Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Creosote and Creosote related substances

ECHA/RAC/RES-O-0000007346-71-01/F

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

14 September 2023

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CREOSOTE AND CREOSOTE RELATED SUBSTANCES

14 September 2023

ECHA/RAC/RES-O-0000007346-71-01/F

8 September 2023

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Creosote and Creosote related substances

EC No.: -

CAS No.: - -

This document presents the opinion adopted by RAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitter's proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

France has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at https://echa.europa.eu/restrictions-under-consideration on **21 December 2022**. Interested parties were invited to submit comments and contributions by **22 June 2023**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Bert-Ove LUND

Co-rapporteur, appointed by RAC: Raili MOLDOV

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted on **14 September 2023 by consensus** in accordance with Article 70 of the REACH Regulation.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON CREOSOTE AND CREOSOTE RELATED SUBSTANCES

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Martien JANSSEN

Co-rapporteur, appointed by SEAC: Luisa CAVALIERI

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **8 September 2023.**

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at https://echa.europa.eu/restrictions-under-consideration on **8 September 2023**. Interested parties were invited to submit comments on the draft opinion by **7 November 2023**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]]**[2].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and] 71(1) of the REACH Regulation.**] [**No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and] 71(1)**]**[2].

The opinion of SEAC was adopted **by [consensus**.**][a simple majority]**[3] of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[2].

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Tables

1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Table 1: Proposed restriction

Substance Identity (or group identity)	Conditions of the restriction
Creosote and Creosote related substances a) Creosote CAS No 8001-58-9 EC No 232-287-5 (b) Creosote oil; wash oil CAS No 61789-28-4 EC No 263-047-8 (c) Distillates (coal tar), naphthalene oils; naphthalene oil CAS No 84650-04-4 EC No 283-484-8 (d) Creosote oil, acenaphthene fraction; wash oil CAS No 90640-84-9 EC No 283-484-8 EC No 292-605-3 (e) Distillates (coal tar), upper; heavy anthracene oil CAS No 65996-91-0 EC No 266-026-1 (f) Anthracene oil CAS No 90640-80-5 EC No 292-602-7 (g) Tar acids, coal, crude; crude phenols CAS No 65996-85-2 EC No 266-019-3 (h) Creosote, wood CAS No 8021-39-4 EC No 232-419-1 (i) Low temperature tar oil, alkaline; extract residues (coal), low temperature coal tar alkaline	1. Wood treated with such substances shall be placed on the market in the conditions and derogations defined by the Biocidal Product Regulation (EU) No 528/2012. 2. Wood treated with such substances and placed on the market irrespective of the date of impregnation with these substances: a. shall not be distributed, reused or subject to secondary use; b. shall not be placed or made available on the second-hand market. 3. By way of derogation from paragraph 2.a, wood treated with such substances can be reused, in accordance with paragraph 1, for the same use in the same country, under similar conditions and by the same original user. 4. Once considered as waste, treated wood referred to under paragraphs 1 and 3 should be handled according to the Waste Framework Directive framework 2008/98/EC. 5. The restriction shall apply from xx.xx.202x [12 months after its entry into force].

CAS No 122384-78-5 EC No 310-191-5	

1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and options to reduce the risk, as documented in the Annex XV report and submitted by interested parties, as well as other available information as recorded in the Background Document. RAC considers that the restriction proposed by the Dossier Submitter on **Creosote and Creosote related substances**[1] is the **most appropriate Union wide measure** to address the identified risk in terms of the effectiveness in reducing the risk, practicality and monitorability.

The conditions of the restriction proposed by RAC are provided below (changes from the DS proposal are in bold and strikeout):

Table 2: Restriction proposed by RAC.

Substance Identity (or group identity)	Conditions of the restriction
Creosote and Creosote related substances a) Creosote CAS No 8001-58-9 EC No 232-287-5 (b) Creosote oil; wash oil CAS No 61789-28-4 EC No 263-047-8 (c) Distillates (coal tar), naphthalene oils; naphthalene oil CAS No 84650-04-4 EC No 283-484-8 (d) Creosote oil, acenaphthene fraction; wash oil CAS No 90640-84-9 EC No 283-484-8 EC No 292-605-3 (e) Distillates (coal tar), upper; heavy anthracene oil CAS No 65996-91-0 EC No 266-026-1	1. Wood treated with such substances shall be placed on the market in the conditions and **according to the** derogations defined by the Biocidal Products Regulation (EU) No 528/2012. 2. Irrespective of the date of **treatment** with these substances, wood treated with such substances and placed on the market: a. shall not be further distributed, reused or subject to secondary use; b. shall not be placed or made available on the second-hand market. 3. By way of derogation from paragraph 2.a **and 2.b**, wood treated with such substances can be **placed on the second-hand market or** reused **in the same Member State,** if it is for the same **professional** use **permitted under the Biocidal Products Regulation**. **When placing on the second-hand market or reusing wood treated with such substances, suppliers and professional users shall apply the same risk management measures as identified in accordance with the Biocidal Products Regulation (EU) No 528/2012. The users shall maintain documentation of the purchase and sales and disposal of the creosote treated material.**

[1] Where the name of the substance is too long or complicated, the name can be replaced by 'the substance'.

(f) Anthracene oil CAS No 90640-80-5 EC No 292-602-7 (g) Tar acids, coal, crude; crude phenols CAS No 65996-85-2 EC No 266-019-3 ~~**(h) Creosote, wood**~~ ~~**CAS No 8021-39-4**~~ ~~**EC No 232-419-1**~~ (i) Low temperature tar oil, alkaline; extract residues (coal), low temperature coal tar alkaline CAS No 122384-78-5 EC No 310-191-5	4. Once it becomes a waste, treated wood referred to under paragraphs 1 and 3 should be handled **as hazardous waste** according to the Waste Framework Directive 2008/98/EC. 5. The restriction shall apply from xx.xx.202x [12 months after its entry into force].

1.2. THE OPINION OF SEAC

Text

Explanatory notes:

- The COMMISSION IMPLEMENTING REGULATION (EU) 2022/1950 of 14 October 2022 provides the renewal of the approval of creosote as an active substance according to the Biocidal Products Regulation (EU) No 528/2012 (BPR) and stipulates that, as from 30 April 2023, wood treated with creosote (only railway sleepers, or utility poles for electricity or telecommunications) may only be placed on the market in Member States agreeing to it and when included on a list maintained by ECHA. However, once the treated wood has been placed on the market in the territory of one Member State and placed on the ECHA list (as per the BPR), it could then be further distributed to a second Member State and "placed on the market" as per REACH definition, even though that second Member State is not on the ECHA list. Under such circumstances, the treated wood can be freely marketed throughout the EU regardless of where it was first treated and placed on the market. Because the BPR no longer applies to the treated wood after the first placing on the market, this loophole can best be addressed via a REACH-restriction.
- In case of further distribution, the labelling of the treated wood falls under the REACH regulation. Thus, referral to the need of the same risk management measures as under the BPR, for the placing on the second-hand market would ensure that the same labelling requirements would apply under REACH.
- The restriction aims to prohibit the import from third countries (placing on the market) of pre-used (second-hand) railway sleepers and utility poles. This would fall under the prohibition on placing treated wood on the second-hand market set out in paragraph 2.b.
- The similar conditions referred to in paragraph 3 of the initial restriction proposal

should be read as the same conditions as defined in the BPR for newly creosote-treated wood[2] for human health and environmental risk mitigation, as reflected in the amended text by RAC and SEAC.

- According to RAC's evaluation, re-use should be allowed not only for the original user (as proposed by the Dossier Submitter) but also for other professional users within the same Member State as far as they apply the same risk management measures required by the BPR. Paragraph 3 of the restriction proposal is suggested to be updated accordingly.
- For more effective enforcement, a requirement to keep the documents related to the creosote treated articles until their end of life could be placed on the users as proposed in paragraph 3 of the restriction proposal. This would also ensure that professional users receive relevant information on human health and environmental risks as well

