or other professional users, should be allowed, provided the same conditions and risk management measures identified in accordance with Regulation (EU) No 528/2012 for the first placing on the market and use are applied, and the reuse is for the original use and takes place in the same Member State where it was used for the first time.

¹² <https://echa.europa.eu/documents/10162/60f7bfbe-953b-631c-84b3-4a5a78ebbc3d>

¹³

https://echa.europa.eu/documents/10162/988147/creosote_PT8_ms_lists_referred_specific_conditions_in_implementing_regulation_en.pdf

¹⁴

<https://echa.europa.eu/documents/10162/4073ba72-d5b8-ae29-c3c0-b099719ace94>

- (16) SEAC considered that, although technically feasible alternatives are available for railway sleepers and utility poles, due to their technical shortcomings in some circumstances and higher costs, the most likely alternative to the reuse of creosote-treated wood is the use of new creosote-treated wood in those Member States that allow the placing on the market of wood treated with creosote in accordance with Regulation (EU) No 528/2012. As regards other applications of creosote-treated wood, SEAC agreed with the Dossier Submitter that technically and economically feasible alternatives are available, in view of the fact that such applications were not allowed pursuant to Regulation (EU) No 528/2012 due to such availability.
- (17) SEAC concluded that the restriction, as modified by RAC, would entail higher environmental benefits than the restriction proposed by the Dossier Submitter, since it is likely that the alternative to reusing railway sleepers and utility poles treated with creosote would be using newly treated ones, which would have a higher leaching effect than older creosote-treated wood.
- (18) SEAC recommended that any future changes to the conditions of approval of creosote in accordance with Regulation (EU) No 528/2012 should also apply to the reuse by professional users.
- (19) SEAC recommended a 12-month deferral of application of the restriction, in line with the Annex XV dossier, to provide sufficient time to stakeholders to fully implement the restriction requirements.
- (20) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1), point (f), of Regulation (EC) No 1907/2006, was consulted during the restriction process and its recommendations have been taken into account.
- (21) On 31 January 2024, the Agency submitted the opinions of RAC and SEAC to the Commission.
- (22) Taking into account the Annex XV dossier as well as RAC and SEAC opinions, the Commission considers that there is an unacceptable risk arising from the emissions of creosote and creosote-related substances from creosote-treated wood and that the proposed restriction prohibiting the reuse, use for other purposes than the original use and further placing on the market of creosote-treated wood, with a derogation for railway sleepers and utility poles for electricity lines or for telecommunication lines, is the most appropriate Union-wide measure to address that risk. In particular, the Commission considers that the proposed restriction, as modified by RAC and SEAC, is appropriate as it allows the reuse by both the original users as well as by other professional users of railway sleepers and utility poles for electricity lines or telecommunication lines. This is expected to have less impact on the environment than allowing it by the original users only, as was originally proposed by the dossier submitter.
- (23) The Commission agrees with RAC that enforcement should be facilitated by a requirement to keep documentation on acquisitions, further placing on the market and disposal of creosote-treated wood. This obligation should apply for the duration of the use and for ten years after disposal. Since users who further place on the market creosote-treated wood may not necessarily be aware when that wood reaches its end of life, the Commission considers that such users should keep the documentation for ten years after they have placed the wood on the market.
- (24) Since the conditions and derogations for placing creosote-treated wood on the market for the first time, laid down in Regulation (EU) No 528/2012, continue to apply, there

is no need for entry 31 set out in the Table of Annex XVII to Regulation (EC) No 1907/2006 to require compliance with those conditions and derogations. It should be possible for creosote-treated wood not used as a railway sleeper or a utility pole for electricity or telecommunications that is already in place, to remain in use and continue to be used for the same purpose. It should, however, not be reused.

- (25) The Commission notes that the proposal for a revised restriction, as submitted by the Dossier Submitter and assessed by RAC and SEAC, focused on the placing on the market and the reuse of treated wood. The Commission considers that, in view of the scope of Regulation (EU) No 528/2012, other provisions of entry 31 remain relevant and necessary to ensure the overall effectiveness of the restriction. Therefore, those provisions should be retained and updated as necessary, in order to provide legal certainty and maintain a comprehensive and coherent restriction and consistency with the provisions laid down in Implementing Regulation (EU) 2022/1950. In particular, taking into account that Regulation (EU) No 528/2012 does not prevent the use of creosote and creosote-related substances listed in entry 31 to treat wood that is not placed on the Union market, it is necessary to maintain existing restrictions on use and align them with conditions set out by Regulation (EU) No 528/2012.
- (26) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the restriction. Therefore, taking into account RAC's and SEAC's considerations, the application of the provisions of this Regulation should be deferred for 12 months.
- (27) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (28) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from [*OP, please insert the date: 12 months after the entry into force of this amending Regulation*].

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

Done at Brussels,

*For the Commission
The President
Ursula von der Leyen*