

Biocidal Products Committee (BPC)

Opinion on the application for renewal
of the approval of the active substance:

creosote

Product type: 8

ECHA/BPC/274/2020

Adopted

4 December 2020

Opinion of the Biocidal Products Committee

on the application for renewal of the approval of the active substance creosote for product type 8

In accordance with Article 14(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the application for renewal of the approval in product type 8 of the following active substance:

Common name:	creosote
Chemical name:	Grade B and Grade C creosote as specified in European Standard EN 13991:2003
EC No.:	232-287-5
CAS No.:	8001-58-9

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Creosote Council Europe on 27 October 2016, the evaluating Competent Authority submitted an assessment report and the conclusions of its evaluation to the Agency on 16 September 2019. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-36 and BPC-37) and its Working Groups (WG I 2020). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly¹.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at <https://echa.europa.eu/potential-candidates-for-substitution-previous-consultations> on 23 October 2019, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 22 December 2019.

¹ The application by the Creosote Council Europe was submitted to the evaluating Competent Authority UK in 2016. As a consequence of the Brexit, Poland took over as the evaluating Competent Authority as of 1 February 2020.

Adoption of the BPC opinion

Rapporteur: Poland

The BPC opinion on the application for renewal of the approval of the active substance creosote in product type 8 was adopted on 4 December 2020.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including their grounds are published on the ECHA webpage at: <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval>.

Detailed BPC opinion and background

1. Overall conclusion

Since creosote fulfils the criteria set in Article 5(1) of Regulation (EU) No 528/2012, the overall conclusion of the BPC is that the approval of creosote in product type 8 should normally not be renewed, unless one of the conditions for derogation in Article 5(2) is met. The process related to the demonstration of whether the conditions for derogation set in Article 5(2) are met, is not in the remit of the BPC. The detailed grounds for the overall conclusion are described in the assessment report.

In view of the evaluation, it is concluded that biocidal products containing creosote as an active substance in product type 8 may not be expected to meet the criteria laid down in points (b)(iii and iv) of Article 19(1) of Regulation (EU) 528/2012.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of creosote in product type 8, approved as an existing active substance under the Biocidal Products Directive in 2011 via Directive 2011/71/EU. Following the application for renewal it was decided that according to Article 14(2) of the BPR a full evaluation was necessary. Due to this and some delays in the peer review process, the expiry date of the approval was postponed twice and is now 31 October 2021 as laid down in Implementing Decision (EU) 2020/1938.

The following information was generated since the initial approval and was submitted by the applicant:

- i) scenarios for exposure assessment and risk characterisation for human health on the uses in tree support posts and in equestrian and agricultural fencing;
- ii) data for scenario for exposure assessment for human health concerning brushing application;
- iii) scenario for environmental exposure from the use of creosote-treated posts with no contact with fruit and plants in vineyards and orchards;
- iv) monitoring data in soil, wood and fruits concerning tree support posts in orchards;
- v) monitoring data concerning soil around utility poles, fence posts, railway sleepers, adsorption/desorption in moraine soils;
- vi) results of literature screen on endocrine properties of some selected PAHs;
- vii) some additional monitoring data (air and urine) and some conditions concerning hot and cold impregnation.

Creosote is a brownish-black oily liquid and is a distillation product of coal tars which themselves are by-products of the high-temperature destructive distillation of bituminous coal to form coke. Creosote is the intermediate cut, ranging from 200 to 355 °C.

Creosote is a complex mixture of hundreds of distinct substances, including bi- and polycyclic aromatic hydrocarbons (PAH), phenols as well as heterocyclic, oxygen-, sulphur- and nitrogen-containing substances. On average 35-43% of creosote remains unidentified.

European creosotes must comply with EN 13991. In Directive 2011/71/EU this was specified as "Grade B or Grade C creosote as specified in European Standard EN 13991:2003". In the renewal application, information was submitted that the reference sources comply with this standard. A 5-batch analysis of creosote should be required before the next renewal (see section 2.5).

The physico-chemical properties of the active substance which is also authorised as a biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance/biocidal product.

Validated analytical methods are available for the active substance as manufactured. Analytical methods are available for selected PAHs in air, water, soil and fruit. Residues of creosote were defined (in the absence of detailed data on the composition from a 5 batch analysis) as 16 EPA + 2 PAHs. However, as this definition may not reflect actual residues, further data is required (see section 2.5) so that the definition can be clarified. If the residue definition changes, appropriate validated analytical methods for monitoring in air, water, soil and food/feed should be required.

Creosote is included in Annex XVII of Regulation (EC) No 1907/2006 in entry number 31 which regulates the conditions for the use of creosote in wood treatment and the placing on the market of wood treated with creosote.