[2] The renewing of the approval of creosote as an active substance for use in biocidal products (EUR-Lex - 32022R1950 - EN - EUR-Lex (europa.eu)) states in preamble point 14 that "….*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. ... 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."* and in point 20 that "*…..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,…."*
The Biocidal committee opinion further specify the risk management measures workers need to consider:
• Stringent adherence to the protective measures that are already in place.
• The PPE should be changed frequently, and immediately after contamination.
• The personal hygiene shall be strict and washing with suitable cleaning solutions shall be performed as soon as possible after each work task where there is a risk of exposure.
• Risk of exposure means direct skin contact or inhalation of the vapours. However, risks vary depending on the construction of the plant and during non-routine activities. Risks can, for example, occur when opening and maintaining of the vessel or entry into treating or preservative storage vessels. In these cases, additional protection can be advised.
• Respiratory protection, such as a full face mask with particle filter P2 or preferably P3 in combination with gas filter A (brown) should be worn at critical work tasks when there is a risk of inhalation exposure.
• Chemical resistant (coated) coveralls, or equivalent, should be worn over the regular work clothes at critical work tasks when there is a risk of exposure, and a thinner pair of (cotton) gloves should be worn under the chemical resistant gloves.
• Sky lifts (aerial access platforms) shall be used if feasible/whenever possible.
• Whenever possible, mechanical or automated processes should be used to avoid manual handling of treated timber (including down-stream work, for example during work with poles in service).
• Creosote-resistant boots should be worn when entering the vessel (e.g. for cleaning or maintenance).
• In order to ensure efficient protection, tight sealings (sleeve capes) may be used at the border of different garments, e.g., at the border of gloves and sleeves and at the border of trousers and boots.
• Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.
• All activities with treated timber must be undertaken at industrial sites where application processes must be carried out within a contained area; situated on impermeable hard standing, with bunding to prevent run-off and a recovery system in place (e.g. sump), and 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 of the product shall be collected for reuse or disposal.
• All treatment of timber must be undertaken within the industrial impregnation facilities on an impermeable surface or in case of brushing the wood components modified after standard vacuum pressure treatment at a construction site outdoors where soil is protected with a plastic foil or tray.
• Any spill or contaminated material must be collected and disposed as hazardous waste.
• It is agreed by the BPC members that additional risk mitigation measures are required; these are to prevent leakage into ground and to minimise contact of the general public with creosote treated material.
• In case of storage of creosote treated timber (temporarily) at other sites than impregnation facilities (e.g. the readiness stocks of transmission poles at the site of installation), the timber should be stored on an impermeable hard standing or on an absorptive material (e.g. bark) as well as under shelter (e.g. roof or covered with a tarpaulin), and if stored in residential or recreational areas an access by general public should be restricted (e.g. using a fence or a cover).

as conditions and risk mitigation measures.

- Paragraph 2 of the initial restriction proposal is suggested to be revised so that "in accordance with paragraph 1" is deleted, to be sure that the restriction applies to all treated wood, regardless of when the wood was treated.
- The "reuse", "secondary use" and "second hand market" mentioned in paragraph 2 of the initial restriction proposal may need to be defined also in the legal text.
- Paragraph 3 of the restriction proposal could be extended reporting the risk management measures identified in the Biocidal Products Committee Opinion (see section 3.4.2).

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

Creosote contains a mixture of polyaromatic hydrocarbons (PAHs) and fulfils the criteria both for PBT and/or vPvB substances and for being carcinogenic (Cat. 1 B). Both properties are regarded as non-threshold properties.

By amending entry 31 of Annex XVII to the REACH Regulation, the restriction proposal aims at reducing health and environmental risks (especially for the general public) associated with the distribution, reuse and secondary uses of wood treated with creosote and creosote-related substances. As defined by the Dossier Submitter (France), in this context 'reuse' means use for the same purpose as the original use, e.g., railway sleepers reused as railway sleepers, whereas 'secondary use' means use for other purposes than the original use, as for example railway sleepers used for agricultural fencing or residential landscaping.

The restriction proposal is intended to align with the renewal of the approval of creosote as an active substance under the Biocidal Products Regulation (BPR)[3]. This renewed approval applies from 30 April 2023 and specifies that the only creosote-based biocidal products that may be authorised to be placed on the market and used are those for vacuum pressure impregnation of railway sleepers and utility poles for electricity and telecommunications. Such railway sleepers and utility poles may only be placed on the market in the Member States which have indicated their agreement to ECHA (ECHA maintains and publishes a list of these Member States)[4]. The BPR does not cover (i.e., does not regulate or limit) any subsequent supplies of the treated wood after the first placing on the market in any Member State, e.g., transfer to a second 'unlisted' Member State for placing on the market there.

The restriction proposal is also expected to work in synergy with the Waste Framework Directive (2008/98/EC). At the end of its life cycle, wood treated with creosote or creosote-related substances is considered as hazardous waste and must be disposed of accordingly.

The Dossier Submitter clarified the following key aspects in the proposal:

- Creosote-treated wood will be permitted to be reused solely by the same actor in the same Member State and for the same use as specifically allowed under BPR: e.g., railway sleepers reused as railway sleepers, communication poles reused as communication poles.
- No secondary use or second-hand market of creosote-treated wood will be permitted, including wood treated with creosote before December 2002. The creosote-treated wood already in use in secondary applications will eventually become a waste and therefore need to be disposed of as foreseen by the Waste Framework Directive.
- The proposal will not affect current uses, i.e., uses approved in the past according to older legislation can continue until the article becomes waste.

Regarding the risk reduction potential of the proposed restriction, the Dossier Submitter was not able to quantify the environmental and human health benefits of the proposed measures. However, they emphasised the need for minimising the exposure of the general public

[3]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. L269/1-8.
[4] Microsoft Word - Creosote-PT8_DraftlistofMSfortreatedwood.docx (europa.eu)

(consumers) to creosote and creosote-related substances, as well as the emissions of the substances to the environment, due to old creosote-treated wood (sleepers and utility poles for electricity or telecommunications) being sold/available in many Member States.

Following the renewal of the approval of creosote as an active biocidal substance, the Dossier Submitter considered new creosote-treated wood to be the best economically viable alternative to old/re-treated creosote-treated wood under the current market conditions, for the uses where wood is still the best option from a technical point of view.

Overall, regarding railways sleepers, the total cost of the restriction estimated by the Dossier Submitter ranges from approximately €150,000/year to €9 million/year, depending on the reuse volume and the alternative considered. The Dossier Submitter is expecting further information to become available in the consultation to refine the estimates.

2.2. Summary of opinion

2.2.1. RAC opinion summary

- Creosote contains a mixture of polyaromatic hydrocarbons (PAHs) and fulfils the PBT and/or vPvB and carcinogenic 1B criteria. These are all regarded as non-threshold properties, warranting minimisation of emissions and exposure.
- Distribution, reuse and secondary uses of creosote-treated wood are in principle regulated by REACH, but the current wording of Entry 31 of Annex XVII is interpreted or applied differently among the EU Member States, indicating that the existing regulatory management measures are not sufficient to control the risk. In addition, Entry 31 of Annex XVII is not aligned with the renewal of the approval of creosote as an active biocidal substance under the BPR.
- The scope of the restriction proposal is clear and focuses on restricting the use of creosote-treated wood after the first placing on the market (BPR-regulated).
- RAC supports retaining all creosote-like substances under Entry 31 of the REACH Regulation except creosote, wood (CAS 8021-39-4).
- In order to protect the general public (consumers) and the environment, the proposal is aimed at banning secondary uses and the second-hand market of creosote-treated wood, but also aims at restricting how old creosote-treated wood can be placed on the second-hand market or reused for the same purpose (namely, it is proposed to only be allowed by the same actor in the same Member State), by applying the same risk management measures and for the same uses as allowed in the BPR.
- There is evidence that used creosote-treated wood (sleepers and utility poles for electricity or telecommunications) is sold in many EU Member States. Secondary uses and reuse of such wood may give rise to exposure of humans and the environment to the mentioned hazardous substances.
- The human health and environmental risk from the non-threshold PAHs in creosote-treated wood cannot be quantified in a formal risk assessment, but they can still be minimised by restricting reuse and secondary use of such treated wood.
- RAC is not aware of any operational conditions or risk management measures that could be implemented by the general public (consumers) to prevent PAH exposure. No such measures that could decrease the risk during distribution, reuse or secondary use are recommended by the manufactures and/or importers, and even if such information were provided when buying the products, it would not be available for example after ≥ 20 years of outdoor use.

- The BPR sets requirements on professionals treating the wood with creosote, and in general professional users are expected to understand and have access to information on the risks and what measures to take to protect themselves. The BPR also sets conditions for the storage of the treated wood[5]. These conditions required under the BPR apply only when the wood is first placed on the market. However, new labels may need to be added in the reuse phase (allowed reuse for the same purpose in the same Member State), because it is very likely that the original labels would not last, for example after >20 years of outdoor use of the wood. The restriction proposal discusses an introduction of a permanent labelling to overcome this problem.
- RAC supports that a restriction on an EU-wide basis is needed to minimise emissions to the environment and exposure of the general public (consumers) to creosote and creosote-related substances.
- Risk of alternatives to creosote is discussed under the BPR (Opinion on the application for renewal of the approval of the active substance ECHA/BPC/274/2020). An assessment of the risk of alternatives has not been conducted in this restriction proposal. RAC notes that the main alternative is considered to be newly creosote-treated wood although comments in the third-party consultation indicate that alternatives are approved and used in some Member States.
- Since the BPR only addresses the first placing on the market, REACH can address the risks arising from the distribution, reuse and secondary uses of creosote treated wood.
- RAC concludes that the risk management measures, operational conditions, and derogations are appropriate and effective for the original (professional) user because all distribution, reuse or secondary use will be banned for the general public.
- RAC supports to allow the placing on the second-hand market and re-use of wood treated with creosote by professional users (same original professional user and other professional users) provided the same risk management measures (as identified under the BPR for the first placing on the market and use) are applied and the re-use is for the same use and takes place in the same Member State of the first use (option 3).
- Regarding practicality, RAC finds the restriction practical if the wording is improved as suggested in the conditions for restriction. Regarding enforceability, RAC notes that the Forum advice discusses sampling of wood and chemical analysis of PAH, but RAC notes that all railway sleepers and utility poles (most likely to be used for secondary purposes) have been treated, and would expect that visual inspection and the sharp odour would be sufficient for enforcement.
- The restriction can be monitored via surveillance programs of national enforcement bodies and existing reporting systems, via following market trends for alternatives, and via following internet trade of old creosote-treated wood. A permanent labelling system (not in place today) would allow a better follow up of the treated articles all along their service life.
- For more effective enforcement, a requirement to keep the required documents on the creosote treated articles until their end of life could be placed on the users as part of the restriction proposal.

