Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Renewal of approval

Renewal Assessment Report

Creosote

Product-type 8

14 January 2021

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

This assessment report has been established as a result of the evaluation of the active substance creosote as product-type 8 (wood preservatives), carried out in the context of evaluation of applications for renewal provided for in Article 14 of the Biocidal Product Regulation (EU) No 528/2012 (BPR), with a view to the possible renewal of the approval of this substance.

Creosote was approved as an existing active substance, in product-type 8 under the Biocidal Products Directive (Commission Directive 2011/71/EU of 26 July 2011, amending Directive 98/8/EC of the European Parliament and of the Council to include creosote as an active substance in Annex I thereto, OJ L 195, 27.07.2011). The renewal of the active substance has been jointly requested by the members of Creosote Council Europe on 27 October 2016.

On 14 February 2017, the Agency (ECHA) released the creosote dossier to the evaluating competent authority (eCA) the United Kingdom (UK). The eCA UK accepted the dossier as complete for the purpose of the evaluation on 17 May 2017. On the basis of the available information the eCA decided that a full evaluation in accordance with Article 14(2)(2) of the BPR of the application was necessary. The eCA UK informed the Commission on 14 July 2017 that a full evaluation will have to be performed and therefore the expiry date of approval of creosote was postponed to 31 October 2020 (Commission Implementing Decision (EU) 2017/2334 of 14 December 2017 postponing the expiry date of approval of creosote for use in biocidal products of product-type 8, OJ L 333, 15.12.2017).

The renewal assessment report (RAR) of creosote PT8 was prepared based on a template provided by ECHA to UK in 2017. On 14 March 2019, the eCA submitted to Agency (ECHA) and the applicant a copy of the RAR.

An e-consultation was conducted in the ENV WG from 31 May 2019 to 28 June 2019 concerning a new scenario for use of creosote treated posts in vineyards and orchards (non-contact with fruit and plants), based on which a revision of the RAR was made by the eCA UK in September 2019.

In order to review the RAR and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Agency (ECHA). Comments from Member States and issues raised during commenting (from 11 October 2019 till 15 November 2019) and trilateral discussion (from 13 December till 18 February 2020) were combined and the RAR was expected to be amended by the eCA UK accordingly. However, on 1 February 2020 the role of the eCA was taken over by Poland (PL) as a consequence of the Brexit.

The necessary revisions of the RAR were discussed at the Working Groups meetings between 24 March and 02 April 2020 (WG I 2020).

Due to the delay in the peer review process, the expiry date of the approval of creosote was postponed once more to 31 October 2021 (Commission Implementing Decision (EU) 2020/1038 of 15 July 2020 postponing the expiry date of approval of creosote for use in biocidal products of product-type 8, OJ L 227, 16.07.2020).

The further required amendments of the RAR underwent peer review by e-consultations: 13-24 August 2020 on Groundwater exposure, 26 August – 04 September 2020 on the Dermal absorption assessed according to the EFSA Guideline 2017, Dermal exposure on contact with creosoted poles, Livestock exposure, Consumer risk to creosote residues in fruits as well as Risk characterisation (T25).
The revised RAR and draft opinion were discussed in the BPC-36 meeting on 7 October 2020. The Working Group Human Health – follow-up after BPC-36 meeting on Risk characterisation (T25) took place on 19 October 2020. The updated revised RAR and draft opinion were discussed in the BPC-37 meeting on 1 and 4 December 2020.

In a broader context concerning creosote within the EU, during the processing of the request for the biocidal active substance renewal under BPR the following issues were recognized:

- Creosote, its compounds and wood treated with them are subject to restrictions laid down in Regulation (EC) No 1907/2006 (REACH).
- The decision, that the refusal of authorisation for the transmission poles use proposed by France was justified on grounds of the protection of the environment and of the health and life of humans, was taken by the Commission Implementing Decision (EU) 2018/1297 of 25 September 2018 on a derogation from mutual recognition of the authorisation of biocidal products containing creosote by France in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council.
- The provisional measure taken by France under REACH was authorized with effect from the date of the Decision for 27 months, i.e. that wood treated with creosote can only be placed on the market and installed for use as railway sleepers for an indefinite period of time, and for use as electrical or telecommunications transmission poles until 23 October 2019 with a possibility for certain operators to apply for an extension (Commission Implementing Decision (EU) 2019/961 of 7 June 2019 authorising a provisional measure taken by the French Republic in accordance with Article 129 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) to restrict the use and the placing on the market of certain wood treated with creosote and other creosote-related substances, OJ L 154, 12.06.2019 with amendments). It is noted that recital 16 of the Decision requires that France initiates a Union restriction procedure by submitting to ECHA an Annex XV dossier. So far ECHA has not received such a dossier. Further examination needs to take place in order to ensure consistency between the assessment of the renewal of the approval of creosote as an active substance under the BPR and the Union restriction procedure under REACH, and to provide for an effective control of creosote and wood treated with it.

Reports on comparative assessment prepared under national authorisation procedures by various Member States were submitted to the Commission between July 2016 and January 2019.

As creosote is a candidate for substitution, ECHA launched a public consultation in line with Article 10(2) and 10(3) of the BPR between 23 October and 22 December 2019.

A survey among Member States was conducted by ECHA in June-August 2020 to get an overview of creosote containing biocidal products authorised in the EU.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity

Main constituent(s)	
Common name	Creosote
EC number	232-287-5
CAS number	8001-58-9
Chemical name (EINECS-entry)	Distillates (coal tar), intermediate cut ranging from 200 °C to 355 °C
Description (EINECS-entry)	A complex combination of monocyclic aromatic hydrocarbons, polycyclic aromatic hydrocarbons, tar acids and tar bases, obtained by the distillation of coal tars produced by the high-temperature destructive distillation of bituminous coal to form

	coke. It consists of hydrocarbons boiling in the range of approximately 200°C-355°C.
Molecular and structural formula, and molecular mass	Not applicable to a complex mixture (i.e. UVCB-substance)
Purity	Not applicable to a complex mixture (i.e. UVCB-substance)
Impurity and additives	Not applicable to a complex mixture (i.e. UVCB-substance)

2.1.2. Intended Uses

- UC 3: 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. Use class (UC) 3 according to EN Standard 335.
- UC 4: 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 & highways fencing, hop poles, industrial landscape retaining timbers, tree support posts (fruit, vineyards). Use class (UC) 4 according to EN Standard 335.
- UC 5: pressure impregnation: Preventive treatment of wood to be used for marine installations. Use class (UC) 5 according to EN standard 335.
- Surface treatment (UC 3 and UC 4): Treatment of creosote impregnated wood (UC 3 and UC 4) after modifications such as sawing, cutting, shaping and machining. Preventive treatment. Surface treatment by brushing only applies where there has been machining of pressure treated wood after treatment (normally all machining to be done before treatment).
- 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).
- Impregnation of wood (UC 3/4/5) for export of treated articles.
- UC 3 brushing, non-pressure method: Hardwood and softwood railway sleepers, agricultural fencing, equestrian fencing, Industrial and highways fencing, environmental barriers, industrial landscape retaining timbers, cladding for non-residential buildings.
- UC4 brushing, non-pressure method: Poles for overhead electricity and telecommunication, foundation timbers for wood poles, agricultural and equestrian and industrial and highways fencing, hop poles, industrial landscape retaining timbers, tree support posts (fruit, vineyards).

<u>Evaluated uses:</u>

- UC 3: 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. Use class (UC) 3 according to EN Standard 335.
- UC 4: 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 & highways fencing, hop poles, industrial landscape retaining timbers, tree support posts (fruit, vineyards). Use class (UC) 4 according to EN Standard 335.
- UC 5: pressure impregnation: Preventive treatment of wood to be used for marine installations. Use class (UC) 5 according to EN standard 335.

- Surface treatment (UC 3 and UC 4): Treatment of creosote impregnated wood (UC 3 and UC 4) by brushing after modifications such as sawing, cutting, shaping and machining. Preventive treatment. Surface treatment by brushing only applies where there has been machining of pressure treated wood after treatment (normally all machining to be done before treatment).

Note:
Dipping and brushing as separate application methods for the above mentioned uses: *for comments see pages 16, 22-23, 29-30, 44*.
Impregnation of wood (UC 3/4/5) for export of treated articles: the use defined as such "for export" is beyond the scope of risk assessment for renewal of active substance approval (beyond the scope of BPR).

2.2. Summary of the Assessment

2.2.1. Specification of the different sources of the active substances

The European creosote grades must comply with the criteria in the European Standard EN 13991:2003 as outlined in the table below:

Table 2.2.1-1 Specification for creosotes

Normative parameters according to EN 13991:2003	**Unit**	**Creosote Grade B (EN 13991)**	**Creosote Grade C (EN 13991)**
Density (20°C) ((BS 144-annex)	g/mL	1.02-1.15	1.03-1.17
Water content (ISO 760)	%	max. 1	max. 1
Crystallization temperature (EN 13991)	°C	max. 23	max. 50
Water- extractable phenols (EN 1014-4)	%	max. 3	max. 3
Matter insoluble in toluene (BS 144-annex G)	%	max. 0.4	max. 0.4
Boiling range (EN 13991): • Distillate to 235 °C • Distillate to 300 °C • Distillate to 355 °C	 % % %	 max. 20 40-60 min. 70	 - max. 10 min. 65
Benzo[a]pyrene (EN 1014-3)	mg/kg	max. 50	max. 50
Flash point Pensky-Martens (EN 22719)	°C	min. 61	min. 61

Please refer to the confidential annex (separate document) for the method of manufacture, origin of the active substance and batch data relating to the sources of creosote.

2.2.2. Assessment as to whether the conclusion of the initial assessment of approval remains valid

2.2.2.1. Physical chemical properties and methods of analysis

2.2.2.1.1. Physical chemical properties of the active substance and the product

No new information is available since the original approval and the conclusions remain the same although the physical hazards data have been revised according to Regulation (EC) No 1272/2008 (CLP). For creosote the active substance is the same as the product, therefore the physical chemical properties apply to both the active substance and the biocidal product.

Conclusion: The processing and application of creosote implies no particular risks arising from its physico-chemical properties when handled as specified. As the creosote product is the same as the active, the physical chemical parameters elucidated for the active also apply to the product.

2.2.2.1.2. Methods of analysis for detection and identification

2.2.2.1.2.1. Analysis of the active substance as manufactured

No new information is available since the original approval and the conclusions remain the same.

2.2.2.1.2.2. Formulation analysis

See above. The active substance and the product are the same.

2.2.2.1.2.3. Residue analysis

No new data on analytical methods for air and water were provided.
New information that became available since the original approval is briefly described below.

Soil
During the active substance first approval, the applicant stated that the provided US-EPA standard for extraction of polycyclic aromatic hydrocarbons (PAHs), phenols and heterocycles could be used in connection with any of the methods used for characterisation of creosote.
Submission of validation data in support of this statement was set as a data requirement. Additional data was submitted at the product family authorisation stage to verify the applicability of the extraction procedure and extraction efficiency for the determination of PAHs in soil. The analytical results from reference material supported the applicability of the extraction method.

During the renewal, the applicant submitted for the monitoring purposes an analytical method GC-MS for 18 PAHs (16 EPA PAHs + 2 PAHs) in soil. The described method was not fully validated. The laboratory that conducted the analysis has an accreditation for the method, however it covers only 16 EPA PAHs. The submitted data is acceptable.

Food and feeding stuff
During the renewal, the applicant submitted for the monitoring purposes an analytical method GC-HRMS for 18 PAHs (16 EPA PAHs + 2 PAHs) in fruit, however only a short description of the method is given as the applicant states that the method is confidential. The laboratory that conducted the analysis has an accreditation for the method, although it covers only 10 PAHs. Regarding the other 8 PAHs, the applicant states that the method was validated for them, yet no final report had been provided. The submitted data is acceptable.

Residue definition

According to Guidance on information requirements, analytical methods for monitoring purposes of residues of active substance in soil, water, air, food and feed should be made available for the active substance.
Creosote oil, however, is an UVCB substance of variable composition and unidentified 35-43% (w/w) constituents, making it very difficult to define residues that should be monitored.
Based on data submitted by the applicant, no study with goal to clearly determine which constituents of creosote constitute its residues in specific matrices was carried out.
During the RAR commenting period, it was proposed to use a specific number of PAHs as a residue definition for creosote as the active substance comprises mostly of polycyclic aromatic hydrocarbons.
In order to select PAHs that could be used in residue definition, data from the analytical methods concerning determined substances, submitted during a.s. approval, product authorisation and a.s. renewal, was analysed. The findings were summarised in Table C1.10 of the Confidential Annex. Using these information, a definition of creosote residue as 16 EPA PAHs + 2 other PAHs (naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benz[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, benzo[g,h,i]perylene, indeno[1,2,3-cd]pyrene, dibenz[a,h]anthracene, 1-methylnaphthalene, 2-methylnaphthalene) could be adopted.

While this set of PAHs allows to fulfil data requirements of Guidance, the WG and BPC concluded that it may not reflect actual residues and the subject should be investigated as a post-approval data requirement as mentioned in section 2.5 of the BPC opinion.

Reference specification of creosote

The reference specification of creosote oil is given in the standard EN 13991:2003. The specification is mostly based on physicochemical properties of creosote and only a content range of benzo[a]pyrene (BaP) is a parameter that specifies the amount of one constituent. The 5 batch analysis certificates provided by the Applicants show that creosote's parameters are in compliance with the standard. As the creosote exact composition is variable and unknown in 35-43% (w/w), and since BaP content was determined in all submitted CoA by all Applicants, PL CA was of the opinion that this information is sufficient: the submitted CoA confirm the stability of creosote's production in all of the listed sources and their compliance with the creosote standard. However, during the BPC-36 and BPC-37 it was agreed that specification of creosote should be investigated during the next renewal of creosote as mentioned in section 2.5 of the BPC opinion.

2.2.2.2. Classification and Labelling

No new information has been made available since the original approval, the previous classification remains appropriate for renewal.

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 classification and labelling proposed in the original SE CAR (2010) 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

A CLH dossier has not been submitted in order to amend the existing harmonised classification and labelling.

2.2.2.3. Efficacy and resistance

No new efficacy data are required at this stage and the conclusions of the initial evaluation remain the same; the innate activity of the active substance has been sufficiently demonstrated to allow the renewal of the approval of creosote.

2.2.2.4. Human health assessment

The former eCA (United Kingdom) stated that due to the lack of new data, initial human health assessment done by Sweden was valid. However, the applicant submitted new documents, e.g. Risk assessment on fruit grown in orchards constructed with creosote-treated stakes, Dermal contact of general public to agricultural and equestrian fencing, and Livestock Exposure Assessment for Creosote. Therefore, at the BPC WG meeting in March-April 2020, it was decided that the eCA (PL) would quote the previous evaluation and introduce updates, if required, and assessment of new studies.

2.2.2.4.1. Human health effects assessment

The biocidal product creosote and the active substance are one and the same. A database on the toxicity of creosote was submitted by the applicant. It included studies on toxicokinetics, acute toxicity, short-term toxicity, genotoxicity, reproductive and developmental toxicity, combined chronic toxicity and carcinogenicity.

2.2.2.4.1.1. Toxicokinetics and metabolism

Creosote is a complex mixture and is composed of several hundreds and probably several thousand different compounds. Standard Absorption, Distribution, Metabolism and Excretion (ADME) studies according to guidelines are therefore not possible to perform. The submitted database consists of published literature describing some parts of ADME of some of the key components of creosote. Great caution has to be taken when interpreting the ADME results obtained with individual components of creosote. The ADME of a complex mixture like creosote can be vastly different even with respect to the single components themselves.

The absorption from the gastrointestinal tract was relatively rapid following oral administration of phenanthrene and pyrene in the rat and was estimated to be higher than 90% based on the presence of the mother compound in the faeces. The oral route is, however, of minor importance in human exposure. Dermal exposure has been shown to account for about 90% of human exposure, and inhalation exposure accounts for the remaining part. Dermal absorption of creosote is, however, extremely difficult to assess depending on a large number of variables. Please see SE 2010 Doc II-B, section 9.1, for a discussion on this matter.

Information regarding distribution of creosote into tissues is scarce. Results regarding the persistence of creosote over a long period are inconclusive. The total recovery of the mother compounds and their metabolites were in some studies very low. For phenanthrene only about 10% was excreted following oral administration and for pyrene only about 50% of pyrene and the metabolites that were analysable with the technique used in the study, were excreted.

Either it is, as the applicant suggests, that different species of metabolites are formed and excreted but they are not analysable by the experimental conditions used or, alternatively, substantial parts of phenanthrene and pyrene and metabolites of the respective compounds are retained and possibly accumulated in the body. A combination of these two scenarios is also possible. In contrast, other studies show almost complete elimination of benzo(a)pyrene following dermal administration. Only about 0.5% was retained in the body after 7 days. Generally, metabolites of 2-3 ring aromatic compounds are mainly excreted into urine or to similar extent into urine and faeces, while metabolites of 4 –6 ring PAH are mainly excreted into the faeces.