Components of creosote, namely anthracene and polyaromatic hydrocarbons (PAHs), are listed as priority hazardous substances in Annex X to the Water Framework Directive (2000/60/EC). According to that Directive, the Commission shall submit proposals for control measures for the cessation or phasing-out of discharges, emissions and losses of such substances to surface waters.

The current classification and labelling for creosote according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Current classification according to the CLP Regulation	
Hazard Class and Category Codes	Carc 1B, H350
Labelling	
Pictogram codes	GHS08
Signal Word	Danger
Hazard Statement Codes	H350: May cause cancer
Specific Concentration limits, M-Factors	None

The proposed classification and labelling for creosote according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Carc 1B, H350 Repr 1B, H360F Repr 2, H361d Skin irrit 2, H315 Skin sens 1, H317 Eye irrit 2, H319 Aquatic Acute 1, H400 Aquatic chronic 1, H410
Labelling	
Pictogram codes	GHS07 GHS08 GHS09
Signal Word	Danger
Hazard Statement Codes	H350: May cause cancer H360Fd: May damage fertility. Suspected of damaging the unborn child H315: Causes skin irritation H317: May cause an allergic skin reaction H319: Causes serious eye irritation. H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	
	M=10

b) Intended use, target species and effectiveness

Creosote is used as a wood preservative in PT 8 as a fungicide, and insecticide against wood rotting fungi, against wood rot in soil and water contact, and against insects.

Creosote is used by professionals for preventive treatment of wood. The evaluated uses are:

- Use Class (UC) 3 according to EN Standard 335: pressure impregnation: Preventive treatment of wood to be used as railway sleepers, agricultural fencing, equestrian fencing, industrial and highways fencing, environmental barriers, industrial landscape retaining timbers, cladding for non-residential buildings;
- UC 4 according to EN Standard 335: pressure impregnation: Preventive treatment of wood to be used as wood poles for overhead electricity and telecommunication, foundation timbers for wood poles, agricultural fencing, equestrian fencing, industrial and highways fencing, hop poles, industrial landscape retaining timbers, tree support posts (fruit, vineyards);
- UC 5 according to EN Standard 335: pressure impregnation: Preventive treatment of wood to be used for marine installations;
- Surface treatment by brushing (UC 3 and UC 4): Treatment of creosote impregnated wood (UC 3 and UC 4) after modifications such as sawing, cutting, shaping and machining (cut-end treatment). This preventive surface treatment by brushing only occurs where there is a need for machining of pressure treated wood after treatment noting that normally all machining is done before treatment. It occurs at the impregnation facility and installation sites of the treated wood.

The following use was incorporated in the application but was not evaluated:

- UC 4: Hot and cold impregnation, non-pressure method: wooden posts (supports for vineyards and orchards as well as horticulture and landscaping applications: e.g. vineyard posts, fruit tree and tree support posts). The risk assessment for human and the environment has not been completed. For the human exposure assessment weaknesses of the submitted monitoring data were identified: (i) the lack of data for direct comparison of the extent of external contamination with the inner burden of the worker applying non-pressure method, (ii) the lack of sufficient explanation of the fact that cloth contamination with PAH during unloading of tank might be even 100-fold higher in comparison to loading stage. For the environmental exposure a clear maximum application rate (with relevant and reliable leaching data) is not given. Therefore, risk assessment for this surface treatment should be performed at product authorisation stage considering the application rates, which are regulated by national standards.

No new efficacy data are required at this stage and the conclusions of the initial evaluation remain the same: efficacy has been sufficiently demonstrated for the renewal of approval of creosote.

c) Overall conclusion of the evaluation including need for risk management measures

Creosote is meeting the exclusion criteria as set in Article 5(1) as it is classified under CLP as carcinogen category 1B; as it is proposed to be classified as toxic for reproduction category 1B and as it meets the criteria for being PBT and vPvB. This means that creosote in PT 8 shall normally not be renewed, unless one of the conditions for derogation in Article 5(2) is met. Article 5(2) states that: "*The use of a biocidal product containing active substances approved in accordance with this paragraph shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised.*" Furthermore, creosote is considered a non-threshold carcinogen (Directive 2011/71/EU) and the workplace exposure to carcinogenic substances (Cat 1B) must be avoided or minimised as far as technically feasible (Directive 2004/37/EC). Lastly, no conclusion could be made on the endocrine disrupting properties of creosote for human and for non-target organisms with the available information. Therefore, the measures are required to minimise exposure as far as possible of humans and the environment to creosote.