[5] The BPR renewal of creosote states in the Annex some conditions about storage: *"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."*

- The suggested restriction is considered to be the most appropriate EU-wide measure as it aims at amending/clarifying the current Entry 31 of the REACH Regulation.
- The main uncertainties concern the limited exposure information available and how to best phrase the restriction text to obtain the desired outcome.

2.2.2. SEAC opinion summary

Text

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. RISK ASSESSMENT

3.1.1. Scope of the risk assessment

Summary of Dossier Submitter's assessment:

The Dossier Submitter considered the same substances as are in the scope of the current Entry 31 of REACH Annex XVII to be in the scope of the restriction proposal. By amending Entry 31 of Annex XVII, the restriction proposal aims at reducing the health (especially for the general public) and environmental risks associated with the distribution, reuse and secondary uses of wood treated with creosote and creosote-related substances. Additionally, the second-hand market of creosote-treated wood is considered to be of special concern, because used wood treated with creosote and creosote-related substances can be and is sold in many EU Member States.

RAC conclusion(s):

- RAC concludes that the scope of the risk assessment is clearly defined and basically in line with (but clearer than) the present Entry 31 of REACH Annex XVII.
- The substances within the scope of the risk assessment are clearly described and there is a clear justification to target this group of substances.
- RAC would support retaining all creosote-like substances except creosote, wood (CAS 8021-39-4).
- The scope of the risk assessment is justified in sufficient detail and the risks to be addressed with the proposed restriction are also well described.
- The scope of the hazard assessment is justified.
- The uses within the scope of the risk assessment are clearly described and justified.

Key elements underpinning the RAC conclusion(s):

RAC notes that the restriction proposal is mainly targeted to ban any secondary use by consumers of wood treated with creosote or creosote-related substances. Secondary use is not defined in EU legislation, but it is defined in the restriction proposal by the Dossier Submitter as any use of wood treated with creosote or creosote-related products for other uses than their initial use (e.g., railway sleepers and utility poles for electricity or telecommunications used for agricultural fencing or residential landscaping).

RAC notes the diverging interpretation and application of the current wording of the Entry 31 of REACH Annex XVII by different EU Member States as well the misalignments of REACH with the new BPR provisions.

The scope of the substances targeted (creosote, CAS 8001-58-9, and eight creosote-related substances: CAS no. 61789-28-4, 84650-04-4, 90640-84-9, 65996-91-0, 90640-80-5, 65996-85-2, 122384-78-5, and 8021-39-4) is limited to the substances listed in the current Entry 31 of REACH Annex XVII. It is not possible to clearly describe all the uses that will be restricted, as they include any secondary use by the general public (consumers), for example in gardens. All uses by the general public (consumers) are considered to present a risk that

needs to be addressed.

The restriction proposal also aims at restricting the reuse of second-hand treated wood by allowing the placing on the second-hand market only in the same Member State and reuse only by professionals applying the same risk mitigation measures and for the same uses identified in the BPR (railway sleepers or utility poles). The user (actor) is elsewhere defined as any natural or legal person established in a Member State of the EU, with the purpose to stop potential transfer of treated wood to another Member State (e.g., via a daughter company, etc.).

RAC notes that a second-hand market exists and that it can be extensive in several Member States for creosote treated wood.

Creosote-treated (Grade B and C creosote) wood has been used and is presently in use, but there is no current use in the EU of the creosote-related substances included in the restriction proposal. However, as they have been used in the past for wood treatment, and may still be used in other parts of the world, such wood may still be available for secondary use, RAC supports their inclusion within the scope of the restriction. The inclusion of all the substances could be supported by the fact that all of them are already included in the current Entry 31 of REACH Annex XVII.

One of the creosote-related substances, Creosote, wood, (CAS 8021-39-4) does not share the same hazardous properties (ATSDR, 2023) since it has not been identified as carcinogenic or fulfilling PBT and/or vPvB criteria. Additionally, if a PAH-analysis would be carried out to confirm the presence of creosote in the wood (action not supported by RAC), Creosote, wood, would not be detected since it does not contain PAHs. Also, it is unclear if creosote, wood, has ever been used to preserve wood in the EU, and it is also not known if it shares the characteristic properties (e.g., typical odour) of the coal tar-based creosote and creosote-like substances. Thus, for REACH Annex XVII Entry 31, RAC would support retaining all creosote-like substances except creosote, wood (CAS 8021-39-4).

RAC considers that the information provided on uses is underpinned by reliable and relevant data from the market surveys conducted by the Dossier Submitter and from other relevant sources of information. The scope of the risk assessment is also in line with the BPR risk assessment, concluding that no safe uses can be identified when combining the outcomes of the human health and environment risk assessment. The Commission's decision to renew the approval of creosote as a biocidal active substance ((EU) 2022/1950 of 14 October 2022) specifies that creosote-based biocidal products may only be authorised for treatment by vacuum pressure impregnation of wood in industrial installations to specifically make railway sleepers, or utility poles for electricity or telecommunications[6]. The placing on the market of treated wood (railway sleepers and utility poles) is restricted to the Member States that indicate their desire by inclusion on the ECHA list. Once the treated wood is first placed on the market in the territory of a Member State on the ECHA list (as per the BPR) it could then be further distributed while still unused to a second Member State and made available on the market ("placed on the market" as per REACH definition) even though that second Member

[6] The authorisations of such biocidal products are subject to several conditions specified in the renewal, including the fact that a product maybe authorised in a Member State if the condition of the Article 5(2), point (c) of the BPR is met. The decision also specifies that 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. BPR Art.5(2)(c) states: not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

State is not on ECHA's list. However, no legislation regulates the possible further supply of the wood (while still unused) to other Member States because the BPR only covers the first placing on the market in the EU.

3.1.2. Hazard(s)

Summary of Dossier Submitter's assessment:

The Dossier Submitter provided a description of the hazards related to creosote and creosote-related substances and justified the restriction based on the non-threshold effects of these substances (carcinogenicity, PBT, vPvB), which would then require minimisation of emissions and exposures. Creosote, wood (CAS 8021-39-4), is the only exception, because it contains mainly phenolic compounds (phenol, guaiacol and cresol).

RAC conclusion(s):

- RAC concludes that the description of the identified hazards is adequate for the substances covered by the proposed restriction and considers it well justified.
- Creosote is a well-established non-threshold substance, containing constituents fulfilling the PBT and/or vPvB criteria and being carcinogenic Cat. 1B[7].
- Most creosote-related substances included in the restriction proposal are also classified as carcinogenic, with creosote, wood (CAS 8021-39-4) as the only exception.

Key elements underpinning the RAC conclusion(s):

Creosote is a complex UVCB substance containing a mixture of substances with more than 80% polyaromatic hydrocarbons (PAHs), and therefore fulfils the criteria for PBT and/or vPvB substances and for being carcinogenic (some are genotoxic carcinogens). Both properties are regarded as non-threshold properties, and minimisation of exposure and emissions are therefore warranted. Although a proper risk assessment cannot be conducted for a non-threshold substance, the risk assessment under the BPR concluded that no safe uses can be identified when combining the outcomes of the human health and environment risk assessment, further supporting the need for minimisation of emissions and exposure. Some PAHs are also classified Repro. 1B, further stressing the need for minimising exposure. Grade A creosote, containing the highest concentration of the genotoxic carcinogen benzo(a)pyrene (B(a)P), is no longer allowed to be used, but wood treated with Grade A creosote may still be in use and thus available for distribution/reuse/secondary use.

A mouse carcinogenicity study using dermal exposure to creosote (Buschmann et al., 1997) has been used in CICAD 62 to calculate a lifetime cumulative cancer risk of 10^{-4} for a daily dose of creosote corresponding to 1 ng B(a)P/kg body weight. CICAD 62 also states that this is an underestimation (perhaps by a factor of 2) and that the mixture of PAHs present in creosote seems to be five times more potent than only B(a)P.

[7] References related to hazard, risk assessment (data and conclusion) are available in the Renewal Assessment Report (RAR, January 2021) on creosote (https://echa.europa.eu/documents/10162/30f74582-6977-fd42-c24f-b366e67e9c13) supporting the BPC (Biocidal Products Committee) Opinion (December 2020): https://echa.europa.eu/documents/10162/fc41edcf-3732-2ba9-6a14-0fb9b423fd6c

Most of the creosote-related substances contain similar PAHs, and have also been classified as carcinogenic, and would probably also fulfil the criteria for PBT and/or vPvB. The exception is creosote, wood (CAS 8021-39-4) which has no harmonised or self-classification as carcinogenic and no known PBT or vPvB properties. It is not known by RAC whether there is reliable data showing that this substance lacks these properties (carcinogenicity, PBT/vPvB), but based on the available information it seems that there are no hazard reasons to keep creosote wood in the restriction. The substance/mixture contains mainly phenolic compounds.