Aromatic compounds are metabolized by microsomal oxidative enzyme systems in a first step, in particular by the cytochromes P450 system (CYP1A1, CYP2E1 and CYP3A) in liver, lungs and other tissues. Thereby, the PAHs form reactive intermediates (epoxides) that can bind to macromolecules and cause specific toxic effects. Generally, the epoxides are hydrolysed, thereby forming hydroxy-/dihydroxy compounds or are directly conjugated with glutathione. Dihydrodiols may undergo conjugation with glucuronic acid or sulphate. Hydroxylated species may be further oxidised and form quinones. Conjugates of phenols, dihydrodiols, quinones, anhydrides have been the principal metabolic products identified. The metabolic profile varies with compound and species tested.
The primary metabolic reaction of acenaphthene starts with the oxidative cleavage of the 5-membered ring in acenaphthene in rat.
The metabolites following administration with phenanthrene were phenolic and dihydrodiol compounds. In vitro experiments show that a single metabolite, trans-9,10-diOH-9,10-dihydrophenanthrene (K-region oxidation), was formed by liver microsomes from non-induced rats while various inducers stimulated the formation of additional metabolites. Creosote contains several of these potential monooxygenase inducers. Observations by others show that also conjugation with glutathione, may occur to a high degree. Conjugation with methionine may also occur, resulting in methylthioesters. These types of metabolites escaped analysis under the experimental conditions employed in the investigations outlined above.
In the metabolism of fluoranthene mainly 3-dihydro-2,3-diOH-fluoranthene was formed but also 3-OH-fluoranthene, and 1-OH-fluoranthene were identified. The metabolism of fluoranthene in human and rat liver microsomes was qualitatively roughly similar, but the spectra of metabolites differed a lot.
While the trans-2,3-dihydrodiol was the major metabolite in both systems, many more metabolites were seen in the rat samples. Rat liver microsomes were also more proficient at metabolising fluoranthene. Variability was seen in the human samples, with respect to both the extent of metabolism and the metabolite spectra. This probably reflects interindividual differences. There were also differences between the human and rat systems in the formation of R,R enantiomers of the major metabolite, which may have an impact on the mutagenic potency.
The main metabolite following administration of pyrene is 1-OH-pyrene.

2.2.2.4.1.2. Acute toxicity

Creosote has low acute toxicity when administered orally, dermally and via inhalation to rats.

Creosote is a skin irritant. Furthermore, creosote should, despite the negative results from the eye irritation study, on a precautionary basis, be considered to be potentially irritating to eyes, especially since practical experience with hot vapours of creosote has shown that it may display irritating properties to the eyes.

According to Regulation (EC) No 1272/2008 (CLP Regulation) Creosote should be labelled as **Skin Irrit. 2, H315 Causes skin irritation**

In the sensitisation studies creosote proved to be sensitising in the Maximisation test (M&K test), and considerations should therefore be taken if creosote should be labelled with **H317 May cause an allergic skin reaction.**

Additional classification proposed by the Applicant: H319 Causes serious eye irritation.

2.2.2.4.1.3. Short-term toxicity

For repeated administration of creosote via the dermal and inhalational routes the studies did not reveal any evidence for cumulative toxicity in rats.

Most of the changes observed in the dermal and inhalational studies were mild and did not persist after the recovery periods.

2.2.2.4.1.4. Genotoxicity

The mutagenic potency of creosote was studied *in vitro* in bacteria and mammalian cells and *in vivo* test systems in rats and mice. The results show that the creosote types tested were mutagenic in 2 out of 4 *in vitro* tests in the presence of a metabolising system (S9), while creosote was negative in the *in vivo* test systems with respect to genotoxicity. It has to be kept in mind that there was significant cytotoxicity in most of the experiments. This can eventually mask a mutagenic potential of creosote in these assays.

Different creosote types have been shown to display large differences in genotoxic potency and the composition of creosote today has drastically reduced amounts of genotoxic components compared to former creosote types. However, the overall results from this evaluation regarding the genotoxic potency of the creosote types tested are inconclusive. Risk mitigation procedures are important since no threshold can be said to exist for substances containing genotoxic compounds.

The complex composition of creosote includes several mutagenic components, and the results in genotoxicity assays varies, depending on for example, cell type, concentration, metabolising capacity etc.

Taking into consideration all above facts about creosote and conclusions about genotoxicity tests, the studies submitted in the dossier do not allow to exclude a genotoxic effect, but BPC WG considered that the information available on the genotoxicity was not sufficient to conclude on the appropriate classification.

2.2.2.4.1.5. Long-term toxicity and carcinogenicity

One dermal carcinogenicity study was submitted. In addition of oncogenicity a limited number of other endpoints with respect to long-term toxicity were investigated (Fraunhofer Institute, 1997).

Summary of long-term toxicity and carcinogenicity studies. Number of tumour bearing animals													
		Toluene (solvent control)		**CTP 1 [mg] low-BaP** (per treatment)				**CTP 2 [mg] high BaP** (per treatment)					**BaP** (per treatment)
	animals	**1**	**2**	**0.3**	**1**	**3**	**9**	**0.1**	**0.3**	**1**	**3**	**9§**	**0.0075**
1	total number	62	62	62	62	62	62	62	62	62	62	61	62
2	with skin tumours	**(1)***	**0**	**0**	**0**	**1**	**2**	**1**	**3**	**9**	**23**	**n.e.**	**47**
	%	**0**	**0**	**0**	**0**	**2**	**3**	**2**	**5**	**15**	**37**	**n.e.**	**76**
3	with malignant tumours	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**1**	**3**	**16**	**n.e.**	**32**

	%	**0**	**0**	**0**	**0**	**2**	**0**	**2**	**2**	**5**	**26**	**n.e.**	**52**
4	exclusively with benign tumours	**(1)***	**0**	**0**	**0**	**0**	**2**	**0**	**2**	**6**	**7**	**n.e.**	**15**
	%	**0**	**0**	**0**	**0**	**0**	**3**	**0**	**3**	**10**	**11**	**n.e.**	**24**

* Skin tumour type atypical of PAH (cavernous haemangioma), to be considered incidental

§ treatment group terminated after 274 days, therefore: n.e. = no further examinations during the study

The results show that there was a dose-dependent increase in the number of tumours, and the tested creosote types produced 3-5 times more tumours than what could have been expected based on their BaP content.

A threshold cannot be said to exist, and it is generally agreed that there is no threshold for genotoxic substances. Creosote is a complex mixture which contains several substances that are regarded as carcinogenic and mutagenic. A NOAEL could therefore not be set.

According to Regulation (EC) No 1272/2008 (CLP Regulation) Creosote is classified as **Carc. 1B, H350 May cause cancer**.

Regarding other endpoints following long-term exposure, some parameters, in addition of carcinogenesis, were investigated. None of these gave rise to significant findings. Carcinogenesis can, however, be regarded as the most severe endpoint after long-term exposure.

2.2.2.4.1.6. Reproduction toxicity

In the teratology studies in rats there was an increase in post-implantation loss (early resorptions) in the high dose group. There was no difference in maternal body weight and body weight gain between the dose groups and the control when corrected for gravid uterine weight. It seems that creosote has an impact on early intrauterine development (seen as post-implantation loss) under very mild maternal toxicity.

In the developmental toxicity study performed in rabbits there was an increase in abortions and a reduction in the number of live foetuses in the high dose group. This can either be a result of maternal toxicity or reflect a reproductive/developmental toxicity effect of creosote.

All together these results indicate that creosote has an impact on early intrauterine development. It is unlikely that the increases of post-implantation losses are coupled to the decreased maternal food consumption, and there were virtually no other maternal toxic signs. Creosote should therefore be labelled with **Repr. 2, H361d Suspected of damaging the unborn child.**

In the two-generation reproduction study, a significant reduction in the number of live F1 offspring in the mid and high dose groups was observed. There was also a decrease in litter size and in offspring viability in F2, and this effect was even clearer than in F1. The body weight of live pups was decreased among all dose groups (on day 14 and 21 after birth) and showed a clear dose response (less than 10 % in the low dose group). However, there was no difference in body weight on the day of birth.

Overall, the results of the reproduction studies indicate that creosote has an impact on reproduction and fertility under the influence of very mild maternal toxicity (maternal toxicity mainly seen as salivation and reduction of body weight and body weight gain (up to 20%) during gestation and lactation, and note, no corrections were made for gravid uterine weight). The decrease of maternal body weight gain during gestation may therefore be an effect of the decreased number of viable offspring.

According to Regulation (EC) No 1272/2008 (CLP Regulation) Creosote should be classified as **Repr. 1B, H360F May damage fertility**.

2.2.2.4.1.7. Neurotoxicity

No specific data submitted. The results from the other studies do not indicate any neurotoxic potential of creosote.

2.2.2.4.1.8. Medical data

Creosote has been used for more than 100 years. Clinical findings thought to result from occupational exposure have mainly been restricted to the presence of various types of skin rashes, such as pustular folliculitis, tar warts, dermatitis, including phototoxic dermatitis after subsequent or simultaneous exposure to sunlight.

Epidemiologists have attempted to determine whether people who are occupationally exposed to creosote are at a greater risk than the general population for certain cancers. In a historical cross-sectional occupational survey (Henry 1947), skin tumour incidences over 26 years amounted to 35 cases for which "creosote oil" was nominated as causal agent out of 3753 skin cancer cases (about 1 %/26 years), notified by the “British Medical Inspector of Factories” in the first half of the 20th century. This low incidence has to be seen in relation to the less stringent working standards and application of creosotes with much higher PAH levels than today.

Studies conducted in Norway and Sweden and in the United States show conflicting results. Some studies point to a connection between creosote exposure and various forms of cancer and there are also a number of studies that fail to show such an association between occupational creosote exposure and any cancers. Simultaneous exposure to sunlight was a confounding factor.

The significance of the results of the epidemiological studies and exposure studies are difficult to interpret. Many of these studies are limited by their date and/or by uncertainty over the composition of the creosote in use at the time. The latter is a problem even for the more recent studies. Some of the studies were based on questionnaires on past occupational activities, giving rise to uncertainty about the reliability of the information gathered maybe several years after exposure occurred. Furthermore, the number of workers available for the studies were uncertain or few. The studies were also hampered by the lack of follow-up and control of confounders.

A recent cohort study which included creosote-exposed workers of 11 wood-treating plants in the USA from 01 January 1979 through 31 December 1999 failed to reveal any exposure-related mortality increases (Wong and Harris, 2005).

A large risk assessment was conducted for creosote pressure-treating workers using probabilistic distributional methods (Sapphire, 2004). This was not a single study, and it was based on reviews of animal data, case reports, cohort studies, case control studies, cross-sectional studies, and exposure studies. It included some of the studies mentioned above.

The estimates of occupational cancer risk from creosote in the Sapphire study gave the result that the largest part of the cancer risk distribution fell within acceptable risk levels (1×10^{-6} to 1×10^{-4}) traditionally employed for regulatory purposes by the US EPA (Sapphire, 2004). However a small part (95th %-ile) (result of cancer potency factors: $1.5\text{x}10^{-4}$ with probabilistic analysis included, and $3.1\text{x}10^{-4}$ with probabilistic analysis excluded) actually falls above the acceptable risk (that is $1\text{x}10^{-4}$), giving a reason for concern.

Overall, the body of epidemiological data does not indicate an apparent elevated cancer risk for creosote workers. No new medical data was submitted by the Applicant in the context of the renewal of approval of creosote for use in biocidal products.

Direct observations, e.g. clinical cases and poisoning incidents

Fatal cases after ingestion of creosote involves the amount of about 7 g for adults and 1-2 g for children. Death occurs 14 to 36 hours after ingestion of such amounts, and is mainly coupled to cardiovascular collapse.

Symptoms of systemic exposure and illness are salivation, respiratory difficulties, vomiting, headache, irregular pulse, vertigo, hypothermia, cyanosis, and mild convulsions.

2.2.2.4.1.9. Acceptable daily intake (ADI) and acute reference dose (ARfD)

By definition, ADI gives a safety level of daily intake of a substance via ingestion.

The route of exposure to creosote is primarily via dermal exposure, and to some extent via inhalation. Creosote is only used by professional users. The exposure via food or drinks to creosote would be practically non-existent as primary exposure. However, in case of secondary exposure, the intended uses implicate contact of treated wood with fruits and hops.

Creosote is a complex mixture and contains several components that are regarded as carcinogenic and mutagenic, and creosote is classified as carcinogenic Carc. 1B. For non-threshold carcinogens such as creosote, ADI derivation is not relevant. Creosote is regarded as a complete carcinogen (i.e., it has both initiating and promoting capacity with respect to tumour formation). The eCA PL is therefore of the opinion that an ADI or a long-term reference value cannot be established for creosote. For creosote, as a carcinogen without threshold, semi-quantitative hazard characterisation has to be followed (in accordance with BPR Guidance, Parts B and C, section 2.4.1.1).

2.2.2.4.1.10. Acceptable Operator Exposure Level (AOEL)

Creosote is a complex mixture and contains several components that are regarded as carcinogenic and mutagenic, and creosote is classified as carcinogenic Carc. 1B. According to the EU Guidance for the setting and application of acceptable operator levels (AOELs) (rev 10), an AOEL cannot be set for substances that are genotoxic and/or carcinogenic unless a threshold mechanism clearly has been demonstrated. Creosote is regarded as a complete carcinogen (i.e., it has both initiating and promoting capacity with respect to tumour formation).

The PL eCA, similarly to the former RMS, is therefore of the opinion that an AOEL or a long-term reference value cannot be established for creosote. For creosote, as a carcinogen without threshold, semi-quantitative hazard characterisation has to be followed (in accordance with BPR Guidance, Parts B and C, section 2.4.1.1).

2.2.2.4.1.11. Data on exposure for operators

Wood preservation with creosote is restricted to professional users. Several worker exposure studies from industrial impregnation plants have been submitted. two of which were more appropriate for European conditions. In addition, a follow-up study was submitted in October 2008, and a study on down-stream users was submitted in November 2008. The studies focused on work tasks known to result in the highest exposure levels at the impregnation plants and among down-stream users, and are considered to adequately represent exposure for a whole and typical working day, while the plants were run at full capacity.

Since creosote is a complex mixture consisting of several hundreds, and maybe thousands of different compounds, it cannot be measured directly. Instead, pyrene served as a marker substance for skin exposure and 15 of the EPA prioritised PAHs were monitored in the inhalational exposure measurements in the exposure studies.

The main conclusions were that worker exposure occurs primarily via the dermal route and is dominated by hand exposure, **and is clearly connected to the proximity**

of the treating cylinder.

The estimated fraction of total body deposition arising from dermal creosote deposition ranged from **40-57 µg/kg bw/day** in the one study, and from **63 µg/kg bw/day** with additional protection to **210 µg/kg bw/day** without additional protection in another study.

Inhalational exposure was measured to be up to **13 µg/kg bw/day (0.13 µg/kg bw/day with PPE)** (FIOH study, sum of detectable PAHs, dominated by naphthalene at >60 %). The inhalational exposure was measured outside of the respiratory protection, i.e., the resulting systemic exposure was reduced by the respiratory protection with 95-99%. Furthermore, the concentration of naphthalene in air is far below the existing Occupational Exposure Limit (OEL).

The study on down-stream users was focused on installation operations on treated wooden poles for in-service preparation, such as furnishing and cutting of electricity poles, installation of conductors, and installation of a separator. The work also involved setting up poles, climbing of poles by using climbing irons, sawing and drilling.
The results show that the exposure is, for most job tasks, at approximately the same level or lower as at the impregnation plants.

A value of 10 % dermal absorption is used in the quantitative risk characterisation.

The EU Guidance Document on Dermal Absorption (Sanco/222/2000 rev 7) from 2004 and EFSA Guidance documents on Dermal Absorption from 2017 were analysed. Since 2017, the recommended OECD Test Guideline is 427 (instead of OECD TG 428), in which a broader range of measurements is required. However, the Applicant had submitted studies in accordance with OECD 427 and 428. The submitted experimental data on dermal absorption in rats are available and hence they are the basis for calculations. Therefore, the default values, which are mentioned in the new EFSA Guidance in case of lacking of experimental data, are not relevant. The dermal absorption value was re-assessed to check if the calculations are in line with the EFSA Guidance on dermal absorption (2017). The studies which were submitted for initial approval of creosote were evaluated by SE CA 2010. No new study on dermal absorption was provided for the renewal and hence assigned to be evaluated.
The calculation method used in first evaluation in 2010 is in line with the current Guidance (the same equation and usage of maximum flux rates). Therefore, the first assessment of dermal absorption is still valid. Thus, the value of 10% for dermal absorption, as decided at TMII-2008 and TMIV-2008, should be sustained and used for a risk assessment.