Human health

Creosote is considered a non-threshold carcinogen. The genotoxic (non-threshold) effect could not be excluded based on the submitted studies. For non-threshold effects the underlying assumption is that a no-observed-effect-level cannot be established. Instead, a Derived Minimal Effect Level (DMEL) is established which represents a level of exposure that could lead to one increased cancer incidence per 100.000 workers or per 1.000.000 of general population, ie cancer risk levels of 10^{-5} and 10^{-6} , respectively. These cancer risk levels are considered to correspond to low risks and could be seen as indicative tolerable risks. For creosote, a DMEL value for workers has been derived, whereas no DMEL for the general public was set as the conclusion – i.e. "non-tolerable" – for the relevant scenarios² would not change. The exposure assessment of creosote is based on monitoring data from operators and workers in impregnation plants. The resulting margins of exposure (MoE) can subsequently be used in judging the significance of any residual exposure after introducing strict risk management measures and for providing information in further targeting measures. A MoE above 25000 is considered to be of low concern for workers for a non threshold carcinogen.

² So for these scenarios the DMEL value for workers was used.

For the renewal of approval of creosote an assessment of endocrine-disrupting properties is required according to the scientific criteria laid down in Regulation (EU) 2017/2100. Information on several selected constituents of creosote was submitted. However, this information was considered insufficient to conclude on the endocrine-disrupting properties of creosote for humans.

No new information on genotoxicity was submitted for the renewal. However, the information was assessed in light of the exclusion criteria laid down in Article 5(1)(b). Although *in vitro* and *in vivo* information is available, this was considered not sufficient to conclude on the appropriate classification for mutagenicity.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	Primary or secondary exposure and description of scenario	Exposed group	MoE*
Primary exposure for pressure impregnation for UC 3, 4 and 5			
Management Operator	Primary exposure. Changing the creosote buggy wheels and replacing a creosote cylinder door gasket.	Professionals	<p>7 720 non-tolerable</p> <p>RMMs reducing the exposure:</p> <ul style="list-style-type: none"> • 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. • 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.

<p>Worker</p>	<p>Primary exposure. Unloading/loading and charging of the cylinders, repair and maintenance. Load changes included the removal of processed pole buggies from the impregnation/after-treatment cylinder (unloading) and the charging of new buggies into the cylinder (charging). The change took approx. 15-30 minutes, of which a few minutes were spent in the vicinity of the impregnation/after-treatment cylinder.</p>	<p>Professionals</p>	<p>18 750 non-tolerable</p> <p>RMMs reducing the exposure:</p> <ul style="list-style-type: none"> • 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.
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<p>Worker</p>	<p>Primary exposure. Controlling the process, transport of the wood into and out of the cylinder on rail trucks, opening and closing of the covers of the cylinder.</p>	<p>Professionals</p>	<p>5 526 non-tolerable</p> <p>RMMs reducing the exposure:</p> <ul style="list-style-type: none"> • 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.
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Primary exposure for brushing for UC 3 and 4			
Worker	Primary exposure. Wood components after treatment may be cut, bored or shaped. Brushing is subsequently required to protect any remaining bare surfaces. The typical operation includes surface treated ~0.2 m ² and contact time 48 min per day.	Professionals	<p>21 428 non-tolerable (with use of cotton coverall and gloves) 43 209 tolerable (with use of RPE, impermeable coveralls and gloves)</p> <p>RMMs reducing the exposure:</p> <ul style="list-style-type: none"> • 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. • 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 during painting. • 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. • 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.
Worker	Primary exposure. Cleaning of a brush after treatment.	Professionals	<p>4 085 non-tolerable (with gloves)</p> <p>RMMs reducing the exposure:</p> <ul style="list-style-type: none"> • Do not clean the brush after treatment but dispose it as hazardous waste. • 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. • 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.
Secondary exposure for pressure impregnation for UC 3, 4 and 5			
UC 3 and 4			
Post application of treated poles or equestrian fences	Secondary dermal exposure, adult, children 6-12y, children 2-6y, and toddler – contact treated poles or equestrian fences	General public	<p>1 750 non-tolerable 1 332 non-tolerable 1 124 non-tolerable 1 035 non-tolerable</p> <p>No RMMs are available to reduce the exposure.</p>

UC 4			
Down-stream users (electricity pole installers)	Secondary exposure. Furnishing of poles	Professionals	<p>40 384 tolerable</p> <p>RMMs reducing the exposure:</p> <ul style="list-style-type: none"> • Stringent adherence to the protective measures that are already in place. • 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. • The PPE should be changed frequently. • 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 (e.g. if any drilling, mounting or fitting during installation is needed). • 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). • Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.
Down-stream users (electricity pole installers)	Secondary exposure. Installation of conductors	Professionals	<p>95 454 tolerable</p> <p>RMMs reducing the exposure:</p> <ul style="list-style-type: none"> • Stringent adherence to the protective measures that are already in place. • 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. • The PPE should be changed frequently. • 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 (e.g. if any drilling, mounting or fitting during installation is needed). • 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). • Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.