3.1.3. Emissions and exposures

Summary of Dossier Submitter's assessment:

The Dossier Submitter provided an estimate of the volumes of railway sleepers treated with creosote reused in the EU. It was not possible for the Dossier Submitter to quantify the emissions from creosote-treated wood (during reuse and secondary use) of PAHs with PBT and/or vPvB and carcinogenic properties. However, releases and exposure were considered likely during the entire service life of the creosote-treated wood. Therefore, the Dossier Submitter concluded that emissions from the uses in the scope are not minimised and that especially exposure of the general public to non-threshold carcinogens would need to be minimised, because creosote-treated wood is available on the market in many EU Member States.

RAC conclusion(s):

- RAC concludes that the manufacture, import, export and uses of creosote-treated wood are clearly identified and described in the Background Document.
- In spite of a lack of adequate quantitative data on emissions from creosote-treated wood during reuse and secondary use, RAC supports that releases and exposure are likely, and maybe inevitable, during the service life of the creosote-treated wood (BPR-RAR reports provides some data on release).
- Creosote-treated sleepers are available on the market in many EU Member States resulting in a widespread potential for emissions and exposure to PAHs.[8]

Key elements underpinning the RAC conclusion(s):

RAC notes that the Dossier Submitter has performed an estimation of the reuse volumes of creosoted railway sleepers in the EU.

The restriction proposal does not provide any estimates of releases or emissions of PAHs fulfilling the PBT and/or vPvB criteria and having carcinogenic properties from creosote-treated wood. However, the Dossier Submitter states qualitatively that during service life leaching occurs and depends on many factors in the local environment. It is also stated that leaching will continue as long as the wood is intact and protected by creosote, and that it may continue for a long time considering a service life of at least 20 years. The BPR Renewal

[8] Railway sleepers treated with creosote may be placed on the market in 23 Memeber States and in Northern Ireland and Switzerland.
Utility poles treated with creosote may be placed on the market in 13 Memeber States and in Norway and Northern Ireland.
Lists of Member States where wood treated with creosote may be placed on the market for certain uses in accordance with Commission Implementing Regulation (EU) 2022/1950
https://echa.europa.eu/documents/10162/988147/creosote_PT8_ms_lists_referred_specific_conditions_in_implementing_regulation_en.pdf/f029cfc8-6822-ef36-f49c-53fa555497eb

assessment report (RAR)[9] the following figures for release of creosote from treated wood: for the first 30 days there is a daily leakage of 0.366 mg/m^2/day, with a cumulative leakage of 11 mg/m^2. For 20 years of service life the leakage is 0.051 mg/m^2/day, resulting in a cumulative leakage of 384 mg/m^2. RAC acknowledges the limited amount of quantitative data on releases of PAHs fulfilling the PBT and/or vPvB criteria and having carcinogenic properties, but supports that releases are likely during the service life (affecting both the environment and humans) of the creosote-treated wood and that they need to be minimised. Release of PAHs from old railway sleepers is also supported by the finding of small, water-soluble PAHs in olives grown in a garden where a fence was built using old creosote-treated railway sleepers (Moret et al., 2007).

RAC notes that reuses or secondary uses that may give rise to exposure are not fully described, but it is clear from the available information that creosote-treated wood (railway sleepers and utility poles for electricity or telecommunications) can be reused if the condition of the wood allows it. As such treated wood is sold in many EU Member States, a wide variety of secondary uses resulting in environmental and direct human exposure to PAHs fulfilling the PBT and/or vPvB criteria and having carcinogenic properties are likely, and even inevitable. The implementation of reuse and secondary use practices has been reported for some EU Member States.

These secondary uses seem to mainly involve wood primarily used as railway sleepers, and sometimes utility poles. The secondary use of creosote-treated wooden utility poles for fencing, as tree support poles or in harbours and waterways, is considered limited due to the poor condition of the material at the end of its service-life as utility poles.

A WHO document (CICAD 62, 2004) mentions that "as much as 75% of creosote applied to marine pilings will remain in the wood after 40 years of service". However, RAC has not been able to scrutinise this information, but it may support that releases of creosote can continue for a long period.

CICAD 62 (2004) also mentions two studies showing the presence of PAHs (including carcinogenic benzo(a)pyrene) in old railway sleepers, with one German study measuring PAHs in five sleepers of unknown age that were used on a playground (Rotard and Mailahn, 1987) and one Canadian study measuring PAHs in at least 60 years old railway sleepers taken out of service (Gurprasad et al., 1995).

3.1.4. Risk characterisation

Summary of Dossier Submitter's assessment:

The Dossier Submitter could not quantify the environmental and human health risks from the reuse and secondary uses of creosote-treated wood but concluded that such risks should be minimised. Therefore, a qualitative risk characterisation was performed based on the non-threshold properties of the targeted substances.

RAC conclusion(s):

- RAC agrees that the creosote and creosote-related substances containing constituents

[9] References related to hazard, risk assessment (data and conclusion) are available in the Renewal Assessment Report (RAR, January 2021) on creosote (https://echa.europa.eu/documents/10162/30f74582-6977-fd42-c24f-b366e67e9c13) supporting the BPC (Biocidal Products Committee) Opinion (December 2020): https://echa.europa.eu/documents/10162/fc41edcf-3732-2ba9-6a14-0fb9b423fd6c

fulfilling the PBT and/or vPvB criteria and having carcinogenic properties should be considered as non-threshold substances for the purpose of risk assessment and that a quantitative risk characterisation is not appropriate.

- RAC also agrees that emissions should be minimised and the effects of exposure to non-threshold carcinogens should be avoided. As provided in section 3.1.3, the current uses cause emissions and exposure and RAC therefore concludes that there is a risk that needs to be addressed.
- The environmental and human health risks from the non-threshold PAHs in creosote-treated wood cannot be quantified but they are expected to be wide-spread and therefore need to be minimised by regulating distribution, reuse and secondary use of such treated wood.

Key elements underpinning the RAC conclusion(s):

All uses of creosote-treated wood led to emissions of PAHs fulfilling the PBT and/or vPvB criteria and having carcinogenic properties. The initial placing on the market is regulated under the BPR. However, distribution, reuse and secondary uses of creosote-treated wood is not regulated by the BPR, but by REACH.

Creosote is a non-threshold substance because of the PBT and vPvB and carcinogenic properties due to the composition of PAHs in the substance. Minimisation of emissions and exposure is therefore needed according to REACH. Emissions and exposure to PAHs are not quantified in the restriction report but are likely considering that leaching of PAHs may occur during the entire service life, including during distribution (transport and storage), reuse or secondary use in, e.g., in gardens and parks (see Section 3.1.3.). The general public (consumers) may thus be exposed to PAHs with PBT and vPvB and carcinogenic properties, and all exposure, including dermal exposure, to creosote-treated wood should therefore be avoided. Banning the secondary use by the general public would prevent such exposure and therefore would ensure that effects are avoided. There is also potential environmental exposure to PAHs with PBT and vPvB properties that needs to be minimised.

The risk cannot be quantified, but as any exposure to these non-threshold substances should be minimised, environmental and human exposure can be minimised by regulating reuse and banning all secondary uses of creosote-treated wood. Reuse is believed to be conducted by professionals trained for the purpose and with access to information on how to protect themselves and appropriate personal protective measures (see section 3.4.2).

3.1.5. Existing operational conditions and risk management measures already in place

Summary of Dossier Submitter's assessment:

No sufficient and/or effective operational conditions (OCs) and risk management measures (RMMs) were identified by the Dossier Submitter to control the identified risks, especially for the general public.

RAC conclusion(s):

RAC concludes, based on the information provided in the Background Document, that the currently recommended and implemented operational conditions (OCs) and risk management measures (RMMs) are most likely absent (for consumers), or not sufficient or effective to control the risk.

Key elements underpinning the RAC conclusion(s):

RAC is not aware of any OCs and RMMs implementable by the general public (consumers) or recommended by the manufactures and/or importers, that could decrease the risk during distribution, reuse or secondary use, and even if such information were provided (on the packages) when buying the products, it is most likely not available after ≥ 20 years of use in the environment. If re-use is restricted to the original actor, information may still be available, but if reuse by other actors would be allowed (requiring removal of the creosote-treated wood, transport and perhaps storage), such information may not be available. In all reuse, professional users must make sure to apply the same risk management measures as identified in accordance with the renewal of approval of creosote as a biocidal active substance Commission Regulation (EU) 2022/1950 of 14 October 2022) (see first point of the Explanatory notes).

RAC notes that there is a risk for emissions and exposure to PAHs from old creosote-treated wood during reuse or secondary use of creosote-treated wood. The BPR regulates the placing on the market of the treated wood and requires labelling of creosote-treated wood aiming to protect human health and the environment, but it is doubtful that any information provided when the products are new will be available after ≥ 20 years of outdoor use.

Articles consisting of wood treated with creosote and creosote-related substances, when coming to the end of their life (discarded, intended or required to be discarded) fall within the scope of the Waste Framework Directive (2008/98/EC) and shall be considered and processed as hazardous waste. However, the exact practices in all the EU Member States are not elaborated further by the Dossier Submitter and thus not known to RAC. However, RAC notes the clarification by the Dossier Submitter that also creosote-treated wood in use in secondary applications should be treated as hazardous waste. The current restriction proposal sets special emphasis to consider wood treated with creosote or creosote-related substances at the end of its life cycle as hazardous waste and must be disposed of accordingly (incinerated).