It is concluded that there are sufficient MOEs (margin of exposure) only for the downstream users for the scenarios of pole installers for the tasks of Installation of conductors and Furnishing of poles and for workers for the scenario of brushing wooden ends after cutting, whereas for all other scenarios of downstream users and all other scenarios of workers in the European impregnation plants, the MOEs are not sufficient. It should be bore in mind that, as a general rule, a risk for the general public from secondary exposure to a non-threshold carcinogenic biocidal substance is also non-tolerable (according to BPR Guidance, Parts B and C section 2.4.1.1 Semi-quantitative hazard characterisation for non-threshold carcinogens).
It is estimated that the exposure situation can be further improved by extra protective measures during work tasks where there is a risk of exposure – given in section 2.2.2.8.

2.2.2.4.2. Exposure assessment

Data on exposure for bystanders

Creosote is exclusively used by professional users, and there are sufficient MOEs for workers. Any occasional exposure by the public by for example touching a pole can never exceed the exposure for workers, and such eventual exposure would consequently lead to very large MOEs.

Exposure to non-professionals is therefore considered to be of minor relevance.

Furthermore, the exposure has been shown to be clearly connected to the proximity of the treating cylinder, and inhalational exposure account for only a small part of the total exposure levels. Investigations regarding emissions to ambient air at two American pressure treatments plants have shown the ambient air emissions for naphthalene, which is the most significant PAH air emission, are close to background concentrations. Other, more high-molecular weight PAHs are below detection levels. Consequently, there is no apparent elevation in health risks for people living nearby creosote treatment plants.

The relevant route of exposure to creosote is primarily via dermal contact and via inhalation as creosote is used by professionals only. However, indirect exposure of the general public via dermal and oral routes should be taken into account as creosote-treated wood is intended to be used in agricultural branch of the economy (e.g. poles in vineyard, orchard or equestrian fences).

Exposure during contact with treated wood

Applicant has submitted exposure to treated poles using leaching rate instead of application rate explaining that such an approach corresponds to a realistic worst-case calculations. Nevertheless, such a modification is not foreseen in models provided in the TNsG or Headhoc recommendation described below.

Description of Scenario [adult and children – contact treated poles or equestrian fences]		
Secondary long-term exposure, adult, children and toddlers – contact treated poles or equestrian fences, dermal exposure. As treated wood with creosote is not allowed to be used indoors, to construct toys or playgrounds, the infant exposure to creosote is not foreseen. Exposure assessment is based on a model provided in the TNsG on Human Exposure (2002) for secondary long-term exposure of toddlers playing on treated structures.		
	Parameters	Value
Tier 1	Application rate (surface application; applicant)	22 mg a.s./cm^2
	Concentration a.s. in biocidal product	100 % (w/w)
	Amount a.s. available on wood surface for transfer to skin (Application rate x density x concentration a.s.)	22 mg a.s./cm^2
	Hand surface (adult, palms of both hands, Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure)	Adult 410 cm^2 Child 6-12y 213.9 cm^2 Child 2-6y 165.5 cm^2 Toddler 115.2 cm^2
	Proportion of palms of hand in contact with the b.p., percentage contaminated skin TNsG on Human Exposure, part 2 (2002)	20 %
	Transfer coefficient of biocidal product from dried b.p. to hand TNsG on Human Exposure, part 2 (2002)	2 %
	Dermal absorption (RAR 2020)	10 %
	Body weight, adult Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure	Adult 60 kg Child 6-12y 23.9 kg Child 2-6y 15.6 kg Toddler 10 kg

Dermal Exposure	**Units**	**Adult**	**Child 6-12y**	**Child 2-6y**	**Toddler**
Application rate	mg a.s./cm^2	22			
Concentration a.s. in biocidal product	%	100			
Proportion of palms of hand in contact with the b.p.	%	20			
Transfer coefficient of biocidal product from dried b.p.	%	2			
Dermal absorption	%	10			
Hand surface	cm^2	410	213.9	165.5	115.2
Body weight	kg	60	23.9	15.6	10
Exposure$_{\text{dermal ab10\%}}$	mg/kg bw/d	0.0601	0.0788	0.0934	0.1014

Consumer exposure to creosote residues in plant-derived food

The scenario and approach to calculate consumer exposure and risk to creosote residues in fruits was submitted by the applicant. For more details see sections entitled *Risk via residues in plant-derived food* (within 2.2.2.4.3) and *Aspects concerning creosote treated wood in UC4 including the new monitoring studies with determination of selected compounds in creosote treated wooden posts, soil and fruit samples* (2.2.7.).

Livestock exposure

The applicant submitted a scenario for calculating the livestock exposure to creosote-treated wood in fence. The approach by the applicant has been adopted by PL CA, however, with a modification of leaching rate parameter used for calculating oral exposure of grass-eating cattle. 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 is used in RAR.

<table>
<tr><td colspan="3">Description of Scenario for livestock exposure</td></tr>
<tr><td colspan="3">To calculate Livestock Exposure to active substance, the scenarios and examples described in Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017 have been applied. All required parameters have been taken from Appendix 6-1: Default Value Working Tables, p.366 or delivered by applicant.</td></tr>
<tr><td></td><td>Parameters</td><td>Value</td></tr>
<tr><td rowspan="7">Tier 1</td><td>Dose rate[1]</td><td>90 kg as/m^3</td></tr>
<tr><td>Treatment with double vacuum pressure: 50L/m3 (amount in outer 1 cm layer of wood)</td><td>50 kg as/m^3</td></tr>
<tr><td>Conversion of amount of active substance per cubic meter to a.s. per square meter
Thickness of layer "representing" one square meter: 0.05 mm</td><td>50 kg as/m^3 x 0.05×10^{-3}m = 2.5 g as/ m^2</td></tr>
<tr><td>Extraction from wood</td><td>100%</td></tr>
<tr><td>Dermal exposure (30% of skin)
Body surface area in contact with product:
Beef cattle
Dairy cattle
Calf
Fattening pig
Horse
Goat</td><td>
m^2
1.44
1.68
0.87
0.45
1.62
0.45</td></tr>
<tr><td>Oral exposure (wood licking)
Calf / Fattening pig
Surface area of tongue
Frequency of surface licking

Oral exposure (Amount of wood chewing)
Horse[1]

Goat[2]

Oral exposure (grass consumption)
Beef cattle / Dairy cattle
See table below</td><td>

0.008 m^2
10 licks/d

152cm^2 Applicant
152cm^2 Applicant</td></tr>
<tr><td>Body weight:
Beef cattle
Dairy cattle
Calf
Fattening pig
Horse
Goat</td><td>kg
500
650
200
100
400
70</td></tr>
<tr><td>Tier2</td><td>UC 3 Time 1 leaching rate</td><td>0.366mg/m^2/d</td></tr>
</table>

[1] According to ECHA Guidance 2017, 1.9×10^{-5} m^3 of wood is chewed by a horse. Applicant has assumed a stick of a length and width of 19 cm and 1 cm, respectively. A surface of 4x19 +2x1 = 78cm^2. Subsequently, this stick can be cut by a hose into small dices (38 pieces of wood 1cm x1cm x 0.5cm) resulting in available surface of 152cm^2.

[2] The same assumption was done for a goat.

Oral Exposure (eating grass)		**Units**	**Beef cattle**	**Dairy cattle**	**Source**
Tier 1	Leaching rate	[mg/m2/d]	0.366		UK RA draft 2019
	Animal weight	kg	500	650	EFSA 2015/ OECD 2009, OECD2013
	Food intake	[kg DW/d]	12	25	
	Grass in food: Fraction 0.6 kg DW	kg	7.2	15	
	Mass of grass below the fence surface [per m^2]	kg /m^2	0.2		Assumption
	Daily grass intake by the animal (at fence)	%	100		Assumption
	Grass contamination [%]	%	50		Assumption
Tier 2	Daily grass intake by the animal (at fence)	%	30		Assumption

Mass of grass taken up by the animal: assumed 1 kg fresh weight per fence unit, which corresponds to 0.3 kg DW/unit (1.5 m), or 0.2 kg DW/m. (DW = dry weight)
The fence is assumed to consist of units of 1.5 m length and 1.5 m height with five horizontal wooden boards of 0.2 m width between the carrier posts. The effective vertical surface (one-sided) is 1.5*0.2*5 m^2 = 1.5 m^2, unit length 1.5 m. That means a length of 1 m relates to a vertical surface of 1 m^2.

Livestock exposure

Dermal exposure Tier 1	**Unit**	**Beef cattle**	**Dairy cattle**	**Calf**	**Fattening pig**	**Horse**	**Goat**
Dose rate	mg as/m^2	2500					
Extraction from wood		1					
Body surface area in contact with product	m^2	1.44	1.68	0.87	0.45	1.62	0.45
Body weight	kg	500	650	200	100	400	70
Exposure	**mg/kg bw/d**	**7.2**	**6.46**	**10.86**	**11.25**	**10.13**	**16**
Tier 2							
Dose rate	mg as/m^2	0.366					
Extraction from wood		1					
Body surface area in contact with product	m^2	1.44	1.68	0.87	0.45	1.62	0.45
Body weight	kg	500	650	200	100	400	70
Exposure	**mg/kg bw/d**	**0.00105**	**0.00094**	**0.00159**	**0.00165**	**0.00148**	**0.00235**

Oral exposure (chewing or licking) Tier 1	Unit	Beef cattle	Dairy cattle	Calf	Fattening pig	Horse	Goat
Dose rate	mg as/m^2	2500					
Amount of wood chewing	m^2	x	x	x	x	0.0152	0.0152
Surface area of tongue	m^2	x	x	0.008		x	x
Frequency of surface licking				10		x	x
Body weight	kg	500	650	200	100	400	70
Exposure	**mg/kg bw/d**			**1**	**2**	**0.095**	**0.5428**
Tier 2							
Dose rate	mg as/m^2	0.366					
Amount of wood chewing	m^2	x	x	x	x	0.0152	0.0152
Surface area of tongue	m^2	x	x	0.008		x	x
Frequency of surface licking		x	x	10		x	x
Body weight	kg	500	650	200	100	400	70
Exposure	**mg/kg bw/d**	**x**	**x**	**0.00015**	**0.00029**	**1.4x10^{-5}**	**7.9x10^{-5}**

Oral exposure (eating grass) Tier1	Unit	Beef cattle	Dairy cattle
Daily grass intake by the animal (at fence)	%	100	
Surface of fence sections above the grass	m^2	7.2/0.2=36	15/0.2 = 75
Section-related leaching rate	mg	13.18	27.45
Creosote uptake by the animal	mg/d	6.59	13.72
Specific uptake (UT)	mg/kg bw/d	0.0132	0.021
Tier 2			
Daily grass intake by the animal (at fence)	%	30	
Surface of fence sections above the grass	m^2	7.2x0.3/0.2=10.8	15x0.3/0.2=22.5
Section-related leaching rate	mg	3.96	8.235
Creosote uptake by the animal	mg/d	1.98	4.18
Specific uptake (Exposure)	mg/kg bw/d	0.00396	0.006

Data on exposure for workers – brushing

Description of Scenario Application – Brushing and rolling by professionals		
The activities of the professional users are applying a product containing 100% Creosote to wood using a brush indoors or outdoors. The model "Professional brush treatment" (based on Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006) according to Biocides Human Health Exposure Methodology (October 2015) – PT8 is used for the dermal and inhalation exposure estimation. Parameters given by the applicant have been used[1].		
	Parameters	Value
Tier 1	Creosote	100%
	Dermal absorption	10%
	Body weight	60 kg
	Inhalation rate (short - and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m³/h (0.021 m³/min)
	Exposure duration[1]	48 min
	Application area[1]	0.2 m²
	Indicative values (Biocides Human Health Exposure Methodology)	Hands: 0.5417 mg/m² Body: 0.2382 mg/m²
	Inhalation[1]	0.135 mg/m3
	Coated coverall	90% protection
	PPE (gloves)	90% protection
Tier 2	Chemical resistance coverall	95% protection
	PPE (gloves)	90% protection
	RPE	90% protection

For brushing scenario, parameters given by the applicant have been used and presented in the table above. Moreover, applicant has stated that brushing is also a regular application with the worst-case parameters as follows: exposure duration 7h/d and application area 25 m^2/d. However, in accordance to the conservative parameters of the scenario, exposure duration 240 min and application area 31.6 m^2 should be used.
Additionally, exposure to a.s. during washing out of a brush has been calculated based on HEEG opinion 11 using exposure calculator for washing out of brushes. The scenarios description and calculations are included in Appendix VIII.

Data on exposure for workers – hot-and-cold impregnation as separate application

Applicant submitted monitoring data for hot-and-cold dipping impregnation in 2016. The former eCA (UK) did not evaluate these data and this deficiency was pointed just before the BPC-36 meeting.
The assessment by the PL CA has not been completed, due to the identified weaknesses of the submitted monitoring data.
Based on the submitted data, it can be concluded that biomonitoring studies were conducted only for manufacturing plant using pressure impregnation methods. The external contamination

of the working clothes was investigated in three pressure treatment plants and in one plant using hot-and-cold immersion process.
However, all the urinary excretion data presented were obtained from operators in those three pressure-treatment impregnation plants. The applicant highlighted that those measurements had not been performed in temporal conjunction with the measurements of the contaminations of the work clothes.
Therefore, direct comparison of the extent of external contamination with the inner burden of the worker could have not been done. However, it was concluded that based on comparison of external contamination levels between pressure and non-pressure methods, an internal body burden for non-pressure application is in the range of what has been found among creosote workers in pressure-treatment plants.
The results of the findings for the contamination of overalls and gloves in plant using non-pressure method showed that cloth contamination with PAH during unloading of tank in comparison to loading stage might be even 100 –fold higher. The explanation of this fact refers to unusually hot seasonal and higher oil temperature than common at unloading.

The dipping process is an open one and manual action is needed for removing the finished poles from the immersion basket and putting them into a metal cage for bundling and subsequent storage. Applicant mentioned that either technique (understood as pressure method or dipping method) also require manual contact. However, manual loosening and removing of oil-polluted chains or secure belts does not seem to be as time consuming process as removing the finished poles from the immersion basket, where the contact with contaminated part of the basket cannot be excluded. It has also to be highlighted that the workplace exposure to carcinogenic substances (Cat 1B) must be avoided or minimised as far as technically feasible (Directive 2004/37/EC). Further analysis should be considered if authorisation of the application method by hot-and-cold impregnation process should be granted as other methods without the manual removing the finished poles from the immersion basket can be applied.
Taking into account that the dose/ application rate/ retention rate is defined by the national standards, any additional specific RMM may possibly be considered and may be assessed only in relation to the dose/ application rate/ retention rate applicable for each Member State. Therefore, PL CA is in the position that non-pressure impregnation methods should be evaluated at product authorisation stage.

2.2.2.4.3. Risk characterisation

In the revised risk characterisation, the revised dermal absorption value of 10% (as agreed at TMII 2008 and BPC-36 2020) and the exposure values from the European plants are used. Furthermore, two different MOE are presented for some of the toxicity endpoints. One MOE in which the major route of exposure (dermal) is taken into account is presented and one MOE in which the inhalational exposure (with PPE) is included. However, it has to be understood that the toxicological profile for the volatile fraction of creosote is completely different from that of whole creosote to which animals are exposed orally or dermally and to which workers are exposed dermally, and hence, it can be questioned if the volatile fraction really should be included. Moreover, the workers use respiratory protection at critical work tasks. The volatile fraction consists of a few detectable light-boiling PAHs with naphthalene as a major component (60->90%). More toxic and carcinogenic PAHs (e.g., BaP) seem not to volatilize.

Furthermore, it has to be taken into account that experimental data have been developed for the oral route in some studies. Utilising the oral route may be considered as a worst case compared with the relevant dermal exposure route in humans.