Down-stream users (pole installers)	Secondary exposure. Installation of a separator	Professionals	<p>744 non-tolerable</p> <p>RMMs reducing the exposure:</p> <ul style="list-style-type: none"> • Stringent adherence to the protective measures that are already in place. • 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. • The PPE should be changed frequently. • 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 (e.g. if any drilling, mounting or fitting during installation is needed). • 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). • Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.
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* A margin of exposure value below 25000 is presented in bold. It could not be assessed if the RMMs indicated in the summary table for those scenarios for which the conclusion is “non-tolerable” would lead to an amendment of this conclusion (creosote is only for uses by professionals where the frequency of changing PPE is covered by Health and Safety at Work regulations; among the listed RMMs the non-quantifiable ones are also given to be applied in order to minimise the risk as much as possible).

For professionals, there are sufficient MoEs only for the downstream users including pole installers for the tasks of installation of conductors and furnishing of poles. However, it must be highlighted that creosote is a non-threshold carcinogen and therefore professional uses require extra protective measures to minimize contact with creosote during work tasks. For plant workers the dermal and inhalation routes of exposure have been identified. For downstream users, mainly dermal route of exposure is foreseen, however, inhalation exposure might occur (e.g. if any drilling).

With respect to downstream users only data for pole installer were available to perform an assessment. For other uses – for example installation of railway sleepers – no data were available to conclude if the risk can be considered as tolerable or non-tolerable.

For the general public, secondary exposure via the dermal and oral route can occur:

- dermal exposure can occur by touching treated equestrian fences and poles. As the result of the assessment, a non-tolerable risk for all population groups (adults, children, toddlers) was identified;
- oral exposure can occur via residues in plant- and animal-derived food as fruits and other plant crops can grow in the vicinity or in direct contact with creosoted poles and animals are supposed to have dermal contact with fences and eat grass in the vicinity of creosoted fences. The information referring to exposure to the residues in food as well as livestock exposure submitted by the applicant has been analysed. However, it is evaluated as insufficient for consumer and animal risk assessment. For calculating dermal and oral (by licking) exposure the applicant used leaching rate Time 1, whereas for calculating oral exposure (by grass-eaters) the applicant used leaching rate Time 2. As the worst-case scenario refers to newly impregnated wood, the leaching rate Time 1 was used to assess exposure to livestock. However, no data on the consumer exposure to meat or milk derived from livestock having contact with impregnated wood or contaminated grass has been provided by the applicant. The consumer risk assessment could therefore not be finalized due to this lacking information. Additionally, it is considered that any use of creosote - as a non-threshold carcinogen - that leads to food residues is considered unacceptable.

Environment

Creosote contains constituents fulfilling the PBT and/or vPvB criteria. Among these is anthracene, which was identified as a PBT during the initial approval and thus approximately 0.5-1.5% of the creosote constituents were considered to be PBT and 0% were vPvB at that time. Since then, the following constituents were considered to be PBT and vPvB³: chrysene, benz[a]anthracene, fluoranthene, phenanthrene and pyrene. With the new information on these five constituents approximately 7-15% of the creosote constituents are PBT and approximately 17-31% of the constituents are vPvB. Therefore, creosote is considered to be a PBT/vPvB substance.

For PBT and vPvB substances, the quantitative risk assessment method currently available (PEC/PNEC comparison) does not provide sufficient confidence that the environmental compartments are sufficiently protected (Section 1.1 of Guidance on Biocidal Products Regulation: Volume IV Environment - Assessment and Evaluation, Parts B+C, version 2.0, October 2017, and Guidance on Information Requirements and Chemical Safety Assessment

³ These substances have been included in the Candidate List of substances of very high concern for authorisation in accordance with Article 59(10) of the REACH Regulation following their identification as PBT and vPvBs.

Chapter R.11: PBT/vPvB Assessment, version 3.0, June 2017). Chemical substances with PBT/vPvB properties can give rise to toxic effects after a greater time and at a greater distance than chemicals without these properties. Therefore, there may be temporal and/or spatial scale protection goals that are not covered by the standard PEC/PNEC comparison (Section 2.6.1 of Guidance on Biocidal Products Regulation: Volume IV Environment - Assessment and Evaluation, Parts B+C, version 2.0, October 2017). Consequently, the properties of the PBT and vPvB-substances lead to an increased uncertainty in the estimation of risk to the environment when applying standard quantitative risk assessment methodologies such as the PEC/PNEC comparison. The PEC values presented in the assessment report provide an estimation on the magnitude of exposure to each environmental compartment from the intended uses of creosote. Likewise, the PEC/PNEC values can be considered to provide an indicative level of risk for each use class.

For the renewal of approval of creosote an assessment of endocrine-disrupting properties is required according to the scientific criteria laid down in Regulation (EU) 2017/2100. Information on several selected constituents of creosote was submitted. However, this information was considered insufficient to conclude on the endocrine-disrupting properties of creosote for non-target organisms.