3.1.6. Existing regulatory risk management instruments already in place

Summary of Dossier Submitter's assessment:

The Dossier Submitter clarified in the Annex XV report why the existing regulatory management measures in the EU are not sufficient to control the identified risks. This took into account the lack of clarity of the current Entry 31 of REACH Annex XVII, which appears to be interpreted in different ways in different Member States. Action is also needed to avoid misalignments of the Entry 31 of Annex XVII with the new BPR provisions (Commission Implementing Regulation 2022/1950 of 14 October 2022). In addition, the BPR covers the first placing on the market only and not the subsequent supplies.

RAC conclusion(s):

Distribution, reuse and secondary uses of creosote-treated wood are in principle regulated by REACH (and not by the BPR), but the wording of the current Entry 31 of REAC Annex XVII is interpreted or applied differently among the EU Member States, indicating that existing regulatory management measures are not sufficient to control the risk.

Key elements underpinning the RAC conclusion(s):

The BPR regulates the treatment of wood with creosote and the supply of newly treated wood (the first placing on the market). The original proposal did not address subsequent supplies of the newly treated wood that would not be considered as secondary use or part of the

second-hand market. See section 1.2 and the Explanatory notes for further information.

Distribution, re-use, or secondary uses or the second-hand market are not regulated by the BPR, hence the need for a restriction under REACH (Entry 31 of Annex XVII). In theory, the current REACH regulation should be adequate to control the risk, but there are problems with loopholes and possibilities for diverging interpretations of the wording of the Entry 31 of Annex XVII. Thus, distribution, reuse, secondary uses and second-hand market are either not regulated or are regulated differently among the EU Member States, indicating that existing regulatory management measures are not sufficient to control the risk.

3.2. JUSTIFICATION THAT ACTION IS REQUIRED ON A UNION WIDE BASIS

Summary of Dossier Submitter's assessment:

The Dossier Submitter concluded that action is required to ensure a high level of protection at the EU level, addressing the risks associated with reuse, secondary use and second-hand market of wood treated with creosote or creosote related substances especially by the general public (consumers). The restriction proposal made by the Dossier Submitter is also intended to complement the current BPR provisions.

The Dossier Submitter considered it to be a potential for uncontrolled circulation of creosote-treated wood within the EU as it is not labelled or registered and because there is evidence of the existence of informal sales networks for creosote-treated wood in the EU.

RAC conclusion(s):

Based on the key principle of ensuring a high level of protection and a level playing field across the EU, RAC concludes that any necessary action to address the risk(s) associated with the secondary use and reuse of creosote and creosote related substances should be implemented in same manner by all Member States.

Key elements underpinning the RAC conclusion(s):

Currently recommended and implemented OCs and RMMs as well as national measures are not sufficient and effective at controlling the risk in all Member States (uneven application of the Entry 31 of REACH regulation). Risk management action on an EU wide level is needed by minimising emissions and exposure of creosote and creosote-related substances especially to the general public (consumers) and to the environment. In addition, this measure would complement ideally the current BPR provisions applicable to wood treated with creosote or creosote related substances.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3. ANALYSIS OF ALTERNATIVES

3.3.1. Availability and technical and economic feasibility of alternatives

Summary of Dossier Submitter's assessment:

With regard to the Dossier Submitter's approach to the analysis of alternatives, it should be noted that the analysis of and conclusion on the applicability of chemical and non-chemical alternatives as suitable alternatives to creosote is heavily derived from the assessment performed in the context of the BPR. The BPR-related analysis of alternatives already looked at alternatives available for the first placing on the market of creosote for the treatment of wood, which are the same alternatives that are also considered relevant for reuses and secondary uses of treated wood.

In terms of scope, the analysis of alternatives presented in the context of this restriction proposal mainly focuses on the *reuse* of creosote-treated railway sleepers. This is because the condition of creosote-treated utility poles is reported to be too poor in most cases to allow further reuse after their first use and extraction. Thus, there should not be a need to find alternatives specifically for the reuse of utility poles. Moreover, the ban of all secondary uses is already considered justifiable as per the BPR-related alternative assessment. This assessment resulted in the withdrawal of the legal basis for the first placing on the market of creosote for all other uses than railway sleepers and utility poles. In other words, as the first use of freshly creosote-treated wood for these other uses (e.g. agricultural fencing) is not allowed due to the availability of suitable alternatives, it can be considered that the transition to technically and economically feasible alternatives is also possible in the context of secondary uses of recycled railway sleepers and utility poles[10].

In terms of the technical performance requirements of alternative substances or technologies, the Dossier Submitter reports a service life of more than 30 and up to 60 years for railway sleepers and utility poles. The service life (or durability) in turn can be affected by several factors, such as natural decay processes, but also resistance to temperature and humidity fluctuations. In addition, the Dossier Submitter considers the compatibility of alternatives with existing characteristics of the use location (e.g. weight, conductivity and other factors relevant from an engineering point of view). Economic considerations consider the costs of using alternatives which include installation costs, monitoring costs, intervention costs, and tamping costs.

Different chemical and non-chemical alternatives to creosote and creosote-treated wood have been identified, some of which are already commercially available on the market and partly also used already. One of the most promising **chemical alternatives** was identified to be copper hydroxide (incl. copper-water-based wood preservatives, e.g., Tanalith E and Impralit, and copper-oil-based wood preservatives, e.g. Tanasote S40) because it is reported to be relatively affordable. However, there are remaining doubts about technical feasibility in terms of comparable durability.

Non-chemical alternatives include concrete or reinforced concrete, steel, and composite plastic. Concrete material is reported to be an alternative already widely used for utility poles and for railway sleepers; however, consultation responses indicate that, especially in the case of railway sleepers, the economic feasibility of further extending the use is in question. The use of concrete sleepers may require costly modifications in order to accommodate this kind

[10] In the context of uses of creosote-treated wood other than railway sleepers and utility poles, it is useful to note that not only the recycling of railway sleepers and utility poles for such purposes is restricted, but also the reuse of creosote-treated wood specifically marketed for these uses in the past is banned by the proposed restriction. Alternatives for this type of reuse are likewise considered to be covered by the BPR-related analysis of alternatives.

of sleepers on the track and possibly increased maintenance activity. In some locations, the track location or design may not be suitable at all for the use of concrete. The price of composite plastic is also reported to be a concern as it is indicated that the price is four times higher than for wood.

Furthermore, current and future decisions concerning creosote approval and conditions for marketing of creosote-containing products at EU or national level, directly affect the availability and users' choice of alternatives in the context of reuse. The availability of **newly creosote-treated wood** plays an important role for railway sleepers because it means that railway companies in some countries can substitute the reuse of treated sleepers with the acquisition of newly treated sleepers. The renewed approval of creosote as an active biocidal substance was granted in 2022 and creosote-containing biocidal products may thus be authorised by EU Member States for impregnation of railway sleepers and utility poles where no suitable alternatives are available in the national context.

In regard to the adoption likelihood of the different alternatives, the assessment is impacted by considerable uncertainties. The use of concrete sleepers (and utility poles) was reported to be widespread already, yet the Dossier Submitter seems to find limited potential for this alternative to spread further in the context of use as sleepers. This is because concrete is not considered technically and economically feasible for all users and/or all use cases (e.g. specific tunnels, bridges, tight curves, switching points, low traffic lines or areas of temperature and humidity fluctuations). In contrast to this, a lighter material like wood is considered the more suitable option from technical and economic point of view. The Dossier Submitter considers newly creosote-treated wood to be a likely used alternative for the reuse of creosote-treated railway sleepers in relevant EU Member States. This is based on the durability and cost at the time of Dossier development. However, at the time of Dossier preparation, it was not clear yet how many and which Member States would continue to allow the first placing on the market of creosote for use on sleepers and utility poles at national level. It is stated that, if the reapproval of the creosote use under the BPR had not come into effect, copper hydroxide could have become an important alternative. Previously, chemical alternatives to creosote impregnation (e.g. water- or oil-based copper hydroxide products) seem to have been considered less attractive due to limited commercial availability, lower wood protection potential, higher prices, or other effects such as ignitability, conductivity or similar risk profile. Yet, the Dossier Submitter considers that chemical alternatives show potential to become preferred alternatives as research and development efforts continue and economies of scale (resulting from increased adoption) may lower their price. For the time being, the Dossier Submitter seems to assign slightly higher potential to composite plastic sleepers, which could be considered more user-friendly than concrete and more durable than copper hydroxide, but still more expensive than newly creosote-treated wood.

A transitional period of 12 months after entry into force of the proposed restriction is proposed by the Dossier Submitter.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.3.2. Risk of alternatives

Summary of Dossier Submitter's assessment:

The Dossier Submitter has not re-assessed alternatives in detail, but refers to the BPR. Based on the BPR assessment, the Dossier Submitter concluded that the main alternative is still to be considered creosote.

RAC conclusion(s):

- There are different chemical and non-chemical alternatives for different uses, but creosote is the mostly used substance for newly treated wood. As the content of creosote (i.e., PAHs) in the wood decreases with time (e.g., due to leakage), the potential risk from newly treated wood is generally higher than from old wood treated with creosote (this general rule of thumb would not apply if the wood is handled incorrectly by someone not trained or not following advice on how to protect himself).
- Risk of alternatives to creosote has been discussed under the Biocidal Product Regulation and the risk assessment of alternatives has not been conducted in this restriction proposal.