Summary of the potential creosote exposure to operators with respect to different time frames and toxicity endpoints

	NOAEL	**Exposure**	**MOE** [1, 2]
Subchronic dermal toxicity test	400 mg/kg bw/day (revised NOAEL, see commenting table)	6.4 µg /kg bw/day (64 µg /kg bw/day x **10%** dermal absorption) 13.6 µg /kg bw/day (highest value from the FIOH study, **10%** dermal absorption)	**MOE = 62 500** **MOE = 29 411**
Subchronic inhalation toxicity test	22 mg/m^3 corresponds to 5.5 mg/kg bw per rat[3)]	Sum of detectable PAHs: 0.13 µg /kg bw/day (with PPE) (Σ15 PAH, with >60 % naphthalene)	**MOE = 42 307**
Teratogenicity test (rat, rabbit: oral)	50 mg/kg bw/day (rat) 9 mg/kg bw/day (rabbit)	Dermal exposure 6.4 µg /kg bw/day (64 µg /kg bw/day x **10%** dermal absorption) Dermal exposure 6.4 µg /kg bw/day + inhalational exposure 0.13 µg /kg bw/day (Sum of detectable PAHs:: (Σ15 PAH, with >60 % naphthalene) = 6.33 µg /kg bw/day 13.6 µg /kg bw/day (highest value from the FIOH study, **10%** dermal absorption)	**MOE = 7 812** (rat NOAEL, oral vs. dermal bioavailability to be considered) MOE (inhalation included)[1] = 7 657 **MOE = 3 676** **MOE (rabbit) =1 406** (rabbit NOAEL, oral vs. dermal bioavailability to be considered) MOE (rabbit, inhalation included)[1] = 1 378

Two generations reproduction study	25 mg/kg bw/day	Dermal exposure 6.4 µg /kg bw/day (64 µg /kg bw/day x **10%** dermal absorption) Dermal exposure 6.4 µg /kg bw/day + inhalational exposure 0.13 µg /kg bw/day (Sum of detectable PAHs: (Σ15 PAH, with >60 % naphthalene) = 6.53 µg /kg bw/day 13.6 µg /kg bw/day (highest value from the FIOH study, **10%** dermal absorption)	**MOE = 3 906** (rat NOAEL, oral vs. dermal bioavailability to be considered) MOE (inhalation included)[1] = 3 828 **MOE = 1 838**

1. Abbreviations: MOE = Margin of Exposure (NOAEL/Exp.) Generally a MOE of >100 is considered to be adequate. Moreover, an additional factor of 10 should be used, since creosote is classified as Carc. 1B. This results in a factor of 1000, i.e., the MOEs should preferably be at least 1000.
2. The use of respiratory protection has been taken into account when inhalational exposure has been included.
3. The <u>dose</u> (mg/kg bw) received by the rats in the 90-day study
   NOAEL = 22 mg/m^3 = 0.022 mg/L
   Rat breathing rate =175 ml/min = 10.5 L/h = 63 L/day (6 h in this study)
   Rat weight = 250 g
   Dose received at NOAEL= 0.022 mg/L x 63 L/day) /0.25 kg = 5.5 mg/kg bw/day

All MOEs are higher than 1000.

For the short-term (90 day) studies, it can be noted that most NOAELs are derived based on mild effects at the LOAELs. Basically, all findings in the short-term studies were mild and of reversible nature. Creosote is also not considered to be acutely toxic. It exhibits, however, irritation properties to skin (as shown by the studies), and to the eyes and to the respiratory tract (as shown by practical experience). This can be overcome by more stringent use of the best available PPE, including chemical-resistant gloves, coveralls, sturdy boots and respirators.

For inhalational exposure the situation is complex. On one hand, inhalational exposure has proven to be of minor importance quantitatively in comparison with dermal exposure. Inhalational exposure accounts for about 10% of the total exposure. The high-molecular weight PAHs seem not to volatilise and are not considered to be problematic from an inhalational exposure point of view. On the other hand, coal tar creosote constituents such as naphthalene, methylnaphthalenes, acenaphthene, phenanthrene, and fluorene have been detected in emissions at pressure treatment facilities.

This is particularly the case for naphthalene, which accounts for more than 50 % of the emissions. This is problematic and may be of toxicological significance, because naphthalene has recently been identified as a potential carcinogen by the inhalation route in rodents. In two long-term inhalation carcinogenicity studies, naphthalene proved to be carcinogenic to the lung tissue of mice and to the nasal tissue in rats at exposure concentrations of 50 mg/m^3 and above. The relevance to humans is obscure. Air-borne naphthalene concentrations in wood-treatment plants in Finland and USA ranged between 0.04 - 5.7 mg/m^3.

Emissions to air may occur at several points in the treatment process, such as when cylinder doors are opened after a treatment cycle, or when creosote is transferred from the heater to the cylinder at the beginning of the impregnation process.

However, all emissions can be led to incineration and proper inhalational PPE are used at work tasks with a risk of inhalational exposure. Furthermore, dermal exposure has proven to be the most significant exposure pathway.

Risk characterisation of different working scenarios with respect to cancer risk

For the exposure assessment, 10% dermal absorption is used in conjunction with the highest exposure values from monitoring studies in European plants.

For systemic cancers, it is clear that dermal absorption should be taken into account. Even for skin cancer this may very well be the case since several of the components need to penetrate the skin in order to be metabolised and thereby exhibit any potential carcinogenic properties. In any case, the substances need to penetrate into the cells in order to be genotoxic.

A risk characterisation of the working scenarios with respect to cancer risk can (instead of using a NOAEL, which according to the RMS, and other bodies, cannot be identified in the cancer study) be performed by calculating the MOE by using the T25 value. The dose descriptor T25 gives an indication of the dose of a chemical resulting in a fixed incidence of tumours (in this case 25%). The T25 approach has been used for creosote by other bodies (Scientific Committee for Toxicity, Ecotoxicity and the Environment, CSTEE) and for non-threshold carcinogens by the Scientific Committee on Consumer Products (SCCP), and also by EFSA, as well as for other substances within the EU and is also recommended in ECHA (2008): Guidance on information requirements and chemical safety assessment, Chapter R.8) to be used for non-threshold carcinogenic responses and when a linear dose-response can be assumed. In the Guidance on the BPR: Volume III Assessment & Evaluation (Parts B+C) Version 2.1 February 2017, section 2.4.1.1 "Semi-quantitative hazard characterisation for non-threshold carcinogens", the use of T25 is described but also the use of the Benchmark dose (BMD). The BMD usually represents a 10% increase of the tumour incidence. The T25 value was chosen in the present case for the following reasons:
The T25 is recommended in the BPR Guidance when there is a linear dose-response, as is the case with creosote. Furthermore, the T25 has been used quite extensively in the EU, especially for non-threshold carcinogens. Moreover, a T25 value calculated for BaP in creosote was already available and has previously been used in risk assessment for creosote by CSTEE (1999) (link: https://ec.europa.eu/health/node/42577_en). In addition, the results obtained with the two procedures (T25 and BMD) are in most cases, when there is a linear dose-response, virtually identical.

The T25 value has been estimated by CSTEE (1999), based on BaP as a marker of carcinogenic potency of creosote using the data from a dermal cancer study in mice, (see DOC III A6/B6, point A6.7) to be 13 µg/kg bw/day BaP, corresponding to 1300 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). This is corrected by a factor of 5, since the creosote types were 5 times more potent than the control based on BaP content, resulting in 260 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). Please note that the detection limit for BaP in the analysis of the components of creosote is 10 ppm, and BaP was not detectable (i.e. below 10 ppm) in European creosotes WEI type B and C, meaning that the following risk characterisation based on a content of BaP is over-conservative. The T25 value is also corrected to account for differences in exposure conditions in order to obtain a corrected T25 or human T25. Guidance is to be found in ECHA (2008): Guidance on information requirements and chemical safety assessment, Chapter R.8.

In the present case the following modifications are made:
$2/5 \times 75/40 \times 52/48 = 0.8125$
The figures 2/5 are due to the fact that the animals in the dermal cancer study (Fraunhofer Institute, 1997) were exposed 2 times per week and creosote workers work five days per week and may thus be exposed five days per week.

No correction is needed for the daily duration of exposure, since the T25 value from the mice carcinogenicity study was derived as dose per kg bodyweight per day. Therefore, it is not plausible to correct for daily duration of exposure when extrapolating from mice to humans. Such correction has already been made when calculating daily dose. Performing the correction twice leads to an underestimation of risk for humans by a factor of 8 (24 hrs / 3 hrs). The REACH guidance foresees such a correction when the dose metric is a concentration (e.g. in inhalation studies mg/m3). Moreover, there is no assurance that creosote stayed on the skin of the mice entirely until the next application (two applications per week), since the site of application on the mouse skin was not covered.
The figures 75/40 are based on that the animals were exposed their whole lives (75 years is a default figure for a human lifetime), while workers may at maximum be exposed a whole working life, i.e., 40 years. The figures 52/48 are based on the fact that the animals were exposed 52 weeks per year, while creosote workers work at maximum 48 weeks per year.

The following corrected T25 is obtained and used in the risk characterisation:

CorrT25 = 0.8125 x 260 = 210 mg/kg bw/day

Correction of this value for dermal absorption in mouse is needed according to a DE comment submitted in the context of the renewal of approval. Nevertheless, there are no data on dermal absorption in mouse. Considering, in general, the higher dermal absorption in mouse compared to humans and in particular, the treatment-related inflammatory changes of the skin observed in all groups in Fraunhofer Institute (1997) study, it is proposed to use an estimate of 50% dermal absorption in mouse or to apply an Uncertainty Factor of 2:

CorrT25internal: 210 / 2 = 105 mg/kg bw/day

The risk characterisation is presented in three ways: By using the MOE approach and also by using the linearised approach and the large assessment approach as described in BPR Guidance Parts B+C, 2.4.1.1 Semi-quantitative hazard characterisation for non-threshold carcinogens.

The resulting MOEs are presented in the table below. It should be noted that the MOEs should preferably be 25 000 (in addition of the conventional 10 x 10, an additional factor of 10 should be used, since creosote is classified as Carc. 1B, and an extra additional factor of 10 should be used when an effect dose, i.e., T25 is used and not a non-effect dose, i.e., a NOAEL. An extra factor of 2.5 is used for the fact that the T25 value represents a 25 % level of the number of tumours (in comparison with the BMD that usually represents a 10% increase). A MOE of 25000 is obtained if an interindividual factor of 10 (i.e., not a factor of 5 for workers) is used in combination with the extra factor of 2.5.

Summary of the creosote exposure to operators with respect to different exposure scenarios and cancer risk using 10% dermal absorption (for more details on description of the worker exposure assessment, please refer to the CAR 2010, by SE CA)

Exposure scenario[1]	**Potential exposure**	
	µg/kg bw/day [2]	**MOE** [3]
Management Operator (MO, who exhibited the highest exposure in the FIOH study.) Changing the creosote buggy wheels and replacing a creosote cylinder door gasket.	13.6 (**10%** dermal absorption used)	**7 720**
Worker (WO, who exhibited the second highest exposure value next to the MO in the FIOH study) 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	5.6 (**10%** dermal absorption used)	**18 750**

approx. 15-30 minutes, of which a few minutes were spent in the vicinity of the impregnation/after-treatment cylinder.		
Worker (WO, who exhibited the highest exposure value in the van Rooij study). Controlling the process, transport of the wood into and out of the cylinder on rail trucks, opening and closing if the covers of the cylinder.	19 (**10%** dermal absorption used)	**5 526**
Worker. Average exposure at impregnation plants for the two studies (64 µg/kg bw/day)	6.4 (**10%** dermal absorption used)	**16 406**
Down-stream users (pole installers)		
Pole installers. Furnishing of poles. With the use of light chemical resistant overall	2.6 (**10%** dermal absorption used)	**40 384**
Pole installers. Furnishing of poles. Without the use of light chemical resistant overall	3.7 (**10%** dermal absorption used)	**28 378**
Pole installers. Installation of conductors. Without the use of light chemical resistant overall	1.7 (**10%** dermal absorption used)	**61 764**
Pole installers. Installation of conductors. With the use of light chemical resistant overall	1.1 (**10%** dermal absorption used)	**95 454**
Pole installers. Installation of a separator Without the use of light chemical resistant overall	200 (**10%** dermal absorption used)	**525**
Pole installers. Installation of a separator With the use of light chemical resistant overall	141 (**10%** dermal absorption used)	**744**

1. It has to be noticed that a distinction between different job categories and scenarios is difficult to make, since many of the workers perform several job categories. For pole installers the use of and non-use of a light chemical resistant overall, respectively, is assumed to represent a situation equal to that in the exposure study by van Rooij (see SE Doc2.10 and DocII-B, in where the use of an additional overall reduced the exposure considerably).
2. The exposure values are obtained from the study reports and the systemic exposure is obtained by accounting 10% dermal absorption. Please note that the highest exposure values have been used.
3. The inhalation exposure is not included since only a few PAHs were detectable in the volatile fraction and naphthalene accounted for > 60%. The large molecular weight PAHs (and most toxic and carcinogenic, e.g. BaP) were not detected, presumably due to low volatility. The toxicological profile for the volatile fraction of creosote is completely different from that of whole creosote to which animals are exposed orally or dermally and to which workers are exposed dermally, and hence, the volatile fraction was therefore not included. Moreover, the workers wear respiratory protection at critical work tasks.
4. The exposure to creosote can be considered to be chronic, since the workers can be exposed every working day for the entire working life. The MOEs have been calculated by comparing the exposure with the T25 value (corresponds to a dose of BaP in creosote resulting in a 25% increased incidence of tumours over a life span)

(identified by CSTEE (1999)) of 13 BaP µg/kg bw/day, corresponding to 1300 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). This is corrected by a factor of 5, since the creosote types were 5 times more potent than the control based on BaP content, resulting in 260 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). The T25 value is also corrected to account for differences in exposure conditions in order to obtain a corrected T25 or human T25. The corrected T25 is 105 mg/kg bw/day (see text above the Table). The MOEs should preferably be 25000 (an additional factor of 10 should be used, since creosote is classified as Carc. 1B and an additional factor of 10 should be used when an effect dose, i.e., T25 is used and not a non-effect dose, i.e., a NOAEL, and a further extra factor of 2.5 is used when T25 (and not BMD) is used).

Summary of the creosote exposure of operators to different exposure scenarios referring to brushing application.

Exposure scenario	**Potential exposure**	
	µg/kg bw/day	**MOE**
Brushing by professionals of a total surface of 0.2 m^2 within 48 minutes per day Without RPE, with coated coverall and gloves	**4.90**	**21 430**
Brushing by professionals of a total surface of 0.2 m^2 within 48 minutes per day With use of chemical resistance coverall, gloves and RPE	**2.43**	**43 209**
Workers cleaning a brush without gloves	**257**	**408.5**
Workers cleaning a brush with gloves	**25.70**	**4 085**
Brushing by professionals of a total surface of 31.6 m^2 within 240 minutes per day Without RPE, with coated coverall and gloves	**422**	**249**
Brushing by professionals of a total surface of 31.6 m^2 within 240 minutes per day With use of RPE and chemical resistance coverall and gloves	**349.2**	**301**

It is concluded that there is insufficient MOE for the scenario brushing after wood cutting. However, the exposure situation can be further improved by extra protective measures during brushing of a total surface of 0.2 m^2 within 48 minutes per day (MOE above 25 000). The task is done by plant worker wearing adequate protective equipment:

- 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.
- The PPE should be changed frequently, and immediately after contamination.

Brushing of an abovementioned small surface occurs at the impregnation facility and installation sites of the treated wood.
In contrast to exposure and MOE values for brushing of such a small surface area, the total exposure of workers during brushing of a total surface of 31.6 m^2 within 240 minutes per day based on the scenario using conservative parameters is 0.422 mg/kg bw/d resulting in MOE of value 249. Wearing additional PPE (filter mask and impermeable coverall) slightly improves the

exposure situation (MOE 301).
For creosote it has also to be kept in mind that the workplace exposure to carcinogenic substances (Cat 1B) and exposure to such substances must be avoided or minimised as far as technically feasible (Directive 2004/37/EC). It was agreed at the BPC-37 (December 2020) that there is no sufficient protective measures which can improve the exposure situation in case of the brushing as a regular application, thus it should not be authorised.

The exposure of workers cleaning a brush (Tier2 – gloves protection 90%) is 0.0257 mg/kg bw. Thus, MOE has been calculated following the equation: MOE = corrT25 ÷ exposure of workers cleaning a brush = 105 mg/kg/d ÷ 0.0257 mg/kg bw. = 4 085
Taking into account that creosote is a carcinogenic substance (category 1B) and exposure should be minimised, a brush after brushing application should be treated as a disposable tool. Therefore, extra RMM is required: Do not clean the brush after treatment and dispose it as hazardous waste.

Derivation of DMEL

The derivation of a Derived Minimal Effect Level (DMEL) is described in ECHA (2008): Guidance on information requirements and chemical safety assessment, Chapter R.8. It should be pointed out that, although there is theoretically no safe exposure level for non-threshold carcinogens, the DMEL obtained represents a risk level that is considered to be of very low concern. This acceptable risk level is usually 10^{-5} for workers and 10^{-6} for the general public.

In the linearised approach, the reference value, in this case the corrected T25 value, is divided by a factor of 25000 in order to obtain a DMEL representing a risk level of 10^{-5}. This factor of 25000 is thought to adequately cover also intra and interspecies differences. Sometimes an extra factor for allometric scaling is needed. In this case that would be 7, since mice were used in the dermal cancer study (giving an overall factor of 7 x 25000). However, in the ECHA R.8 guidance, it is stated that a factor for allometric scaling should not be applied when the response in question (in this case skin tumours) is induced at the local port of entry. That was the case in the mice dermal cancer study from where the T25 value is derived. If the T25 value was based on systemic tumours in that study, then allometric scaling should be considered.

Therefore, the overall factor in the linearised approach is in this case 25000.

In the large assessment approach, the corrected T25 is simply divided by the assessment factors. In the case of creosote, the conventional 10 x 10 are used, and an additional factor of 10 should be used, since creosote is classified as Carc. 1B, and an extra additional factor of 10 should be used when an effect dose, i.e., T25 is used and not a non-effect dose, i.e., a NOAEL. An extra factor of 2.5 is used for the fact that the T25 value represents a 25 % level of the number of tumours (in comparison with the BMD that usually represents a 10% increase). A MOE of 25000 is thus obtained in the large assessment approach as well.