The table below summarises the exposure scenarios assessed. The conclusion for each scenario assessed with a quantitative risk assessment method (PEC/PNEC comparison) is indicated as "acceptable" when PEC/PNEC is <1 , and as "unacceptable" when the PEC/PNEC is >1 in order to describe the outcome of the assessment.

Summary table: environment scenarios		
Scenario	Description of scenario including environmental compartments	Conclusion
Application phase		
Application: vacuum pressure method for UC 3, UC 4, UC 5	Scenario was not assessed; not considered; industrial application of wood preservatives is regulated by local authorities within Member States, application is only in places sealed to prevent any direct release to the environment.	Timber treatment with creosote 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).
Application: surface treatment by brushing of wood components, which were treated by standard vacuum pressure, but later modified by sawing, cutting or shaping	Scenario was not assessed; not considered; only for wood components modified after standard vacuum pressure treatment to be used in UC 3 and UC 4 (normally machining to be done before treatment), only in places sealed to prevent any direct release to the environment.	Treatment with creosote must be undertaken within the industrial impregnation facilities on an impermeable surface or in-situ at a construction site outdoors where soil must be protected with a plastic foil or tray and any potential spillage must be collected and disposed of by safe means.
Storage of freshly treated timber: vacuum pressure method for UC 3, UC 4, UC 5	Scenario was not assessed; not considered; creosote treated timber must be undertaken at industrial sites, only in places sealed to prevent any direct release to the environment.	Storage place is sealed and run-off from storage places is collected and disposed of by safe means. Freshly creosote-treated timber must be stored under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and any losses of the product must be collected for reuse or disposal.
Storage of treated timber		
Storage of treated wood (waiting for shipment, emergency stocks)	Scenario was not assessed	Storage place is sealed and run-off from storage places is collected and disposed of by safe means.
Service life of treated wood*		
Noise barrier, in service only (UC 3)	Leaching to STP (and secondary via STP to surface water/sediment and application of sludge to soil) and direct emission to soil	PEC/PNEC _{STP} < 1 acceptable (<0.001 at Time2* and <0.01 at Time1) PEC/PNEC_{soil} > 1 unacceptable (2.71 at Time 2 and 0.078 at Time 1)
Bridge over pond, in service only (UC 3)	Direct emission to surface water/sediment due to leaching	PEC/PNEC _{water} < 1 acceptable (0.24 at Time 2 and 0.02 at Time 1) PEC/PNEC _{sediment} < 1 acceptable (0.06 at Time 2 and 0.006 at Time 1) acceptable

Jetty in the lake, in service only (UC 4b)		PEC/PNEC_{water} > 1 unacceptable (6.51 at Time 2 and 0.46 at Time 1) PEC/PNEC _{sediment} < 1 (0.009 at Time 2 and 0.10 at Time 1)
Sheet piling in waterway, in service only (UC 4b)		PEC/PNEC_{water} > 1 unacceptable (75.15 at Time 2 and 410.0 at Time 1) PEC/PNEC_{sediment} > 1 unacceptable (11.48 at Time 2 and 62.64 at Time 1)
Harbour wharf, in service only (UC 5)		PEC/PNEC_{seawater} > 1 unacceptable (7.50 at Time 2 and 41.05 at Time 1) PEC/PNEC_{seasled} > 1 unacceptable (2.30 at Time 2 and 12.55 at Time 1)
House, in service only (UC 3)	Direct emission to soil and groundwater	PEC/PNEC_{soil} > 1 unacceptable (1.05 at Time 2 and 0.20 at Time 1)
Transmission pole, in service only (UC 4a)		PEC/PNEC_{soil} > 1 unacceptable (20.36 at Time 2 and 3.11 at Time 1) Qualitative assessment of exposure to groundwater does not raise significant concern.
Vineyard, in service only (UC 4a)		PEC/PNEC_{soil} > 1 unacceptable (6.43 at Time 2 and 0.98 at Time 1) Qualitative assessment of exposure to groundwater does not raise significant concern.
Railway sleepers, in service only (UC 3)	Emission to groundwater	PEC _{groundwater} < trigger value of 0.1 µg/L acceptable

* In the emission estimation, Time 1 presents 30 d and Time 2 presents 20 years service life. PEC/PNEC ratios higher than one are presented in bold.

With respect to the environmental risk assessment, the only uses which did not result in unacceptable risks based on the quantitative risk assessment were the use for railway sleepers and the use for bridge over pond (UC 3). The quantitative risk assessment indicated unacceptable risks for all other UC 3 uses, UC 4 and UC 5.

However, since creosote is an UVCB substance containing PBT and vPvB constituents, the quantitative risk assessment method currently available does not provide enough confidence that the environmental compartments are sufficiently protected and there is a remaining uncertainty in the estimation of risks to the environment. Therefore, it is not demonstrated that there are no unacceptable effects to the environment.

Overall conclusion

Creosote does meet the exclusion criteria and is considered as a candidate for substitution.