Key elements underpinning the RAC conclusion(s):

The approval of biocidal active substances and authorisation of biocidal products for wood protection (PT08) is a responsibility of the BPR. As the authorisation of biocidal alternatives to creosote is only within the remit of the BPR (and not REACH), the Dossier Submitter has not re-assessed alternatives in detail, but refers with regard to biocidal alternatives' assessment to the BPR (Opinion on the application for renewal of the approval of the active substance ECHA/BPC/274/2020). At present, the BPR has approved 28 chemicals for wood protection, but only few of them are possible alternatives for creosote. The restriction report concludes that although alternatives for sleepers and transmissions poles include copper-based preservatives, concrete, steel, and plastics, there is no drop-in alternative. According to the restriction report, these alternatives are either not yet fully developed, less flexible in use, and more expensive (Table C-1 of the restriction report). The only socio-economically suitable alternative is wood newly treated with creosote. Copper-based preservatives may be affordable but have not been assessed. If they would be introduced, copper is much less toxic to humans, for instance by not being carcinogenic. However, copper may be toxic to the environment, depending on amount released from the wood. Thus, if restricting wide-spread reuse of creosote-treated wood (mainly sleepers), the most realistic alternative seems to be use of wood newly treated with creosote in line with the BPR-approval of creosote. Exposure to creosote and thus the risk could increase unless the workers apply appropriate risk management measures (see section 3.4.2). However, there is development of alternatives and plastic sleepers are now approved and used in at least one Member State (#3948). The approval is based on them being economically feasible in comparison with newly treated creosote sleepers. In contrast, they may not be economically feasible for (touristic) railways using cheaper, reused creosote-treated sleepers. There is also information from another Member State that the state railway uses concrete and steel sleepers where technically feasible (#4295). Thus, some alternatives are available, but the use of alternatives seems to be dependent on economic feasibility for the individual railroad.

3.4. JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Summary of the proposed restriction

Creosote-treated wood is already subject to some regulatory provisions. The first placing on the market of creosote-treated wood (incl. import) is in the remit of the BPR regulation. The subsequent placing on the market is in the remit of REACH and is currently regulated by entry 31. The risks identified by the Dossier Submitter are intended to be addressed by the proposed restriction.

Two different restriction options (ROs) have been assessed by the Dossier Submitter:

- RO1: Ban on all reuses and secondary uses of creosote-treated wood authorised under BPR and already placed on the market.
- RO2: Ban on all secondary uses of creosote-treated wood authorised under BPR and already placed on the market with reuses being allowed solely for the same use as the original use, in the same country, under similar conditions and by the same original user.

Both RO1 and RO2 are considered to entail positive environmental and human health impacts compared to the baseline by eliminating all secondary uses, which are especially relevant for exposure of the general public. Both RO1 and RO2 yet allow residual risk for the environment and human health, as the risk of the original use would stay unchanged. The extent to which the residual risk of RO2 is expected to differ from that of RO1 is considered to be strongly affected by the availability of alternatives. The possibility to use newly creosote-treated wood as an alternative to reuse, would reduce the advantage of RO1 in terms of risk reduction. Since newly treated wood is indeed expected to be available as an alternative, the Dossier Submitter considers that RO1 would likely increase the use of newly creosote-treated wood and chooses RO2 as the preferred restriction option (also taking into account qualitative socio-economic arguments and principles of recycling and circular economy). A transitional period of 12 months after entry into force of the proposed restriction is proposed by the Dossier Submitter.

The proposed restriction includes the following conditions:

- Ban on the placing or making available on the market (incl. import) of all creosote-treated wood with the active substance creosote and substances covered by the entry 31 at the exemption of creosote (Grade B and Grade C creosote as specified in European Standard EN 13991:2003, EC:232-287-5, CAS: 8001-58-9) specifically approved under the BPR.
- Creosote-treated wood will be allowed to be reused solely by the same user in the same Member State and for the same use as specifically allowed under the BPR (e.g. railways sleeper reused as railway sleeper, communication pole reused as communication pole).
- To help the enforceability and monitorability, it is suggested that a permanent labelling of creosote-treated wood with the appropriate information regarding hazards, risk mitigation measures and allowed follow-up of treated articles is discussed under the BPR while authorizing the first placing on the market.
- At the end of life, all creosote-treated wood (even if treated before December 2002) must be disposed under the Waste Framework Directive (WFD, 2008/98/EC) as hazardous waste.

- No secondary use and second-hand market of creosote-treated-wood will be authorized (not even for wood treated before December 2002). The creosote-treated wood already used in secondary application needs to be disposed under the Waste Framework Directive (WFD, 2008/98/EC).

The Dossier Submitter considers the proposed restriction to be the most appropriate EU wide measure to address the identified risk by virtue of its effectiveness, practicality (including enforceability) and monitorability.

3.4.1. Regulatory risk management options other than restriction

Summary of Dossier Submitter's assessment:

The Dossier Submitter conducted an analysis of risk management options (RMOs) to identify the most appropriate measure to address the identified risks. The RMOs assessed included regulatory measures under REACH other than restriction (as SVHC identification (REACH Article 57) and listing on Annex XIV) and labelling requirements. However, all options were not considered as being appropriate.

RAC conclusion(s):

There are no other regulatory risk management options that would effectively address the risks referred to in the restriction proposal arising from the distribution, reuse and secondary uses of creosote-treated wood.

Key elements underpinning the RAC conclusion(s):

The BPR only covers the first placing on the market of creosote-treated wood articles. Creosote-treated wood subject to distribution, reuse or secondary use prior or after being on the second-hand market falls under REACH regulation specifically with regard to the risks to the general public and the environment. The proposed REACH restriction (option 2) and even more so the SEAC's option 3 are considered complementary to the risk management measures for professionals under the BPR and would address the uneven application of the Entry 31 of REACH by Member States.

With regard to the loophole of the distribution (the further supply) of newly treated wood in the EU after the first placing on the market, see section 1 and Explanatory notes.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.2. Effectiveness in reducing the identified risk(s)

Summary of Dossier Submitter's assessment:

The Dossier Submitter proposes two restriction options (option 1 and option 2).

Option 1 restricts all reuse and secondary use of creosote treated wood permitted under the

BPR and already placed on the market.

Option 2 introduces a derogation as follows: the reuse should occur under similar conditions as specified under the BPR for the same use in the same Member State and by the same original user and would ban all secondary uses. The Dossier Submitter considers option 2 as being appropriate to address the identified risks, although not being able to quantitatively quantify the benefits, mainly aiming at protecting the general public. Professional users are already subject to/aware of the risk management measures defined under the BPR for use of creosote-treated wood.

RAC conclusion(s):

- RAC agrees to address the creosote-related substances containing constituents being carcinogenic or fulfilling PBT and/or vPvB-criteria.
- RAC concludes that the proposed restriction is targeted to the exposures causing the identified human health and environmental risks.
- RAC concludes that the risk management measures and operational conditions associated with the derogation (Option 2 and the SEAC's new option 3) are appropriate and effective for the original and/or professional user as all reuse or secondary use will be banned for the general public.
- RAC notes that the human health or environmental risks resulting from the first placing on the market of creosote treated wood are addressed under the BPR.
- RAC considers that if reuse by other actors will be allowed, a permanent labelling should be introduced (e.g., in the form of durable engraved steel plates).
- For a more effective enforcement a requirement to keep the documents on the creosote-treated articles until their end of life could be placed on the users as part of the restriction proposal.
- RAC concludes that a transition period of 12 months is appropriate for the restriction proposal.

Key elements underpinning the RAC conclusion(s):

The proposed restriction aims to amend the current Entry 31 under REACH, being not aligned with the renewal of the approval of creosote as an active biocidal substance under the BPR.

Option 1 restricts all reuse and secondary use of creosote treated wood authorised under BPR and already placed on the market.

Option 2 introduces a derogation as follows: the reuse should occur under similar conditions as specified under the BPR for the same use (as primary use), in the same Member State and by the same original user and would ban all secondary uses. The BPR already regulates the biocidal use of creosote and the placing on the market of the treated wood and requires labelling of new creosote-treated wood when made available on the market for the first time, including risk management and waste treatment instructions. The original users are assumed to be aware of the BPR conditions which would make it easier to apply the RMMs and OCs regarding the specific labelling as well as the waste handling requirements.

RAC notes that the Dossier Submitter argues that such derogated reuse under controlled conditions will allow to limit or avoid the amount of newly treated wood on the market. According to the Dossier Submitter, the derogation should be effective as long as the reuse is limited to the same actor in the same Member State, as the user is the same professional aware of, and following, the conditions defined under the BPR for newly creosote-treated

wood[11].

RAC takes also note of the additional restrictions option (option 3, 4 and 5) evaluated by SEAC considering the potential re-use of wood treated with creosote by other professional users than the first user, either for the same use under the same conditions as defined in the BPR (option 3) or for any secondary use (option 4 and 5).