If the overall assessment factor of 25000 is applied, the equation is then:

DMEL = CorrT25 105 mg/kg bw/day ÷ 25000 = **4.2 µg/kg bw/day** for 50% dermal absorption

It is concluded that there are sufficient MOEs only for the downstream users for the scenarios of pole installers for the tasks of Installation of conductors and Furnishing of poles and for workers for the scenario of brushing wooden ends after cutting, whereas for all other scenarios of downstream users and all other scenarios of workers in the European impregnation plants, the MOEs are not sufficient.

In addition, in the CSTEE report apart from the T25 value for BaP, the lifetime risk for cancer for humans from the dermal exposure to 1 ng BaP/kg bw/day is calculated, which is in the order of 10^{-4} (reported also in WHO evaluation) and corresponds to 20µg creosote/kg bw/d (max level of BaP in EU creosote Grade B BPD composite is 0.005% by mass). This value also indicates that the dermal exposure to creosote at the levels reported in the exposure studies is of concern. In the CAR 2010, it is reported that strict risk reduction measures are to be applied, since PPE in the exposure studies was used in an inadequate way. Gloves were, for example contaminated already before the work shift. Proper use of PPE will reduce the exposure considerably. It can also be noted that this kind of work is not performed every day all year around. This special work task can be dealt with on MS level.

Moreover, a MOE of 10000 (25000 if T25 is used as in creosote case) has been considered to be of low concern by other bodies, for example with respect to genotoxic carcinogens in food (EFSA, 2005).

It has also to be kept in mind that, although BaP has long been used as a marker for carcinogenic potency, the appropriateness for a complex mixture like creosote can be considered not to be fully clear.

Moreover, the suitability of the mouse cancer study for estimating cancer risk in humans can be questioned. The data from the mouse study are likely to over-estimate cancer risk in humans. The conditions used in mouse skin painting study were not representative of those that are common to humans (workers). Workers are exposed to undiluted creosote, i.e., 100% creosote, which is not mixed with any solvent.

In the Fraunhofer Institute (1997) cancer study a solvent (toluene) was continuously applied at the same site, which may have impaired the integrity of the skin barrier function. Furthermore, the permissive effect of solvents on skin penetration of PAH is well known in the scientific literature (see i.e. Sartorelli et al. 1999). However, the use of a solvent does not rule out the fact that there was a dose-dependent increase in the number of tumours in the study.

Moreover, the Fraunhofer Institute (1997) study suffers from the following limitations, as presented in Doc IIIA of CAR 2010 and in the WHO, 2004 evaluation of creosote (CICAD 62):

1. Only male mice were used
2. Treatment: only 2x/week without cover on treated area
3. Food consumption: not obtained
4. Hematology: only differential WBC count done
5. Clinical chemistry: limited parameters examined
6. Organ weights: only of liver and kidney
7. Histopathology: only treated skin area
8. Treatment-related inflammatory changes of the skin were observed in all groups and consisted either of slight to severe ulcerative dermatitis (ulceration) or superficial purulent dermatitis, epidermal erosion and inclusion cysts
9. An increase was observed in dead or moribund animals with enlarged spleen and enlarged lymph nodes in all treated groups as compared to the control. These effects were attributed to infections subsequent to skin ulcerations
10. The composition of creosote tested is different than EU creosote
    Grade B BPD composite. Creosote contains other components that may also affect its carcinogenic potential; therefore, different compositions may have different carcinogenic potency.

In the CAR 2010, the following is reported regarding the epidemiological data on workers. It has to be noted that no update of this data was done in the context of the renewal.

An increased cancer incidence among creosote workers is not evident despite the long history of creosote use, and despite the fact that former creosote types were "dirtier", e.g., had higher contents of for instance BaP, and despite the fact that the working conditions have been much less stringently regulated historically compared to working conditions used today. Furthermore, American creosote oils still contain about 100-1000 times higher content of BaP. A recent cohort study which included about 2000 creosote-exposed workers at 11 wood-treating plants in the USA failed to reveal any exposure-related mortality increases (Wong and Harris, 2005).

The epidemiological and medical data are, however, difficult to interpret. This does not rule out the fact that creosote is classified as carcinogenic, category 1B.

Furthermore, it is estimated that the exposure situation can be further improved by extra protective measures during work tasks where there is a risk of exposure. Protective measures not mentioned below can also be of importance and hence be applied as well:

- 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.

In addition:

- The working areas such as the treatment/equalisation hall shall be cleaned when judged necessary based on monitoring or inspections. Other areas such as changing and washing rooms, break rooms and control rooms shall be cleaned weekly. Relevant equipment and tools shall be cleaned in case of contamination.
- Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.
- After brushing application, do not clean the brush and dispose it as hazardous waste.

It is estimated that the above mentioned protective requirements or measures would reduce the exposure substantially, and hence, lead to larger MOEs than those already obtained in the current risk assessment.

General public risk

Risk during a contact with treated poles or equestrian fences.

Dermal Exposure	**Units**	**Adult**	**Child 6-12y**	**Child 2-6y**	**Toddler**
Exposure	mg/kg bw/d	0.0601	0.0788	0.0934	0.1014
DMEL	mg/kg bw/d	0.0042			
% $_{\text{dermal ab10\%}}$ of DMEL	%	1431	1876	2223	2414
corr.T25	mg/kg bw/d	105			
MOE		1750	1332	1124	1035

The secondary exposure of the general public via the dermal route by contact with impregnated wood (e.g. fences) was assessed. For all population groups the exposure by dermal route is well above the DMEL value. Therefore, the risk for the general public is not tolerable.

In case no threshold is possible to be identified for carcinogenicity/mutagenicity, a semi-quantitative approach to derive a DMEL can be considered, if it is feasible (in line with the BPR Guidance volume III, parts B + C, v.4.0, December 2017). The workplace exposure to carcinogenic substances (category 1B) must be avoided or minimised as far as technically feasible.

Derived Minimal Effect Level (DMEL) for non-threshold carcinogen, represents an increase of lifetime cancer risk in 1 per 100.000 exposed individuals (10^{-5}) for workers or 1 per 1.000.000 exposed individuals (10^{-6}) for the general population. As the correction factors have been derived for occupational exposure, the corr. T25 should not be used for the general public (for the general public a 10^{-6} cancer risk applies). However, even using parameters (corr T25) for workers, a risk for all age groups (adults, children and toddlers) was identified. A DMEL for the general public was not derived due to not providing added value to the decision making process.

Risk via residues in plant-derived food

Based on the study, the applicant has concluded that the major part of the fruit is not in direct contact with the stakes. For fruits that have been grown in an orchard where creosoted stakes are used, the intake of PAHs will be lower than 10% of the TDI and therefore these fruits will not cause a consumer concern, for both, adults or toddlers.

In the PL CA opinion, the studies submitted (lists of studies: Addition 2020) contain some limitations, which undermine the final applicant’s conclusions. One of the main limitations refers to the selection of PAH determined in the samples as well as to the analytical method deficiencies. In the former consumer dietary risk assessment conducted by the applicant the assumption of fraction of fruit having a contact with fully creosoted posts was done, but no assumption was for vineyard posts, hop poles or other crops usage. Therefore, the uptake of creosote residues during consumption of other commodities than apples and pears was not studied and assessed. See also section 2.2.2.7.
Overall, in the PL CA opinion, there is no sufficient data available to assess risk concerning the potential creosote residues in plant-derived food when creosote treated wood is used in agriculture, although two reports concerning the recent monitoring studies were submitted.
Additionally, it was concluded at WG I 2020 that inclusion of the human health assessment of use of creosote in tree support posts is not requested and that any use of creosote that leads to food residues is considered unacceptable.
Therefore, if the use of creosote treated tree support posts (fruit, vineyards or any other defined) and/or hop poles is to be accepted, it should be decided what constituents of creosote should be monitored in fruits and other food commodities and it should be confirmed if the validated analytical methods for determination of those are available.

Risk to livestock and human risk via residues in animal-derived food

Internal dose received by the animal					
[Indicate the model/calculations/database used]					
	Animals	Inhalation exposure	Dermal exposure	Oral exposure	Total exposure mg a.s./kg bw/d
Scenario livestock exposure Tier1	Beef cattle	negligible	7.2	0.0132	7.2132
	Dairy cattle		6.46	0.021	6.481
	Calf		10.86	1	11.86
	Fattening pig		11.25	2	13.25
	Horse		10.13	0.095	10.225
	Goat		16	0.5428	16.5428
Scenario livestock exposure Tier2	Beef cattle	negligible	0.00105	0.00396	0.005
	Dairy cattle		0.00094	0.006	0.007
	Calf		0.00159	0.00015	0.00174
	Fattening pig		0.00165	0.00029	0.00194
	Horse		0.00148	0.000014	0.001494
	Goat		0.00235	0.000029	0.002379

In Tier 1 the total exposure (internal dose received by the animal) exceeds the trigger value of 0.004 mg a.s./kg bw/d by up to 2,500 times. Therefore, in Tier 2 a realistic worst-case estimation has been proposed by the applicant.
In Tier 2 the dose rate has been replaced by UC 3 Time 1 leaching rate of 0.366mg/m2/d resulting in total exposure below the trigger value of 0.004 mg a.s./kg bw/d in case of calf, fattening pig, goat and horse. In case of dairy and beef cattle the total exposure is above the trigger value indicating a risk for mentioned animals.
However, the trigger value of 0.004 mg a.s./kg bw/d given in the Guidance on BPR: Volume III Parts B+C, Ver.4.0, Dec. 2017, section 6.3, is not applicable for a non-threshold carcinogen, as noted in section 6.4.1 of the guidance. Therefore, the information submitted by the applicant has been analysed, but it is evaluated as insufficient for risk assessment.
Moreover, 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 not be finalized due to this data gap. Additionally, it was concluded at WG I 2020 that inclusion of the human health assessment of use of creosote in tree support posts is not requested and that any use of creosote that leads to food residues is considered unacceptable. Therefore, if the use of creosote for equestrian and agricultural fencing is to be accepted, it should be decided what constituents of creosote should be monitored in livestock and other food commodities and it should be confirmed if the validated analytical methods for determination of those are available.

Taking into account that (i) the possibility of secondary exposure of the general public via the dermal route by contact with impregnated wood was identified, (ii) the livestock residues might contribute to human exposure, but the data were not sufficient to estimate such exposure, (iii) no conclusion could be made on the endocrine disrupting properties of creosote for human and for non-target organisms with the available information, (iv) creosote is carcinogenic and reprotoxic, therefore the secondary exposure of the general public should be minimised.

2.2.2.5. Environmental assessment

Following the first approval of the active substance, the applicant submitted new documents, e.g. six new studies on fate and distribution in the environment (including the vineyard post model), two Daphnia acute toxicity tests (which were not evaluated for initial approval of the active substance), two reports on monitoring studies in orchards with creosote-treated fruit tree stakes (see also section 2.2.2.7). Therefore, at the BPC WG meeting in March-April 2020, it was decided that the eCA (PL) would quote the previous evaluation and introduce updates, if required, and assessment of new studies.

2.2.2.5.1. Fate and distribution in the environment

Creosote is an UVCB substance of multiple constituents. The data submitted are almost exclusively on polycyclic aromatic hydrocarbons (PAH), which are among the constituents of creosote. For abiotic degradation, biodegradation, distribution and accumulation the evaluation of the dossier done for the purpose of active substance approval by Sweden (i.e. SE CAR 2010) holds for the purpose of active substance approval renewal, as presented below:

No data was submitted on hydrolysis of creosote constituents. The justification given was that the constituents of creosote do not have hydrolysable groups, and this was considered to be acceptable.

In water, PAHs present in creosote are rapidly photolysed under best case, laboratory conditions and an increasing trend in photoreactivity with increasing molecular weight was indicated. Due to effects of light attenuation, simulated realistic case half-life values for photolysis in natural waters were approximately two orders of magnitude longer than best case half-lives and varied between approximately half a day and 300 days depending on the PAH studied. Regardless of water type, direct photolysis is much more important than photosensitized oxygenation of PAHs. One major transformation product from aqueous photolysis of PAHs seemed to be quinone derivatives. It was indicated that photolysis of alkylated PAHs generated a greater number of transformation products than photolysis of parent PAHs.
For volatile PAHs, gas phase reaction with OH radicals is an important removal process. The half-lives of the selected PAHs ranged from approximately 1 to 7 hours. The mean half-life for the selected PAHs was estimated to approximately 3 hours. For some PAHs, reactions with NO_3 radicals are very important but for PAHs in general this transformation pathway is of less importance compared to the OH radical-initiated reactions.

A majority of the compounds present in creosote contain fused polyaromatic ring systems (e.g. PAHs) which are very stable chemical structures, but a wide variety of bacteria, fungi and algae do have the ability to metabolise these compounds.
Mineralisation half-lives in sediment-water systems can be summarised as follows: For non-alkylated PAHs with two rings; DT_{50} is approximately 30 d, for alkylated PAHs with 2 rings and PAHs with 3 rings; DT_{50} higher than or equal to 60 d and finally, for PAHs with four rings, DT_{50} is from several years till infinity (∞) (all at 22 °C). The rate of aerobic and anaerobic degradation of creosote constituents like PAHs increase in previously contaminated sediment water environments compared to pristine environments. In pristine, anaerobic sediment water environments mineralisation rates of PAHs are indicated to be too slow to be measured.
Dissipation half-life in the water phase of all PAHs (and creosote) was estimated to one month. The dissipation of creosote constituents from the water can most likely be ascribed to a combination of removal processes like volatilisation, adsorption, uptake by biota, photolysis and biodegradation.
Results of additional aquatic tests (non-key studies) showed that under favourable microbial conditions PAHs show significant degradation with rapid or gradual adaptation. This is true for compounds with three rings or less but among compounds with four rings some PAHs do not degrade even under favourable conditions. The rate of degradation in water for PAHs with three rings or less seemed to be enhanced when the water had been previously contaminated with hydrocarbons and/or PAHs. Alkylated PAHs seemed to degrade slower than parent PAHs.

The acceptability of degradation results obtained with adapted inoculum cannot be considered as high as results obtained with non-adapted inoculum.
Soil degradation half-lives at 20 °C ranged from approximately two days for two ringed PAH compounds to more than a year for the four ringed PAHs. Shorter degradation half-lives were measured for PAHs when incubated as constituents in creosote. No degradation could be measured in anaerobic soil. PAHs may however be microbially degraded in soil under anaerobic, denitrifying conditions. The rate of degradation under anaerobic denitrifying conditions was slower than under aerobic conditions.

For compounds present in creosote, the log K_{oc} values are found in the following approximate intervals; aromatic hydrocarbons range from 2.5 to 5.4, phenolic compounds from 1.0 to 1.8, nitrogen containing heterocycles from 1.1 to 3.0, sulphur containing heterocycles from 2.7 to 3.9 and finally, for the oxygen-containing heterocycle, dibenzofuran, the log K_{oc} is approximately 3.6. All K_{oc} values have been estimated from literature values of K_{ow} by using the following correlation between the two partition coefficients; $K_{oc} = 0.35\ K_{ow}$.
If the log K_{ow} and log K_{oc} values of single compounds are weighted by their content in creosote (in percent), the log K_{ow} and log K_{oc} values of the different creosote oils can be estimated. The results of such calculations indicate that the composite sample of Grade B type (log K_{oc} 3.67) shows less tendency to partition to organic matter than the single Grade B creosote oil (log K_{oc} 3.97). Since the content of low molecular weight PAHs is lower in Grade C creosote oil its log K_{oc} is higher (4.17) than that for Grade B.

It is not possible to determine a single value for bioaccumulation potential of creosote, since the individual constituents of creosote all have different bioaccumulation potential. In bioconcentration tests with fish, the measured bioconcentration factors (BCFs) of some PAHs in creosote (phenanthrene, fluorene, fluoranthene, and pyrene) ranged from 78 to 540. However, some other creosote constituents had higher BCFs, e.g. anthracene showed a BCF of 2500. The depuration rate in fish was rather rapid with 95% of the accumulated substance eliminated within 2-5 days for most PAHs. Since data was missing for many creosote constituents, the BCF-values were also calculated using the mean log K_{ow} values. These calculated BCFs ranged from 61 to 17660 for individual aromatic hydrocarbons. For the creosote oils BCF-values of 634, 1163, and 1720, were calculated for composite Grade B, Grade B, and Grade C, respectively, using estimated log K_{ow} values. The bioaccumulation potential of creosote constituents in terrestrial organisms was low.
The results from the bioaccumulation studies in the aquatic environment show that most PAHs that are creosote constituents are rapidly taken up and bioaccumulated in organisms. Biomagnification in food webs are not to be expected, though, since vertebrates and also some invertebrates have efficient metabolism and/or excretion of PAHs. There are species, however, that metabolise PAHs to little or no extent, like algae, oligochaetes, molluscs, and the more primitive invertebrates (protozoans, porifera, and cnidaria), which can accumulate high concentrations of PAHs. Therefore, predatory organisms may be exposed to significant levels of PAHs when feeding, but organisms from higher trophic levels are expected to eliminate these PAHs rather rapidly.