Non-tolerable risk in all the scenarios for professional workers in the impregnation plants was identified, but it shall be minimised to the extent as technically possible with personal protective equipment (PPE; chemical resistant (coated) coveralls, respiratory protection and gloves changed frequently) and with risk mitigation measures (RMM) on application only at industrial facility and on storage of creosote treated timber.

Transmission poles (overhead electricity and telecommunication) impregnated by pressure method in UC 4 pose tolerable risks for installers for the tasks of Installation of conductors and Furnishing of poles only with RMM (PPE as mentioned above). For other downstream uses of treated wood – for example installation of railway sleepers, tree support posts and agricultural and equestrian fencing - no data were available to conclude if the risk can be considered as tolerable or non-tolerable.

For agricultural fencing and equestrian fencing, the use poses a non-tolerable dermal exposure risk for the general public (child, toddler and adult).

The assessment for consumer dietary exposure for the uses agricultural and equestrian fencing and tree support poles was inconclusive due to the lack of adequate data on animal exposure and on residues in animal-derived food. However, it is considered that any use of creosote that leads to food residues is unacceptable.

Surface treatment by brushing in UC 3 and UC 4, which is done occasionally after modifications (such as sawing, cutting, shaping and machining) of pressure treated wood after treatment (normally all machining to be done before treatment) by professionals does not lead to unacceptable risks for the environment with soil protection preventing drips and spills and does not lead to non-tolerable risks for workers when RMMs are applied (PPE and RPE). Additionally, a required measure is to dispose the brush after treatment instead of cleaning it. The need to cut treated wood should be avoided however as much as possible.

Acceptable risks to the environment were identified in UC 3 in service scenarios: bridge over pond as well as railway sleepers. For the other scenarios in UC 3, UC 4a, UC 4b and UC 5 unacceptable risks to the environment were identified.

However, since creosote is an UVCB substance containing PBT and vPvB constituents, the quantitative risk assessment method currently available does not provide enough confidence that the environmental compartments are sufficiently protected and there is a remaining uncertainty in the estimation of risks to the environment. Therefore, it is not demonstrated that there are no unacceptable effects to the environment.

Overall, it can be concluded that no safe uses can be identified when combining the outcomes of the human health and environment risk assessment.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	Cat 1B	Creosote does fulfil criterion (a) and (c) of Article 5(1)
	Mutagenicity (M)	The information available on genotoxicity was not sufficient to conclude on the appropriate classification	
	Toxic for reproduction (R)	Cat 1B and 2	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	P and vP	Creosote does fulfil criterion (e) of Article 5(1) and does fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	B and vB	
	Toxic (T)	T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No conclusion can be drawn based on the available data	No conclusion can be drawn whether creosote fulfils criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No conclusion can be drawn based on the available data	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. Creosote does not fulfil criteria (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Creosote does fulfil criterion (e) of Article 10(1) as it is a non-threshold carcinogen where there are concerns even when applying restrictive risk mitigation measures.		
Proportion of non-active isomers or impurities	Not applicable to a UVCB substance. Creosote does not fulfil criterion (f) of Article 10(1).		

The exclusion and substitution criteria were assessed in line with the “Note on the principles for taking decisions on the approval of active substances under the BPR”⁴, with “Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR”⁵ and with “Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment”⁶ agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

With respect to mutagenicity further *in vivo* mutagenicity studies would be required to enable to conclude on the appropriate classification. However, it must be noted that according to Annex II of the BPR such *in vivo* studies do not generally need to be conducted if the substance is known to be a carcinogenic Cat 1A or 1B, which is the case for creosote.

With respect to the endocrine-disrupting properties no conclusion can be drawn based on the available data for section A and B of Regulation (EU) No 2017/2100. As creosote already meets the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012 and because creosote containing biocidal products are used only by professionals, it was decided to not proceed further with the evaluation of the endocrine-disrupting properties of creosote. Furthermore, the identification of creosote as an ED would not impact the conclusion as exposure should be already avoided or minimised to the extent as technically possible due to creosote being a non-threshold carcinogen.

Consequently, the following is concluded:

Creosote does meet the exclusion criteria laid down in Article 5(1)(a), (c) and (e) of Regulation (EU) No 528/2012. For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn on the available data.

Creosote does meet the conditions laid down in Article 10(1)(a), (d) and (e) of Regulation (EU) No 528/2012 and is therefore considered as a candidate for substitution.

2.2.2. POP criteria

In the absence of confirmation that all major components of creosote rapidly degrade in air (so do not have the potential for long term transport) it may be considered to classify creosote as a substance potentially containing POP constituents.