Option 3 (see below), proposed by SEAC, addresses the human health and environmental risks by banning secondary uses but allowing reuse by both the original user and other professional users in the same Member State and under the same conditions as defined by the BPR for workers and the environment[11]. SEAC believes the benefits of the restriction

[11] The renewing of the approval of creosote as an active substance for use in biocidal products (EUR-Lex - 32022R1950 - EN - EUR-Lex (europa.eu)) states in preamble point 14 that "….*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. ... 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."* and in point 20 that *"…..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,…."*
The Biocidal committee opinion (Opinion on the application for renewal of the approval of the active substance: Creosote https://echa.europa.eu/documents/10162/fc41edcf-3732-2ba9-6a14-0fb9b423fd6c)further) specify the risk management measures workers need to consider:
- Stringent adherence to the protective measures that are already in place.
- The PPE should be changed frequently, and immediately after contamination.
- The personal hygiene shall be strict and washing with suitable cleaning solutions shall be performed as soon as possible after each work task where there is a risk of exposure.
- Risk of exposure means direct skin contact or inhalation of the vapours. However, risks vary depending on the construction of the plant and during non-routine activities. Risks can, for example, occur when opening and maintaining of the vessel or entry into treating or preservative storage vessels. In these cases, additional protection can be advised.
- Respiratory protection, such as a full face mask with particle filter P2 or preferably P3 in combination with gas filter A (brown) should be worn at critical work tasks when there is a risk of inhalation exposure.
- Chemical resistant (coated) coveralls, or equivalent, should be worn over the regular work clothes at critical work tasks when there is a risk of exposure, and a thinner pair of (cotton) gloves should be worn under the chemical resistant gloves.
- Sky lifts (aerial access platforms) shall be used if feasible/whenever possible.
- Whenever possible, mechanical or automated processes should be used to avoid manual handling of treated timber (including down-stream work, for example during work with poles in service).
- Creosote-resistant boots should be worn when entering the vessel (e.g. for cleaning or maintenance).
- In order to ensure efficient protection, tight sealings (sleeve capes) may be used at the border of different garments, e.g., at the border of gloves and sleeves and at the border of trousers and boots.
- Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.
- All activities with treated timber must be undertaken at industrial sites where application processes must be carried out within a contained area; situated on impermeable hard standing, with bunding to prevent run-off and a recovery system in place (e.g. sump), and 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 of the product shall be collected for reuse or disposal.
- All treatment of timber must be undertaken within the industrial impregnation facilities on an impermeable surface or in case of brushing the wood components modified after standard vacuum pressure treatment at a construction site outdoors where soil is protected with a plastic foil or tray.
- Any spill or contaminated material must be collected and disposed as hazardous waste.
- It is agreed by the BPC members that additional risk mitigation measures are required; these are to prevent leakage into ground and to minimise contact of the general public with creosote treated material.
- In case of storage of creosote treated timber (temporarily) at other sites than impregnation facilities (e.g. the readiness stocks of transmission poles at the site of installation), the timber should be stored on an impermeable hard standing or on an absorptive material (e.g. bark) as well as under shelter (e.g. roof or covered with a tarpaulin), and if stored in residential or recreational areas an access by general public should be restricted (e.g. using a fence or a cover).

option 3 (reuse is substituted by use of newly creosoted wood articles) are greater than benefits of the Dossier Submitter proposal restriction option 2.

RAC notes that e.g., some railway companies, previously depending on buying cheap, old creosote-treated wood for reuse, now may buy new creosote-treated wood. Choosing new creosote-treated wood is possible according to the BPR if the Member State is accepting the placing on the market, which potentially would increase environmental releases as newly treated wood is expected to release more creosote than old, treated wood, thus increasing the risk to the environment and possibly to humans via the environment for PAHs. There is, however, no risk expected to workers as the BPR requires certain risk mitigation measures and the Biocidal Committee opinion further specifies the risk management measures workers need to consider (see footnote 9). Professional users are also expected to understand and/or have access to information on the risks and what measures to take to protect themselves.

An advantage with restricting reuse to the same use in the same Member State is that trade with old creosote-treated wood between Member States is stopped, and thus resulting in an increased control. An increased control will reduce the possibilities for any user to purchase old creosote-treated wood (for instance via the internet), which reduces risks to the general population (mainly through diminished exposure to carcinogenic PAHs).

As regards risk, it is a matter of weighing the carcinogenic risk to the general public and the environment caused by the wider dispersive second-hand use of old treated wood, i.e. having less control versus the known risk to the environment and man via the environment through the use of more newly creosote-treated wood. In the view of RAC, an increased control of old creosote-treated wood and reduced cancer-risk is assessed as more important than any increase in controlled use. The reason being the high carcinogenic potency of PAHs and that only a very small daily exposure is needed to cause an unacceptable cancer risk.

Of the two proposals prepared by the Dossier Submitter, RAC supports the DS-proposal (option 2) to only allow reuse:

- by same actor in
- the same Member State and for
- the same use as specifically allowed under the BPR.

RAC notes that SEAC has proposed a new option 3, which they consider to be the most proportionate restriction option that maximises the health and environmental benefits while minimising the costs. SEAC notes that a derogation conditional on proper buyer verification and the use of adequate risk mitigation measures could achieve similar health benefits as the ban of reuse by other professional users, while simultaneously increasing environmental benefits relative to option 2 if the alternative is newly treated wood. This is because there would be lower release into the environment in the case of reuse compared to the alternative use of new creosote treatment.

RAC supports option 3 as professional users are expected to be aware of the required risk management measures. Additionally, reuse of articles is in line with the waste hierarchy and beneficial to the environment.

RAC considers that a permanent labelling requirement (e.g., in the form of durable engraved steel plates) on each old creosote treated wooden object would increase available information and enhance controls on old creosote-treated wood.

The users are assumed to keep the necessary documentation proving to enforcement authorities that they did not sell treated wood to general public users, but only to other professional companies in the same Member State. Enforcement could most likely be achieved

through documentation on acquisition, sales and/or disposal of treated articles by users and audits via surveillance programs by national enforcement authorities and existing reporting systems.

RAC notes that there are probably no requirements to keep the required documentation for the duration of the life cycle of the treated wood articles (for 20 years or more), and lack of documentation as well as the long timeframe of the activities would further complicate enforcement in practice. For more effective enforcement a requirement to keep the required documents on the creosote-treated articles until their end of life could be placed on the users as part of the restriction proposal. This would also ensure that professional users receive relevant information on human health and environmental risks as well as conditions and risk mitigation measures. The BPR addresses the risk to human health and the environment for the original users. The associated risks are assessed under the BPR for humans and the environment for BPR-allowed uses (as railway sleeper and transmission pole) in the EU for the service life (of 20 years) of the treated article.

The proposed restriction does not address any additional uses or processes that need to be applied other than already regulated under the BPR for the original users. Alternatives are to some extent available and in use and, where not, newly creosote-treated wood is still available. Therefore, the transition period of 12 months proposed in this restriction proposal is assumed sufficient and need not to be longer as the restriction proposal aims to modify the current Entry 31 in REACH Annex XVII.

3.4.3. Socioeconomic analysis

3.4.3.1. Costs

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.3.2. Benefits

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.3.3. Other relevant impacts

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.3.4. Proportionality

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.4. Practicality, including enforceability

Summary of Dossier Submitter's assessment:

The proposed restriction is considered by the Dossier Submitter practical since it is implementable, manageable and enforceable. Factors considered by the Dossier Submitter include: secondary uses of creosote-treated wood are already partly restricted under the Entry 31 of Annex XVII, the proposed restriction is easy to understand and communicate down the supply chain to affected parties, enforcement authorities are already enforcing the Entry 31.

RAC conclusion(s):

- RAC concludes that the proposed restriction options 1-3 are practical in terms of implementation and manageability. RAC supports SEACs' additional option 3 taking into account the risk reduction for the general public while still allowing re-use under controlled conditions that will reduce exposure and limit the occurrence of creosote-treated wood on the second-hand market.
- RAC agrees with the Dossier Submitter that the proposed restriction is easy to understand and communicate down the supply chain and can be enforced. Enforceability can be improved by ensuring a better access to documentation. The wording of the restriction should be improved to avoid misinterpretations, as suggested the restriction conditions.
- Overall, the restriction proposal can be considered enforceable as it can be expected that the authorities are capable of setting up efficient supervision mechanisms to monitor the involved actors compliance with the proposed restriction.

Key elements underpinning the RAC conclusion(s):

Option 1 addresses all risks related to reuse and secondary-use by introducing a complete ban of these uses. However, risks from newly treated creosote-wood are not addressed as this is covered by the BPR approval renewal (Regulation (EU) 2022/1950).

Option 2 also bans secondary use but allows reuse by the same actor in the same Member State under same conditions as the primary use. Risks from reuse by the same actor are not addressed as it is assumed that the actor is aware of and uses the same risk management measures requested by the BPR approval renewal for the newly creosote-treated wood.

Option 3 proposed by SEAC, allows reuse for other professional users in the same Member State under the same conditions as proposed by the BPR.

Options 1 and 2 both discuss proper risk and waste management recommendations in the form of labelling, but labelling is not part of the restriction text. This labelling can according to the restriction proposal be a physical one, such as an engraved steel plate, a bar code, a QR code or can be a more technological one, such as a NFC or RFID chip. BPR-required "labels, and where provided, safety data sheets", should give a lot of information on how to handle newly creosote-treated wood, but contains no information for later use or how the labels should look like. RAC is therefore unsure if the recommended risk reduction measures will be available at the time of reuse (allowed in option 2 and 3) after the life cycle of the creosote-treated wood (ca 20 years for sleepers).