New information under renewal assessment

Although six new studies on fate and distribution in the environment have been made available at renewal, the majority of newly submitted information does not provide results that can reliably be used to refine the emissions assessment.
Three studies submitted summarise environmental monitoring performed either at limited numbers of EU locations or around limited numbers of treated timber structures (A2.10.2/14: poles, A2.10.2/17: posts, or A2.10.2/18: railway sleepers). These studies demonstrate some evidence of limited horizontal and vertical migration of polycyclic aromatic hydrocarbons (PAHs) such that the measured levels quickly fall to background levels or show (in the case of railway networks and maintenance yards) that PAHs could also be associated with placement of concrete sleepers. However, the relatively limited nature of the monitoring information provided was considered insufficient to refine standard environmental exposure assessments in line with the current OECD ESD PT8 (2013). The reports (A2.10.2/19a and A2.10.2/19b) on studying

the role of creosote-treated sleepers in the migration of PAHs in the ground were included in the dossier. The leachate gained from a laboratory study, in which the pieces of newly impregnated sleeper and separately the pieces of older sleeper were immersed, was further used in sorption and desorption tests. The leachates were analysed for content of 16 PAH and from the newly impregnated sleeper acenaphtene, fluorine, phenanthrene, anthracene, fluoranthene and pyrene were detected, whereas from the older sleeper anthracene, fluoranthene, pyrene, benz(a)anthracene and chrysene were detected (A2.10.2/19a). The leachate from the newly impregnated sleeper was used to study the fate of PAH in moraine soil with different concentrations of artificially added organic matter (sand medium, taken from a site in Sweden, was mixed with differing concentrations of peat in the laboratory: making up 0 %, 2 %, 5 % and 10 % of final "soil" medium). Sorption testing was conducted according to a leaching test for determination of non-volatile, organic compounds from contaminated soils and follows the ER-H method (Equilibrium Recirculation column test for hydrophobic organic compounds). The Kd values at 2% peat were considered to be comparable to those derived by QSAR in the original creosote review for relevant PAH compounds. However, it was concluded that whilst PAHs, that leached from creosote-treated wood, can be sorbed to soil, migration of hydrophobic, organic substances needs to be further investigated to more accurately estimate this process.

A summary of the new reports for the renewal assessment are presented here:

Reference	**Author**	**Conclusion**
A2.10.2/14	[redacted] 2012	Monitoring data looking at PAHs around a small number of SE utility poles (18 in total). The report may be a limited support that selected PAHs remain close to treated poles (horizontally and vertically). The results show high variability within the soil type and may reflect uneven distribution in soil. No data on groundwater level and no statistical analysis are the limitations of the study. The results are examples of some PAH levels around creosoted utility poles. Not used in latest emissions estimations.
A2.10.2/16	DHV, 2013	Proposal for a vineyard post model to cover specific use pattern under UC 4a: original version submitted to SE RMS in 2013. No consideration made by the UK (former eCA) as newer 2015 version has also been submitted.
A2.10.2/16a	DHV, 2015	Updated proposal for a vineyard posts model to cover specific use pattern under UC 4a: this (second) version takes account of comments raised by SE CA in 2013 when acting as RMS for creosote review. Model builds on principles outlined in ESD for utility poles and fence posts and uses default values specific to vineyard posts so is not a novel concept. New "vineyard post" model has been included in creosote renewal (see text below the table).
A2.10.2/17	Hudson and Murphy, 1997 + Bergqvist and Holmroos, 1994	Monitoring data looking at selected PAHs around a small number of SE and UK fence poles or posts. The report may be a limited support that selected PAH are detected in surrounding soil. No statistical analysis due to low number of samples. Not used in latest emissions estimations.
A2.10.2/18	Marechal and Favre, 2013	Monitoring data looking at PAHs in ballast and subsoil under FR railway sleepers at >100 specific SNCF locations. The report concluded that many sites were found to have detectable PAH levels but below background levels in FR soil and that PAHs were detected at similar concentrations under concrete sleepers and creosote treated wood. Not used in latest emissions estimations.

A2.10.2/19b	Enell *et al*, 2008	Adsorption and desorption behaviour of selected PAH (originating from a leachate gained from the immersion of creosoted sleeper) in non-contaminated moraine soils enriched with peat. Results obtained for soil with 2% peat were comparable to values already obtained by QSAR, in original SE CAR 2010.

As part of an updated dossier to support creosote in PT 8 at renewal, the applicant submitted emissions modelling specific to the use of posts partially treated with creosote in vineyards and orchards, which are not in direct contact with crops. At the time of the evaluation no EU agreed models existed for this specific use pattern. The proposed model follows the principles outlined in the OECD ESD PT8 (2013) for emissions assessment of transmission poles and fence posts. This non-standard model was therefore accepted for more detailed evaluation by the UK (the former eCA) and further details on surface areas and volumes treated are provided in Appendix IIIA of the assessment report.

During the formal ENV WG e-consultations in 2019 the following parameters were discussed between MS:

- if posts are shown to be spaced less than 1 m apart, then the soil volume must be decreased accordingly to represent the smaller space around each individual post,
- the post length below ground could be supported (possibly due to various national working practices in agriculture) if it continues to provide sufficient protection goals, especially where leaching rates of an active substance may vary significantly in UC 3 and UC 4a,
- the use of treated posts in vineyards and orchards may also result in exposure of fruit and grapes to polycyclic aromatic hydrocarbons via air or soil and this must be addressed; as a result, approval of this use pattern will be dependent upon risks being identified in both the human health and the environmental risk assessment,
- if porewater screening models indicate that unacceptable levels of an active substance could reach groundwater, then it will be necessary for a higher tier groundwater assessment to be performed (using FOCUS PEARL modelling); 1100 posts per hectare has been considered realistic,
- the service life of 20 years is realistic for a generalised scenario and the current guidance recommends the use of a maximum of 20 years in emissions assessment (and this has been used to determine $Q_{\text{leach, Time 2}}$); since a service life of 25 - 30 years is stated by the applicant, such an increase in service life in this case will be of minor impact regarding the soil exposure.

At the BPC WG ENV meeting March-April 2020 it was agreed that the proposed scenario could be accepted as a realistic approach to determine environmental exposure from the use of creosote-treated posts with no contact with fruit and plants in vineyards and orchards.

The accepted model (presented in Appendix IIIA), used to assess emissions of creosote from treated posts, assumes that:

- circular posts are all spaced 1 m apart and soil volume has been determined on the basis that each post has 0.5 m of soil around it,
- total post length of 0.8 m will be treated and, in order for the post to be stable, 0.55 m of the treated zone is below the soil surface (UC 4a) and the remaining 0.25 m the post above ground and not in direct soil contact (UC 3).

Calculations of Predicted Environmental Concentrations

Microsoft Excel sheets used in deriving PEC values for all use classes are embedded in Appendix IIIB. Note that the exposure assessment was conducted by the UK CA during 2017, prior to the release of the ECHA harmonised calculation sheets for PT8. The UK sheets are therefore embedded in order that all calculations can be independently verified. The PEC values were accepted at the BPC WG ENV meeting March-April 2020.

Leaching Rates

Although no new leaching data have been provided, it has been considered important to present previously agreed decisions reached within Document II-A of the original SE CAR in terms of flux rates in UC 3, 4a, 4b and 5 for ease of reference. Furthermore, decisions reached within Appendix 7 of the revised the OECD ESD PT8 (2013) now impact upon determination of $Q^*_{\text{leach, Time 2}}$ values since Time 2 is considered to cover the period 0 d – service life. The previous assessment in the CAR treated the two time periods separately. As such, use of the Time 2 rate has been updated with regard to calculating long term losses in that it also includes the Time 1 losses (i.e. material lost from 0-30 d).
All flux rates in UC 3 – 5 agreed in the original SE CAR were based upon leaching rates derived from pine. It is noted that there was a recommendation made within the original SE CAR to use pine based data as a standard approach.

UC 3 leaching rates have been derived from experimental data from pine treated at a retention of 86 kg/m^3 but linearly corrected to 90 kg/m^3 in line with typical retentions used by the wood preservative industry:

Use Class	**Test flux rate (CAR) (mg/m^2/d)**	**Flux corrected for retention rate (mg/m^2/d)**
UC 3 Time 1* [A2.10.2/02, van Dongen]	Phe: 0.0095 Ant: 0.00057 Flu: 0.0089 B(a)A: 0.0051 **Cre: 0.35**	Phe: 0.00994 Ant: 0.000597 Flu: 0.0093 B(a)A: 0.00534 **Cre: 0.366**
UC 3 Time 2** [A2.10.2/03, van Dongen + Oldeman & Haverman]	Phe: 0.0017 Ant: 0.00003 Flu: 0.0013 B(a)A: 0.00013 **Cre: 0.046**	Phe: 0.00178 Ant: 0.0000314 Flu: 0.00136 B(a)A: 0.000136 **Cre: 0.0513**

* Flux rate based on results at 30 – 50 d as these were considered more conservative than values obtained at 0 -30 d
** Flux rate based upon results obtained between 273 – 431 d
Abbreviations: Phe - phenanthrene, Ant - anthracene, Flu – fluoranthene, Pyr – pyrene, Cre - creosote.

UC 4a and 4b leaching rates have been derived from experimental data from pine treated at a retention of 91.5 kg/m^3 and subjected to continual immersion in (fresh) water. The original SE CAR concluded that the only reliable data set available in UC 4 applied to UC 4b (direct contact with surface waters) but it was agreed in principle that this could be tentatively extrapolated to UC 4a (direct soil contact).
Flux rates have again been corrected to 90 kg/m^3 in line with expected retentions used by the wood preservative industry (based upon a 2002 SE NTR standard, it has been assumed that the same retention rate would be applicable to timber in contact with surface water and permanent ground contact):

Use Class	**Test flux rate (CAR) (mg/m^2/d)**	**Flux corrected for retention rate (mg/m^2/d)**
UC 4a + 4b Time 1* [A2.10.2/07, Berbee]	Phe: 12.6 Ant: 0.85 Flu: 4.0 Pyr: 2.6 **Cre: 100**	Phe: 12.4 Ant: 0.84 Flu: 3.93 Pyr: 2.56 **Cre: 98.4**
UC 4a + 4b Time 2** [A2.10.2/07, Berbee]	Phe: 1.7 Ant: 0.33 Flu: 0.9 Pyr: 0.68 **Cre: 18**	Phe: 1.67 Ant: 0.32 Flu: 0.89 Pyr: 0.67 **Cre: 17.7**

* Flux rate based on results at 0 – 31 d
** Flux rate based on results obtained between 31 – 180 d
Abbreviations: Phe - phenanthrene, Ant - anthracene, Flu – fluoranthene, Pyr – pyrene, Cre - creosote.

The fence post and transmission pole assessment in the original SE CAR considered emissions of creosote (Cre), phenanthrene (Phe), anthracene (Ant), fluoranthene (Flu) and pyrene (Pyr). As no data are available for leaching of pyrene (Pyr) above soil, the approach taken in Section 8.3.2.2.4 of Document II-B of the original SE CAR has been adopted here, in that data relating to UC 3 leaching of fluoranthene (Flu) will be used as a surrogate. The same principle could apply when considering above water losses in UC 4b assessment.

UC 5 leaching rates have been based upon reliable results obtained in UC 4b (fresh water) as only limited data were available specifically for UC 5. The original SE CAR concluded that because UC 4b data were derived from testing where wood is continuously immersed in water, then leaching in freshwater and salt water would be comparable. However, different values were presented for UC 5 leaching flux rates based upon further correction using comparison of seawater and freshwater fluxes from the limited UC 5 data made available. Furthermore, a different, higher retention of 150 kg/m^3 has been considered necessary for marine timbers so flux rates were extrapolated as follows:

Use Class	**Corrected flux rate (mg/m^2/d)**	**Remarks**
UC 5 Time 1* [using A2.10.2/07, Berbee]	Phe: 5.1 Ant: 0.35 Flu: 1.6 Pyr: 1.1 **Cre: 40.8**	Derived from UC 4b Time 1 data, which is then corrected for freshwater vs saltwater flux and notional retention of 150 kg/m^3
UC 5 Time 2** [using A2.10.2/07, Berbee]	Phe: 0.69 Ant: 0.13 Flu: 0.40 Pyr: 0.28 **Cre: 7.33**	Derived from UC 4b Time 2 data, which is then corrected for freshwater vs saltwater flux and notional retention of 150 kg/m^3

* Flux rate based on results at 0 – 31 d
** Flux rate based on results obtained between 31 – 180 d
Abbreviations: Phe - phenanthrene, Ant - anthracene, Flu – fluoranthene, Pyr – pyrene, Cre - creosote.

2.2.2.5.2. Effects assessment

Two new GLP studies on acute toxicity to *Daphnia magna* are available since the original approval of creosote. In both studies the test item is not equivalent to the Creosote Grade B, Creosote Grade C or Creosote Grade B Composite; however, the similarity claimed by the applicant and the same tar source for read-across purposes are acknowledged by the eCA. The Water Accommodated Fraction (WAF) was prepared from each separate loading of the test item in the test medium, the tests were conducted in a closed system and the total organic carbon (TOC) content was to be determined, according to the OECD Guidance Document No. 23 (ENV/JM/MONO(2000)6 and its revision of 2019). The closed system was used to reduce volatilisation losses. However, it is not reported if the WAF were prepared in darkness (light impacts stability of test item components), at what temperature (impacts solubility), with a headspace of unknown volume (impacts evaporation). Feeding frequency during pre-treatment and light intensity in the test were not reported. Validation of TOC determinations was not reported.

In the study Aniol S et al 2009a (A7.4.1.2/06) the EL$_{50}$ (48h) value is 2.7mg/L with no confidence interval nor slope of the dose-response curve reported and based only on a single loading rate (WAF) with a partial immobility observed at exposure termination. For comparison, in the original dossier the *Daphnia magna* acute toxicity study with creosote and acetone as an organic solvent and with no analytics (Doc III-A7.4.1.2/01) resulted in the EC$_{50}$ value of 1.14 mg/l (nominal) and this study is of similar reliability. The endpoint values from those two studies are within the same range, however by a worst case approach the lowest endpoint value is used for risk assessment.

In the study Aniol S et al 2009b (A7.4.1.2/07) all TOC results are close to a value of 1 mg TOC/L in absence of any data on method validation. For comparison, the *Daphnia magna* acute toxicity study with Wash Oil prepared WAF (2009a, Doc III-A7.4.1.2/06) was with lower loadings but with higher determined TOC content in test vessels. It cannot be excluded that the solubility limit of most of the components of test item is exceeded already at the lowest loading rate (WAF). Therefore, the endpoint value from the *Daphnia* acute toxicity study with Anthracene Oil is not to be used for risk assessment.

In comparison to the Anthracene Oil, the Wash Oil contains low molecular weight and polar substances, what impacts its solubility and bioavailability in aquatics. Moreover, *Daphnia magna* is not the most sensitive aquatic invertebrate species in an acute test with creosote. The results of these two studies do not impact the original SE assessment and the original conclusions remain the same, based on results from acute and chronic aquatic toxicity studies on US creosote using *Americamysis bahia*.

Summary table – acute aquatic toxicity

Method, Guideline, GLP status, Reliability	**Species**	**End-point**	**Exposure**		**Results**		**Remarks**	**Reference**
			Design	**Duration**	**NOELR**	**EL$_{50}$**		
Invertebrates								
OECD 202 GLP Reliability 2	*Daphnia magna*	Immobility	Static	48 h	1 mg/L	2.7 mg/L	Test substance: Wash oil	Aniol S., Blum Th., Honnen W., 2009a
OECD 202 GLP Reliability 3	*Daphnia magna*	Immobility	Static	48 h	5 mg/L	22.4 mg/L	Test substance: Anthracene Oil	Aniol S., Blum Th., Honnen W., 2009b

For effects on organisms the evaluation by SE 2010 remains valid, as follows:

Creosote has very high toxicity to aquatic invertebrates and fish, and moderate toxicity to algae. Predicted No-Effect Concentration (PNEC) in surface water was estimated to 0.1 µg/l based on the lowest NOEC from chronic studies with fish and invertebrates (1 µg/l) and an assessment factor (AF) of 10. PNEC$_{sw}$ values were also calculated for some individual components of creosote. These PNECs were in general in the same range as the PNEC for creosote, ranging from 0.042-0.3 µg/l, although a higher AF of 50 was used since only chronic data for two trophic levels were available for these PAHs.