2.2.3. Identification of potential alternatives substances or technologies, including the results of the public consultation for potential candidates for substitution

Based on the evaluation of the information submitted during the public consultations the alternatives for uses of creosote are identified for wooden railway sleepers, transmission poles as well as for fencing (equestrian, agricultural), agricultural posts/stakes and hop poles. However, their availability and/or suitability to fulfil technical requirements is limited. Therefore, most of the entries submitted state that an additional time is needed to enable

⁴ See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from <https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc>)

⁵ See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from [https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art%20\(1\).doc](https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art%20(1).doc))

⁶ See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (available from <https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details>).

the necessary progress on availability and technical applicability of the most promising alternatives.

The possible non-chemical alternatives are concrete, steel, plastic.

For railway sleepers concrete (reinforced) is already used especially in main lines of rail tracks but cannot always be an applicable substitution due to greater weight and stiffness of the material (i.e. on bridges, in switching points, old tunnels, tight curves). Steel railway sleepers are already in use, but they are expensive and weather conditions may deteriorate their properties. Concrete and steel poles are already in use in areas where the general public may be in direct contact more frequently (near schools, protected areas), but due to greater weight are rarely used in forests and mountains. Wooden poles may be mounted on a concrete foundation, what excludes the direct contact with soil fungi, nevertheless weathering impacts the wood properties (leaching). Concrete and steel used for fencing may possibly cause more animal injuries as well as for agricultural posts/stakes/poles are claimed to be incompatible with orchard designs, because in case if one support is lost (due to storm wind) the whole row/line is affected and may be incompatible with harvesting machines.

Using underground cables instead of overhead transmission cables is another possibility, although applicable only in certain areas. Non-impregnated wooden sleepers, made of oak or azobe, are expensive and applicable only for special areas (e.g. open track bridges).

Plastic (recycled composite or FFU) railway sleepers need standards for safety usage certifications, which are in development, and their production capacity is limited. Plastic poles are already in use and these may be hollow or not, structures made of composite glass fibre reinforced polyester or polyethylene, but also wooden poles covered with polymer composite or polyethylene. All plastic poles/stakes/posts are of long service life, light weight, as well as no rotting or vermin decay. Plastic poles have very good insulation properties. Plastic fence is less attractive to cattle for rubbing and cribbing. The environmental impact of production and use of high number of plastic articles should be assessed as well as possibly leaching of compounds from recycled plastics.

The alternative copper-based preservatives are to be possibly used for wooden railway sleepers, transmission poles as well as for fencing (equestrian, agricultural), agricultural posts/stakes and hop poles. The water-borne preservatives contribute to a short service life of a sleeper due to crack formation, bending, decay and their use is limited due to conductivity. If using such a preservative is followed by vacuum drying in oil, some of the limitations are diminished, but the technical process is currently in development phase. Using ignitable tall oil is not applicable due to safety reasons. For transmission poles, fencing and agricultural posts/stakes/poles the copper-based preservatives usage may be limited by leaching to soil and by activity of copper-resistant fungi (*Pioria vaillantii*), since these wooden articles are in direct contact with soil. Using copper oil-based preservatives (either mineral or organic bio-oil) for railway sleepers, transmission poles or fencing and agricultural posts/stakes/poles is the most promising alternative, which is in the development phase with some technology problems still to overcome.

Overall, it can be concluded that suitable alternatives are available for the use of creosote, chemical as well as non-chemical. However, additional time is needed to enable the necessary progress on the availability and technical applicability of these alternatives. In addition, it must be noted that the technical applicability of the alternatives for the use of creosote differs per Member State, for example due to a difference in geographical conditions.

2.3. BPC opinion on the application for renewal of the approval of the active substance creosote in product type 8

The conditions for the use of creosote in wood treatment and for the placing on the market of wood treated with creosote is regulated by entry number 31 in Annex XVII of Regulation (EC) No 1907/2006 or REACH. Product authorisations for biocidal products containing creosote are therefore subject to compliance with this restriction and Directive 2011/71/EU contains two conditions related to this restriction:

- *"Creosote may only be used under the conditions mentioned in point 2 of the second column of entry No 31 in Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.*
- *Creosote shall not be used for the treatment of wood intended for those uses referred to in point 3 of the second column of entry No 31 of Annex XVII to Regulation (EC) 1907/2006."*

It is considered that this articulation between REACH and the renewal process under the BPR is not within the remit of the BPC. The opinion of the BPC on the application for renewal below does subsequently not take this into account.

As the exclusion criteria are met, creosote should normally not be renewed unless one of the conditions for derogation set in Article 5(2) of BPR is met.

In view of the evaluation, it is concluded that biocidal products containing creosote as an active substance in product type 8 may not be expected to meet the criteria laid down in points (b)(iii and iv) of Article 19(1) of Regulation (EU) 528/2012.