The Dossier Submitter also argues that the communication on risks could increase if a labelling is developed under the BPR for creosote-treated wood for waste management. The same uncertainty on the longevity of such labelling after the life cycle applies here, and if not present after some 20 years it would not achieve the purpose of better communication. If instead a permanent labelling would be required, it would also improve the enforceability when it is considered that these articles could be followed all along their service life and would ensure a proper follow up especially at their end of life solely based on the labelling presented on the wood. However, as noted above, the BPR requirement on labels does not require the labels to be permanent or connected to each treated piece of wood (e.g., each sleeper).

RAC notes that the techniques for appropriate hazardous waste management for restriction options 1-3 are available (i.e., incineration of hazardous waste).

RAC notes the issue of the current Entry 31 of REACH with regards to the difficulties in the enforceability of wood treated with creosote or creosote related substance before 31 December 2002 as it is considered impossible to distinguish or determine the date when the wood has been treated with a specific substance and it is difficult to determine the chemical identity of the exact substance the wood has been treated with.

The restriction proposal is overall aiming for improvement of the current Entry 31 of REACH Annex XVII and can be considered manageable as all the involved actors (the industry and the authorities) would suffer no additional administrative burden. RAC notes that for better understandability and with a reference to paragraph 3 of the conditions proposed for the restriction option 2, the definition of 'original user' should be further elaborated. RAC also notes that the proposed conditions and risk management measures applicable for professional users must be clear for the other actors as well.

RAC notes that the restriction is implementable as it mainly aims at amending the current Entry 31, the involved actors are well aware of the conditions for use under the BPR for creosote treated wood, and alternatives or newly creosote-treated wood are available for those that are no longer able to reuse creosote-treated wood (e.g., sleepers).

The Dossier Submitter notes that the secondary uses of creosote treated wood are already partly restricted under the current Entry 31. In addition, the proposed restriction gives sufficient time to the impacted supply chains to transition. The restriction proposal mentions a transition period on 12 months, which RAC supports.

Regarding paragraph 2, the Forum has doubts whether the restriction applies to wood treated with the substances in the scope of the restriction proposal before 2003, and RAC notes that the restriction text should be clear on this aspect as the intention of the proposal is that it will apply irrespective of when the wood was treated with creosote. It is not clear for the Forum how the restriction targets treated wood with creosote that is already in use, especially if the treatment was made according to an older legislation previous to the BPR, but RAC notes that the Dossier submitter has clarified that the intention is that creosote-treated wood already in use can continue to be used according to older legislation.

Regarding enforceability, the Forum discusses problems associated with sampling sleepers or poles and considers that it would be appropriate to include the four specific marker PAHs (acenaphthene, phenanthrene, fluoranthene and pyrene) for chemical analysis (as proposed in #3767), still anticipating that inspectors in most cases will enforce this restriction by checking documentation or asking the resellers for other relevant additional information.

The Forum recommends setting a limit value in case an analysis is required. On the other hand, the Forum advice states that labelling and sampling requirements would be unlikely to be needed as no distribution occurs in those Member States not included in the ECHA list.

RAC notes that all sleepers (most likely to be used for secondary purposes) have been impregnated and would expect that visual inspection and the sharp odour (CICAD 62) would be sufficient for enforcement. The Dossier Submitter is not proposing chemical analysis or a limit value, and RAC is not able either to propose a limit value if a chemical analysis would be needed as the concentration of PAH in newly treated and old wood is not known, and the PAH concentration also may vary within a treated piece of wood (e.g., sleeper).

Should a PAH-analysis be considered necessary, RAC notes that CICAD 62 (2004) mentions three studies where PAHs have been analysed in wood using GC-MSD or a combination of GC-MSD and GC-FID.

Comment #3767 suggests removing the creosote-related substances from the restriction, but a PAH-analysis would then not be able to distinguish banned creosote from not regulated creosote-related substances and then additional chemical analysis would be needed to make sure that the old sleepers were treated with creosote and not with any of the creosote-like substances, making enforcement more difficult.

Creosote-treated wood already in reuse or secondary use will probably not be in a proper condition to allow further reuse/secondary use, and this possibility has therefore not been considered further either by the Dossier submitter or RAC.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.5. Monitorability

Summary of Dossier Submitter's assessment:

The Dossier Submitter considered the proposed restriction to be monitorable. Elements supporting this conclusion include the following: the implementation of the proposed restriction options can be monitored via surveillance programs of national enforcement bodies and existing reporting systems, information on market trends related to the use of alternatives in wood treatment may provide valuable additional information on the regulatory effectiveness of the restriction.

RAC conclusion(s):

RAC concludes that the restriction options 1-3 are monitorable.

Key elements underpinning the RAC conclusion(s):

The monitorability issues are interlinked with the enforcement issues as covered already in the previous section 3.4.4 as one possibility is to monitor the implementation of the proposed restriction options via surveillance programs of national enforcement bodies and existing reporting systems.

No monitorability systems or labelling currently exist allowing to follow the age and the dispersion of treated wood in the environment and the volume of exchange occurring officially and unofficially. Unofficial trade is therefore occurring in many EU Member States, as indicated by internet searches. Following the internet trade of old creosote-treated wood provide another possibility for monitoring how successful the restriction is.

The Dossier Submitter also proposes that the introduction of a specific labelling for creosote treated wood under the BPR by national authorities or EU-harmonised codes would allow a better follow up of the treated articles all along their service life. RAC notes that the restriction proposal contains no requirements for labelling, and if such labelling would be proposed they need to be more or less permanent on each item (e.g., sleeper) in order to be effective after the service life of some 20 years use under environmental conditions. See uncertainties on the proposed specific labelling in section 3.5.1.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.4.6. Conclusion whether the suggested restriction is the most appropriate EU-wide measure

RAC conclusion(s):

- RAC concludes that the proposed restriction (option 2) is an appropriate EU-wide risk management measure for the secondary use and reuse of creosote treated wood. Restriction option 3 as proposed by SEAC is considered more appropriate as further mitigation of human health and environmental risks are addressed by allowing controlled professional reuse of treated wood in the same Member States.
- RAC concludes that the restriction is targeted to the exposures that cause the

environmental and human health risks identified, capable of reducing these risks within a reasonable period of time and proportional to the risk posed by the secondary use of creosote-treated wood for general population.

- RAC concludes that the restriction is in general implementable and monitorable in the EU and also that the restriction is practical and manageable.
- RAC concludes that the restriction is enforceable.

Key elements underpinning the RAC conclusion(s):

The wording of the current Entry 31 under REACH Annex XVII is open for different interpretations and is therefore not considered practical, or effective in addressing risks that would affect the general population through secondary use of creosote treated wood (see section 3.4.1). This restriction proposal aims at amending the Entry 31 to align it with the renewal of the approval of creosote as an active biocidal substance under the BPR, and clarifying how the restriction measures would apply to protect the general public. No other legislation could cover the "distribution", "reuse", and "secondary use", as the BPR only applies to the first placing on the market of treated articles.

RAC notes that there are some minor uncertainties regarding the enforceability and monitorability that arise from the unclear proposal for labelling in the proposed restriction. Thus, no labelling is proposed in the restriction proposal, but the text acknowledges the advantages for enforceability and monitorability of having a specific labelling for creosote-treated articles.

Please see section 3.4.4 for justifications on the practicality, including enforceability and section 3.4.5 on the monitorability of the proposed restriction.

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

3.5. SUMMARY OF UNCERTAINTIES

3.5.1. Uncertainties evaluated by RAC

Summary of Dossier Submitter's assessment:

The Dossier Submitter acknowledges that data are not sufficient to perform a quantitative risk assessment. However, data have been considered sufficient to perform a qualitative risk assessment.

RAC conclusion(s):

Exposure to PAHs during secondary use is very likely but there is limited data available to allow a quantitative exposure assessment. However, RAC supports that sufficient information is available to justify the need to minimise exposure from reuse and secondary use of wood treated with creosote or creosote-like substances.

Key elements underpinning the RAC conclusion(s):

The scientific uncertainties mainly concern the exposure assessment. It is clear that the level of creosote in impregnated wood decreases with time as a consequence of leaching, and even though exposure during reuse and secondary use is very likely, there are limited data available on the extent of exposure during reuse and secondary use, and also limited data on releases of PAHs fulfilling the PBT and/or vPvB criteria and having carcinogenic properties.

A regulatory uncertainty concerns how to best phrase the restriction entry to obtain the desired outcome. See "Explanatory notes" in section 1 for more details.

Another uncertainty concerns how to enforce the restriction. The RAC view is that chemical analysis may not be needed at all since all sleepers need to have been impregnated (with creosote or creosote-like substances). Coal tar-based creosote has a very typical and strong odour, and that could easily assist in identifying a creosote-treated wood.

3.5.2. Uncertainties evaluated by SEAC

Summary of Dossier Submitter's assessment:

[Text added by ECHA-S]

SEAC conclusion(s):

Text

Key elements underpinning the SEAC conclusion(s):

Text

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