PNECs were also calculated for marine water with the same data set as for surface water, which also included short-term tests for creosote with two taxonomic marine invertebrate groups. The PNEC$_{marine}$ for creosote was estimated to 0.02 µg/l by using an AF of 50 and the PNEC$_{marine}$ for individual PAHs were estimated to 0.0044-0.03 µg/l, by using an AF of 500 except for fluoranthene, to which an AF of 1000 was applied.

The effects of creosote-treated pilings on sediment dwelling organisms were assessed in long-term field studies investigating benthic infaunal community composition. The PNEC$_{sediment}$ for creosote normalised to standard sediment organic carbon content was estimated to be 2 mg/kg ww sediment, based on threshold effect levels of measured concentrations of 15 PAHs (assumed to be equivalent to creosote). PNEC$_{sediment}$ derived for two individual PAHs, phenanthrene and fluoranthene, were estimated to be 0.4 and 0.6 mg/kg ww, respectively, with normalisation to standard sediment. If no normalisation to organic carbon content was made, the PNEC$_{sediment}$ for creosote, phenanthrene, and fluoranthene was 0.4, 0.08, and 0.12 mg/kg ww, respectively.

The EC$_{50}$ for inhibition of microbial activity in activated sludge by creosote was estimated to be 13 mg TOC/l and the PNEC$_{STP}$ was set to 0.13 mg creosote/l.

Terrestrial toxicity of creosote was studied in three trophic levels (microorganisms, plants, and earthworm/springtail). The PNEC$_{soil}$ for creosote was estimated to be 0.3 mg/kg ww, based on the NOEC from a long-term test (28d) with creosote Grade B and springtails and an AF of 10. There was also data available to calculate PNEC$_{soil}$ for some individual PAHs with an AF of 50.

These were in the same range as the $PNEC_{soil}$ for creosote, with a value of 0.34 mg/kg ww for 1-/2-methylnaphthalene, and between 0.24 and 0.55 mg/kg ww for five PAHs with increasing molecular weight from phenanthrene to pyrene.

2.2.2.5.2.1. PBT and POP assessment

Creosote contains constituents fulfilling the PBT and/or vPvB criteria. Among these is Anthracence (CAS 120-12-7), which was identified as a PBT and thus approximately 0.5-1.5% of the creosote constituents were PBT and 0% were vPvB in the original SE CAR. Since then, the creosote constituents Chrysene (CAS 218-01-9) and Benz[a]anthracene (CAS 56-55-3) 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. Chrysene fulfils the criteria for PBT, vPvB and carcinogenicity (decision ED/01/2018) and Benz[a]anthracene as well fulfils the criteria for PBT and vPvB (decision ED/01/2018). Furthermore, the constituents Fluoranthene (CAS 206-44-0), Phenanthrene (CAS 85-01-8) and Pyrene (CAS 129-00-0) have been included in the above mentioned list: Phenantrene fulfils the vPvB criteria, but also Fluoranthrene and Pyrene fulfil the vPvB as well as PBT criteria (decision ED/88/2018).
With the new information on the five constituents mentioned above, approximately 7-15% of the creosote constituents are PBT and approximately 17-31% of the constituents are vPvB. Therefore, creosote is a PBT/vPvB substance.

It is acknowledged that 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 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 RAR 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. These estimated effects on the environment may not be the only elements for concluding which uses of creosote are supported but could still be of interest in the decision making phase (for instance regarding the relative level of risk between the assessed scenarios).

With regard to POP assessment, this is a measure of the persistence of a chemical substance combined with its ability for airborne transport over long distances. Therefore, whilst there are compounds within creosote that could/would be classified as being "P" or even "vP", information within Document II-A of the original SE CAR indicates that many components such as naphthalene, 1-methylnaphthalene, 2-methylnaphthalene, 1-ethylnaphthalene, 2-ethylnaphthalene, dimethylnaphthalene, acenaphthalene, acenaphthene, fluorene and phenanthrene all have predicted DT_{50} values in air of <7 h (due to reaction with hydroxyl radicals). As a consequence, they are not likely to remain in the air compartment for significant periods of time and would not travel long distances such that creosote may not require consideration as a POP.
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 prudent to consider the active as a substance *potentially* containing POP constituents.

2.2.2.5.3. Exposure assessment

General Information

Assessed PT	PT8
Assessed scenarios	Scenario 1: Use Class 3 (Situation in which the wood or wood-based product is not covered and not in contact with the ground. It is either continually exposed to the weather or is protected from the weather but subject to frequent wetting). Scenario 2: Use Class 4a (Situation in which the wood or wood-based product is in contact with the ground and thus is permanently exposed to wetting). Scenario 3: Use Class 4b (Situation in which the wood or wood-based product is in contact with fresh water and thus is permanently exposed to wetting). Scenario 4: Use Class 5 (Situation in which the wood or wood-based product is permanently exposed to sea water).
ESD(s) used	Emission Scenario Document for Product Type 8: OECD Series on Emission Scenario Documents No 2, Revised ESD for Wood Preservatives (September 2013)
Approach	Average consumption
Distribution in the environment	Calculated based on the OECD ESD PT8 (2013): Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013) and ECHA Guidance on ERA, Volume IV, Part B + C (which replaced TGD, 2003) where appropriate.
Groundwater simulation	For the soil compartment the PEC/PNEC ratios >1 are identified. The Tier 1 screening approach using porewater calculations resulted in values exceeding 0.1 µg/l (in the original SE CAR). Therefore, FOCUS PEARL 4.4.4 modelling for UC 3 railway sleepers has been performed to refine predictions of groundwater exposure.
Confidential Annexes	No – not in relation to environmental emissions and risk assessment
Life cycle steps assessed	Production: **No** Formulation: **No** Use: **Yes** – vacuum-pressure impregnation at treatment plants by industrial operators Service life: **Yes -** using representative ESD scenarios
Remarks	Note that UC 1 and UC 2 (indoor application or use in enclosed spaces) have not been considered due to the restrictions for creosote in Annex XVII of the REACH.

Emission estimation

The revised environmental exposure assessment of creosote has been performed following the latest Emission Scenario Document for wood preservatives (OECD, 2013) and the latest ECHA Guidance on ERA, Volume IV, Part B + C (2017) where appropriate. In PT 8, it should be noted that creosote is both the active substance and the wood preservative biocidal product.

According to SE CAR, creosote was to be applied to timber only in industrial plants for preventive treatment of wood by vacuum pressure impregnation. However, according to the applicant's claim in the current renewal process, the brushing of a small surface after cutting, sawing, machining of the pressure treated wood is a non-pressure method for UC 3 and UC 4 to be considered for the active substance approval renewal.

Creosote treated wood is used in the use classes detailed in the previous table.

Calculations have not been carried out to assess environmental risks from application and storage of timbers industrially pre-treated with creosote. Where the industrial application of wood preservatives is regulated by local authorities within Member States, it can be assumed that storage places are sealed to prevent any direct release to the environment.
According to the OECD ESD PT8 (2013), in the case that the storage place is sealed and run-off from storage places will be collected and disposed of by safe means, the storage place scenario does not need to be considered. Therefore, the renewal condition is that labelling and associated obligatory instructions must state that all 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 (ENV 110 in the TAB v.2.1 of 19 December 2019). The possibility of storage at other sites where treated timber is (temporarily) stored before installation is included in the "treated-wood in service (service life)", given in the OECD ESD PT 8 (2013), hence no further assessment is considered. However, the risk mitigation measures are to be adjusted for the product at the product authorisation stage.

The surface treatment method by hot and cold impregnation (dipping) is not supported with clear application rates as well as relevant and reliable leaching data as part of the applicant's original renewal dossier. In general, superficial treatment methods result in higher leaching rates with different pattern over time than the pressure treatment methods (Report of the Leaching Workshop, Arona Italy, EC 2005). The default values of 50% loss (at 30 days) and 100% loss (at 20 years) must be assumed with no superficial leaching data (Guidance on BPR: Vol IV Environment Parts B+C, v.2.0, October 2017).
Some extrapolation for dipping immersion processes might be possible in UC 3, so that superficial application rates can be derived from penetrative retentions using minimum correction factors outlined in ENV 114 of TAB ENV v.2.1, December 2019. However, since the retention rates vary among Member States, without the application rates using superficial treatment method, the emission estimation in UC 4 was not conducted for hot and cold impregnation (dipping).

Calculations have not been performed to assess environmental risks from application by brushing for wood components modified after standard vacuum pressure treatment to be used in UC 3 and UC 4. According to the OECD ESD (2013), during brushing any product losses are due to spills and drips and they will end-up in soil, if soil is not protected with a plastic foil. Therefore, the renewal condition is that labelling and associated obligatory instructions must state that all treatment of timber must be undertaken within the industrial impregnation facilities on an impermeable surface or in-situ at a construction site outdoors where soil is protected with a plastic foil or tray.
In case that any potential spillage is collected and disposed of by safe means, emission to the environment may be considered negligible, what is in line with the product authorisation reports (SE PAR 2016 and PL PAR 2016).

For calculating the local emissions, the input parameters are the typical application rate of a biocidal product, which is 100% of the active substance, based upon assumptions made in the original SE CAR. The retention claimed by the applicant for a product depends on standards and schemes applicable in Member States. However, the maximum retention rate in UC 5 is based on available data defined in product authorisation reports (SE PAR 2016 and PL PAR 2016) and in the submitted overview ([redacted], 2015), which is the highest value in the table below.

No retention rates change nor new relevant leaching loss data were submitted in the renewal dossier. Therefore, the assessment continues to be based upon typical retention rates assessed in the original SE CAR, that have been shown to be efficacious. What is more, the PEC/PNEC >1 was identified for creosote treated wood in service already for the typical retention rates and no recalculation was made with the maximum retention rate in UC 5; the exception is for the local emission to groundwater in the tiered assessment, i.e. in the Tier 2 calculation for UC 3 (using a railway sleepers scenario) both typical as well as maximum retention rate in UC 5 (as a worst case approach) were used – see section 2.2.2.5.4 Groundwater.

Input parameters for calculating the local emission			
Use Class	Value	Unit	Remarks
Application rate of biocidal product:			
UC 3	90	kg/m^3	Based on assumptions made in the original SE CAR regarding typical retention rates
UC 4 a + 4b	90		
UC 5	150		
UC 5	400	kg/m^3	Maximum retention rate (worst case)
Concentration of active substance in the product:			
Creosote	100	%	--

The model input parameters for the active substance are given below. The physical and chemical properties used can be found in the List of End Points (LoEP) and do not differ from the original SE CAR. Leaching rates are also based upon data presented within the original SE CAR (which were corrected for notional typical retention rates of 90 kg/m^3 in UC 3 + 4 and 150 kg/m^3 for UC 5). The only change to the values originally presented in the CAR is where the long-term Q*leach values for Time 2 now also include the cumulative loss from days 0 – 30 to comply with Appendix 7 of the OECD ESD PT8 (2013). Microsoft Excel calculation sheets used to derive the various PEC values are embedded in Appendix IIIB.

Summary Table of Cumulative Leaching Rates (mg/m^2) for creosote		
Use Class	**$Q^*_{\text{leach, Time 1 (30 d)}}$**	**$Q^*_{\text{leach Time 2 (20 yr service life)}}$**
Use Class 3	10.98	383.93
Use Class 4a		
Above soil (UC 3 component)	10.98	383.93
Below soil (UC 4a component)	2952	131631
Use Class 4b		
Planks (UC 3 component)	10.98	383.93
Poles (UC 4b component)	2952	131631
Use Class 5		
Poles and planks (combined)*	1224	54513.1

*ESD guidance recommends that, for UC 5 calculations, poles must be considered as being completely submerged. In addition, whilst planks are not in permanent contact with water, they are expected to comply with the demand of permanent wetting so one leaching rate will cover all treated wood.

Fate and distribution in exposed environmental compartments

Only the direct pathways, i.e. primary compartments, are indicated in the table below. Only the worst case scenarios per compartment need to be calculated, in line with a tiered approach for treated wood in service, according to the current OECD ESD PT8 2013 and TAB ENV v.2.1, December 2019 (e.g. the House scenario is the worst case scenario for the soil compartment).

In case of the Noise barrier scenario the Surface water and Sediment compartments are secondary via STP. The revised Bridge over Pond scenario is used to derive risk for these compartments as it is likely to lead to higher direct emissions.

Identification of relevant receiving compartments based on the exposure pathway						
	Surface water	Sediment	STP	Air	Soil	Groundwater
Fence/House	N	N	N	N	Y	Y
Railway sleepers	N	N	N	N	N	Y
Noise barrier	N	N	Y	N	Y	Y
Bridge over Pond	Y	Y	N	N	N	N
Transmission Pole/Fence post/ Vineyard scenario	N	N	N	N	Y	Y
Jetty in the lake/Sheet piling in waterway/Harbour wharf	Y	Y	N	N	N	N

Calculated PEC values for creosote

Scenario 1 (UC 3) including degradation where relevant	TIME1	TIME 2
PECsoil mg/kg wwt		
House (In-service only)	6.12E-02	0.32
PECsurfacewater µg/l		
Bridge over Pond (In-service only)	2.14E-03	2.39E-02
PECsediment mg/kg wwt		
Bridge over Pond (In-service only)	1.11E-02	0.12
PECstp mg/l		
Noise barrier (In-service only)	2.06E-04	2.96E-05
PECporewater µg/l (Tier 1 screen) *		
House (In-service only)	0.37	1.91

* Tier 2 FOCUS PEARL 4.4.4 modelling (especially for use of creosote on railway sleepers) has been addressed later in the Risk Characterisation section.
TIME1 is 0 – 30 days
TIME2 is 0- 7300 days, i.e. 20 years

Scenario 2 (UC 4a) including degradation where relevant	TIME1	TIME 2
PECsoil mg/kg wwt		
Transmission Pole (In-service only)	0.93	6.11
Vineyard scenario (In-service only)	0.29	1.93
PECporewater µg/l		
Transmission Pole (In-service only)	5.67	37.08
Vineyard scenario (In-service only)	1.78	11.71*

* Note that TIME2 emissions are based upon a default service life of 20 years but it is possible that creosote treated posts may remain effective for 25 – 30 years.
TIME1 is 0 – 30 days
TIME2 is 0- 7300 days, i.e. 20 years

Scenario 3 (UC 4b) including degradation where relevant	TIME1	TIME 2
PECsurfacewater µg/l		
Jetty in the lake (In-service only)	4.57E-02	0.651
Sheet piling in waterway (In-service only)	41.00	7.51
PECsediment mg/kg wwt		
Jetty in the lake (In-service only)	0.20	1.78E-02
Sheet piling in waterway (In-service only)	125.30	22.96

TIME1 is 0 – 30 days
TIME2 is 0- 7300 days, i.e. 20 years

Scenario 4 (UC 5) including degradation where relevant	**TIME1**	**TIME 2**
PECsurfacewater µg/l		
Harbour wharf (In-service only)	0.82	0.15
PECsediment mg/kg wwt		
Harbour wharf (In-service only)	2.51	0.46

TIME1 is 0 – 30 days
TIME2 is 0- 7300 days, i.e. 20 years

2.2.2.5.3.1. Aggregated exposure

The guidance on assessment of aggregated exposure is currently under development (Guidance on Biocidal Products Regulation: Volume IV Environment - Assessment and Evaluation, Parts B+C, version 2.0, October 2017).
For creosote the PEC/PNEC values are higher than 1 in many exposure scenarios for the environmental compartments. Creosote contains the persistent and bioaccumulative or very persistent and very bioaccumulative constituents and it is carcinogenic. Based on these characteristics, the possible accumulation of creosote constituents in the technosphere may contribute to the aggregated exposure assessment.
The diversity of applications contributes to the overall aggregated exposure of the environment. Uses with similar exposure patterns (e.g. direct exposure to soil) should be summed up in an aggregated exposure assessment, and for that the annual tonnage per product type should be informative. Articles treated with biocidal product can lead to consumer and environmental exposure if chemical constituents of the active substance are released in any way. The duration of the service life of the creosote-treated article may exceed 20 years and it is given in the current OECD ESD PT8 2013, that creosote-treated railway sleepers have an average service live of 26 years. Exposure from treated articles during service life may be the significant exposure to the active substance. Therefore, once the guidance is available the aggregated exposure should be assessed.

2.2.2.5.4. Risk characterisation

Summary table PNEC values (creosote)		
Compartment	**PNEC**	**Units**
STP	130	µg/l
Surface Water	0.1	µg/l
Seawater	0.02	µg/l
Sediment (normalised)* Sediment (non-normalised)	2.0* 0.4	mg/kg wwt
Sediment (marine)**	0.2	mg/kg wwt
Soil	0.3	mg/kg wwt

* Normalised value will be used for sediment risk assessment in line with original SE CAR 2010
** Notional value for marine sediment is a ten-fold reduction of $PNEC_{sediment}$ for freshwater; the calculation was done by the UK eCA.