If creosote is renewed, the renewal shall be subject to the following specific conditions:

1. Specification: Grade B and Grade C creosote as specified in European Standard EN 13991:2003.
2. Creosote is considered a candidate for substitution in accordance with Article 10(1)(a), (d) and (e).
3. The authorisations of biocidal products are subject to the following condition(s):
 - a. The product assessment shall pay particular attention to the exposures, 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.
 - b. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.
 - c. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
 - i. professional users;
 - ii. secondary exposure of the general public and consumers exposed via food;
 - iii. the soil and aquatic compartments.

- d. Labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses from the application of the product shall be collected for reuse or disposal.
 - e. Labels and, where provided, safety data sheets of products authorised shall indicate that for in-situ treatment at a site outdoors the soil shall be protected with a plastic foil or tray and any losses from the application of product shall be collected and disposed of by safe means.
 - f. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009⁷ or Regulation (EC) No 396/2005⁸ shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
4. The placing on the market of treated articles is subject to the following condition(s):
- a. The person responsible for the placing on the market of an article treated with or incorporating the active substance creosote shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.
 - b. Measures should be taken at temporary storage sites to prevent unauthorised access e.g. by fencing or covering and should normally not be accessible for the general public. For more permanent storage sites treated articles should be stored on an impermeable hard standing or on an absorptive material (e.g. bark) to prevent runoff to the environment. Furthermore, the materials should be stored under shelter or covered with a tarpaulin. Access to the general public should be prevented, e.g. using a fence. Any spill or contaminated material must be collected and disposed as hazardous waste.
 - c. Creosote treated articles should be labelled with these conditions for storage.⁹
 - d. Creosote treated articles shall be labelled containing a statement that the marketing of second-hand creosote treated articles to the general public is not allowed for articles treated after 31 December 2002 (as laid down in entry number 31 in Annex XVII of Regulation (EC) No 1907/2006 or REACH).

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012.

⁷ Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11.

⁸ Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1.

⁹ The BPC considered that as an alternative to conditions b and c the following two conditions could be used:

b. creosote treated articles shall be labelled that: i) articles stored at temporary storage sites shall normally not be accessible for the general public; ii) measures should be taken at such sites to prevent unauthorised access; iii) any spill or contaminated material must be collected on such sites and disposed as hazardous waste;

c. creosote treated articles shall be labelled that: i) articles stored at more permanent storage sites shall be stored on impermeable hard standing or on absorptive material to prevent runoff to the environment; ii) articles shall be stored on such sites under shelter or covered with a tarpaulin; iii) any spill or contaminated material must be collected on such sites and disposed as hazardous waste.

2.4. Elements to be taken into account when authorising products

1. The active substance creosote is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for national authorisation.
2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products or renewing product authorisations, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:
 - a. The use of a biocidal product containing creosote shall be subject to appropriate risk mitigation measures to ensure that exposure of humans, animals and the environment is minimised as far as possible.
 - b. If a non-tolerable risk is identified for industrial and/or professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to a tolerable level by other means.
 - c. If an unacceptable risk for the environment is identified losses during industrial treatment must be contained and recycled or collected and treated as waste in accordance with the national regulations of the Member State authorising creosote products.
 - d. A non-tolerable risk for general public in contact with impregnated poles and equestrian fencing is identified. If the risk cannot be reduced to a tolerable level by appropriate risk mitigation or by other means, products for impregnation of poles and equestrian fencing should not be authorised.
 - e. The consumer or animal risk assessment with respect to dietary exposure via food could not be finalised for several uses. Therefore, in order to perform the assessment: i) if the use of creosote treated tree support posts (fruit, vineyards or any other defined) and/or hop poles is authorised, it should be decided what constituents of creosote should be monitored in fruits and other food commodities (residue definition) and it should be confirmed if the validated analytical methods for determination are available; ii) if the use of creosote for equestrian and agricultural fencing is authorised, it should be decided what constituents of creosote should be monitored in livestock and other food commodities (residue definition) and it should be confirmed if the validated analytical methods for determination are available. Any use leading to residues in food is considered as unacceptable.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the renewal of the approval of creosote.

However, to enable evaluation of uses in agriculture and fencing the following information is required and must be provided together with the 5-batch analysis.

The following information must be provided as soon as possible but no later than 6 months after the date of the renewal of the approval to the evaluating Competent Authority (eCA):

- A proposal for a residue definition for the use of creosote treated tree support posts (fruit, vineyards or any other defined) and/or hop poles (which constituents of creosote should be monitored in fruits and other food commodities) including validated analytical methods for determination. Appropriate residue data of the selected constituents shall be generated in the relevant commodities;
- A proposal for a residue definition for the use of creosote for equestrian and agricultural fencing (which constituents of creosote should be monitored in livestock and other food commodities) including validated analytical methods for determination. Appropriate residue data of the selected constituents shall be generated in the relevant commodities.

The following information is required for the next renewal and must be provided to the evaluating Competent Authority (eCA):

- A 5-batch analysis, where consultation is required between the applicant and the eCA on the requirements of the analysis.