<u>Atmosphere</u>

Conclusion: In line with conclusions reached in the original SE CAR 2010, it is not considered that concentrations of creosote or creosote components in air will be of concern for the environment.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC$_{STP}$ values		
	TIME1 (30 d)	**TIME2 (service life)**
Scenario 1 (UC 3) Noise barrier (In-service only)	<0.01	<0.001

TIME1 is 0 – 30 days
TIME2 is 0- 7300 days, 20 years

Conclusion: The PEC/PNEC ratio is << 1 at STP in Scenario 1 (UC3) from use of creosote treated wood in-service at both Time 1 and Time 2, using the typical retention rate.

Aquatic compartment

The PEC calculations were made using the revised Bridge over Pond scenario with a water volume of 1000 m^3 instead of 20 m^3 and with a volume of sediment default value 3 m^3, as well as using the revised Jetty in a lake scenario with a volume of sediment default value 23.56m^3, as compared to the original SE CAR, what is in line with the current OECD ESD PT8 2013 and TAB ENV v.2.1, December 2019.

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{water}$		**PEC/PNEC$_{sediment}$**	
	TIME1	**TIME2**	**TIME1**	**TIME2**
Scenario 1 (UC 3) Bridge over Pond (In-service only)	0.02	0.24	0.006	0.06
Scenario 3 (UC 4b) Jetty in the lake (In-service only)	0.46	**6.51**	0.10	0.009
Sheet piling in waterway (In-service only)	**410.0**	**75.15**	**62.64**	**11.48**

TIME1 is 0 – 30 days
TIME2 is 0- 7300 days, 20 years

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{seawater}$		**PEC/PNEC$_{seased}$**	
	TIME1	**TIME 2**	**TIME1**	**TIME 2**
Scenario 4 (UC 5) Harbour wharf (In-service only)	**41.05**	**7.50**	**12.55**	**2.30**

TIME1 is 0 – 30 days
TIME2 is 0- 7300 days, 20 years

Conclusion: For the aquatic compartment (based upon leaching data for creosote when applied at 90 kg/m^3) modelling in UC 3 indicates the PEC/PNEC ratio is < 1 for sediment and aquatic organisms at both Time 1 and Time 2 in the Bridge over Pond scenario.

Modelling in UC 4b (based upon leaching data for creosote when applied at 90 kg/m^3) indicate the PEC/PNEC ratio is < 1 for aquatic organisms at Time 1, but the PEC/PNEC ratio is > 1 for aquatic organisms at Time 2 in the Jetty in the lake scenario, whereas the PEC/PNEC ratio is < 1 for sediment at both Time 1 and Time 2 in the Jetty in the lake scenario. However, modelling in UC 4b indicate the PEC/PNEC ratio is > 1 for sediment and aquatic organisms at both Time 1 and Time 2 in the Sheet piling in waterway scenario.

For the aquatic compartment modelling in UC 5 (when creosote is applied at 150 kg/m^3) indicate the PEC/PNEC ratio is > 1 for sediment and aquatic organisms at both Time 1 and Time 2 in the Harbour wharf scenario.

Terrestrial compartment

Calculated PEC/PNEC values		
	PEC/PNEC$_{soil}$	
	TIME1	**TIME 2**
Scenario 1 (UC 3) House (In-service only)	0.20	**1.05**
Scenario 2 (UC 4a) Transmission Pole (In-service only) Vineyard (In-service only)	**3.11** 0.98	**20.36** **6.43***

* Note that TIME 2 emissions are based upon a default service life of 20 years but it is possible that creosote treated posts may remain effective for 25 – 30 years.

Conclusion: For the terrestrial compartment modelling in UC 3 indicate the PEC/PNEC ratio is < 1 at Time 1, whereas the PEC/PNEC ratio is > 1 at Time 2 in the House scenario.

Modelling in UC 4a indicate the PEC/PNEC ratio is > 1 at both Time 1 and Time 2 in the Transmission Pole scenario. However, modelling in UC 4a indicate the PEC/PNEC ratio is < 1 at Time 1, whereas the PEC/PNEC ratio is > 1 at Time 2 in the Vineyard scenario.

Groundwater

Porewater screening was a Tier 1 approach and it identified possible exceedances of the 0.1 µg/l, which is the trigger concentration under the Drinking Water Directive (Council Directive 98/83/EC of 3 November 2015 on the quality of water intended for human consumption, OJ EC L 330 05.12.1998 as amended) and under Directive 2006/118/EC (Directive of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, OJ L 372 27.12.2006 as amended). The result indicated that unacceptable levels of creosote could reach drinking water from typical uses in UC 3 and UC 4a. Moreover, for the terrestrial compartment the modelling indicate the PEC/PNEC ratio is > 1 at Time 2 in the House scenario, Transmission Pole and Vineyard scenarios.
Creosote contains the PBT/vPvB constituents and hence no safe threshold can be derived for the environmental soil compartment. However, creosote contains also the constituents, which have greater water solubility e.g. phenolic compounds, which may possibly leach out of soil into groundwater. The modelled risk in soil and pore-water is not a sufficient indicator for the groundwater assessment, therefore the further Tier 2 refinement of groundwater concentration using FOCUS PEARL 4.4.4 modelling has been undertaken at renewal.

Creosote is assessed as a mixture of constituents, hence the worst-case K_{oc} (i.e. Creosote Grade B Composite) is used for groundwater assessment. However, some of the hazardous constituents have a significantly lower K_{oc} and therefore the selected worst case constituents are used for separate additional groundwater modelling to align the approach used for another approved mixture active substance (i.e. Ampholyt 20). Due to potential human health effects (based upon exposure of human via the environment), two such hazardous constituents were selected, i.e. Naphthalene and Quinoline.

Exposure assessment to groundwater from in-service use of creosote-treated wood in UC 3
The simulation model FOCUS PEARL v.4.4.4 is used for the evaluation of groundwater exposure to Creosote Grade B Composite, as well as its constituents naphthalene and quinoline. The estimation of the groundwater is performed for the service life of 20 years, because further service life of 26 years is assumed to be covered by this assessment.
The calculation of $PEC_{groundwater}$ in case of direct emission of Creosote Grade B Composite, as well as emission of naphthalene and separately quinoline is based on the railway sleepers scenario. The railway sleepers scenario in PT 8 covers in situ outdoor treatments, treated wood in service as well as combinations from both life stages.

The use of wood preservatives on railway sleepers was attributed to UC 3, since the sleepers are not in direct contact with soil but placed on a bed of railway ballast (e.g. crushed granite, basalt or limestone). The wood preservatives are leached by rainfall from the railway sleepers (industrially treated using pressure impregnation) into the ballast and further through the underlying subgrade layers into groundwater, which is considered to be the main receiving compartment. The emission to soil (subgrade) is not considered to be relevant since the soil beneath the ballast is a disturbed (artificial) environment belonging to technosphere. The ballast prevents lateral run-off due to its higher inner surface. Therefore, emission to adjacent surface waters is not considered to be relevant. On bridges, railway tracks are embedded in sags, preventing direct emission to surface water (OECD ESD PT8, 2013).
The cumulative quantity leaching to a field of one hectare value is based on the leachable surface area of the sleepers, the number of sleepers in the field and the cumulative leaching rate from the treated wood. The wood preservative leaching out from railway sleepers in the area of the railway line consisting of two sets of rails. The width of this area is defined by the lower width of the ballast of 9 m and the length of this area is 1111 m, because the calculation basis of the model is one hectare. Surface area of a sleeper is its upper surface and the four sides (bottom side is excluded).

$Qleach,1 = AREAsleepers \times Nsleepers \times Q*leach,time1$
$Qleach,2 = AREAsleepers \times Nsleepers \times Q*leach,time2$

The amount of Creosote Grade B Composite, as well as its constituents naphthalene and quinoline, that leaches out of 1 m^2 of the treated wood over 30 days (time1; from 0 to day 30) and over service life of 20 years (time2; from 0 to day 7300) is calculated based on the leaching test results (study by van Dongen, 1987; Doc III A2.10.2/02). However, it should be borne in mind that the leaching rates determined in those studies were not for creosote itself, but for its components, and the flux was calculated back for creosote as a whole based on an initial proportion of those determined creosote components. Most probably, different components of creosote show different leaching behaviour due to their physico-chemical properties (according to text in SE Doc II-B, section 8.3.1).
The degradation time DT$_{50}$ in soil values are based on test results (Doc III A7.2.1).
The cumulative quantity values with other parameters are below.

Parameter for FOCUS PEARL simulation	Symbol	Unit	Value
Input			
Leachable wood area of one railway sleeper (surface and sides)	$AREA_{sleepers}$	m^2	1,59
Number of sleepers in a rectangular field of 1 hectare	$N_{sleepers}$	ha^{-1}	2583
Duration of initial assessment period	TIME1	d	30
Duration of long term assessment period	TIME2	d	7300*
Cumulative quantity of a substance leached out of 1m^2 of treated wood over the initial assessment period	$Q*_{leach,time1}$	kg/m^2	0.000011
Cumulative quantity of a substance leached out of 1m^2 of treated wood over a longer assessment period	$Q*_{leach,time2}$	kg/m^2	0.000384
Output			
Cumulative quantity of a substance leached over the initial assessment period of one hectare	$Q_{leach,time1}$	kg/ha	0.045095
Cumulative quantity of a substance leached over a longer assessment period on one hectare	$Q_{leach,time2}$	kg/ha	1.576793

* According to OECD ESD PT8 ENV/JM/MONO(2013)21, the duration of the long-term assessment period (TIME2) should be 9490 days (for railway sleepers treated with creosote based products of average service life of 26 years (Kohler, 2000); however, 20 years was used as the worst-case approach and based on analysis of the output, the simulation using the longer service life is not needed.

The application rate is reflecting release rate from the treated wood to the soil at events of emission. The application rate is calculated from the annual leaching rate (i.e. application rate divided by the service life) converted to 10 equal applications per annum (kg/ha).
Application scheme depends on the retention rate. The retention rate for Creosote Grade B Composite is 90 kg/m^3 in UC 3, however the highest worst case retention rate on treated wooden railway sleepers (via industrial pressure impregnation) is 180 kg/m^3 in UC 3, according to the

SE PAR 2016 and PL PAR 2016 for a product which is 100% of active substance. The worst case among use classes is a retention rate of 400 kg/m^3 for UC 5. Despite that the UC 5 is for marine applications and is not applicable for groundwater assessment, the modelling was performed also with retention rate of 400 kg/m^3, which is the worst case of all, because the lower values of retention rate for other use classes are assumed to be covered by this assessment. Separately, the modelling was performed with a retention rate of 90 kg/m^3, as given by the Applicant for UC 3.

For modelling with single substances, the proportional adjustment of retention rate was based on the content of each of them, i.e. naphthalene content is 6.024% and quinolone content is 1.260% (w/w) in Creosote Grade B Composite, according to Rütgers 2008a.

In the application scheme it is assumed that ten equal applications take place to the soil surface of grassland per year (at dates: 10.01, 15.02, 24.03, 29.04, 05.06, 11.07, 17.08, 22.09, 29.10, 04.12). The representative for grassland crop is alfalfa.

A dilution factor of 10 was used as a correction for the FOCUS-PEARL, assumes that whole groundwater aquifer is covered by the railway track.

Substance related input parameters and further details of the application scheme used are listed below.

Summary of PEC$_{gw}$ simulations with FOCUS PEARL v.4.4.4

Active substance	Creosote Grade B Composite		Naphthalene		Quinoline	
Molecular weight (g/mol)	200 [1]		128		129	
Vapour pressure [2] (Pa)	0.5		10.4		10.4	
Water solubility [3] (mg/L)	8		5.177		5.177	
DT$_{50}$ in soil at 12°C (d)	734 [4]		4.2 [4]		4.2 [4]	
Log Koc	3.67		2.91		1.61	
Koc	4677.3514		812.8305		40.7380	
Kom (=Koc/1.724)	2713.08087		471.4794		23.6300	
Freundlich sorption exponent (1/n)	1 [5]		1		1	
Exponent for the effect of liquid	0.7 [5]		0.7		0.7	
Molar activation energy (kJ/mol)	65.4 [5]		65.4		65.4	
Coefficient for uptake by plant (-)	0 [5]		0		0	
Retention rate (kg/m^3)	90 creosote	400 [6] creosote	90 creosote	400 [6] creosote	90 creosote	400 [6] creosote
Leaching rate time1 (mg/m^2/d)	0.35 [7]	1.627907	0.021084 [8]	0.098065 [8]	0.00441 [8]	0.020512 [8]
Leaching rate time2 (mg/m2/d)	0.046 [7]	0.213953	0.002771 [8]	0.012889 [8]	0.00058 [8]	0.002696 [8]
Application scheme [9] (kg/ha) *per application to the soil surface*	**0.007216**	**0.032073**	**0.000435**	**0.001932**	**0.0000909**	**0.000404**
Crop	alfalfa (grassland)		alfalfa (grassland)		alfalfa (grassland)	

1 Fictive average value, used in SE Risk Assessment Report (2010).

2 Vapour pressure: for Creosote grade B composite assumed 0.5 Pa at 25ºC (for Creosote Grade B and Creosote Grade C data are in the dossier), for naphthalene assumed 10.4 Pa at temperature assumed 20ºC (Doc III A3.2/01), for quinolone (no data in the dossier) taken as for naphthalene.

3 Water solubility: for Creosote 8 mg/L at 25ºC (Doc III A3.5/01, for Creosote Grade B and Creosote Grade C data are in the dossier), for naphthalene 5.177 mg/L at temperature assumed 20ºC (as in Doc III A3.5/03, but not 31.7 mg/L as in a publication mentioned in Doc III A3.5/05), for quinoline (no data in the dossier) taken as for naphthalene.

4 DT50 values are according to SE Doc III A7.2.1; creosote Grade B Composite 734 days at 12ºC and 387 days at 20ºC, for naphthalene 4.2 days at 12ºC and 2.2 days at 20ºC, for quinoline no degradation half-life in the dossier hence taken as for naphthalene.

5 Default values, according to ENV 23, TAB ENV v.2.1 (2019).

6 400 kg/m^3 for UC5, according to SE PAR (2016) for the biocidal product which consists of 100% active substance creosote – this is the worst-case assumption (taken from a different UC) among retentions across EU MS.

7 Leaching rate values for retention 90 kg/m^3 are according to Doc III A2.10.2/02 and for retention 400kg/m^3 they are corrected.

8 By linear proportion; based on the composition of creosote Grade B Composite, naphthalene content is 6.024% and quinoline content is 1.260% (w/w), according to Rütgers 2008a.

9 Using a dilution factor of 10 (considering a 9m wide railway line passing through ca. 100m wide stretch of land above a groundwater catchment of one hectare, according to OECD ESD PT8, ENV/JM/MONO(2013)21.

PEC$_{groundwater}$ - Output FOCUS PEARL v.4.4.4 in µg/L

Results related to active substance	**Creosote Grade B Composite**		**Naphthalene**		**Quinoline**	
Retention rate (kg/m^3)	90 creosote	400 creosote	90 creosote	400 creosote	90 creosote	400 creosote
Location						
Chateaudun	0.000001	0.000002	0.000000	0.000000	0.000000	0.000002
Hamburg	0.000037	0.000165	0.000000	0.000000	0.000030	0.000132
Jokioinen	0.000000	0.000000	0.000000	0.000000	0.000111	0.000495
Kremsmunster	0.000000	0.000002	0.000000	0.000000	0.000001	0.000004
Okehampton	0.000037	0.000163	0.000000	0.000000	0.000019	0.000086
Piacenza	0.000201	0.000892	0.000000	0.000000	0.000005	0.000024
Porto	0.000025	0.000109	0.000000	0.000000	0.000002	0.000009
Sevilla	0.000006	0.000026	0.000000	0.000000	0.000003	0.000015
Thiva	0.000007	0.000032	0.000000	0.000000	0.000001	0.000005

The results of six different simulations, performed with all 9 locations across the EU (representative, defined by soil properties and weather data), are given in the above table. In the above mentioned table for the different locations it is shown that all values are clearly below the 0.1 µg/L trigger value (the highest value is 0.000892 µg/L).

Conclusion: The highest predicted environmental concentration in groundwater resulting from the simulation with FOCUS PEARL using the railway sleepers scenario was 0.000892 µg/L. Therefore, the maximum permissible concentration laid down by the Directive 2006/118/EC on the protection of groundwater against pollution and deterioration, i.e. 0.1 µg/L for biocides, is not exceeded.

The predicted levels of active substance in groundwater resulting from in service use in UC 3 do not exceed the maximum permissible concentration in drinking water laid down by the Drinking Water Directive 98/83/EC, hence is not a sign of indirect exposure of humans through drinking water."

Exposure assessment to groundwater from in-service use of creosote-treated wood in UC 4

According to entry ENV 112 of the current TAB ENV (v.2.1, Dec 2019), currently no harmonised guidance on groundwater assessment for UC 4 scenarios (both soil and groundwater) is available and it was agreed that the scenario for railway sleepers should be used as the first tier to assess the exposure to the groundwater compartment for UC 4.

Based on the UC 3 scenario (given above), the predicted environmental concentrations in groundwater are lower than the trigger value of 0.1 µg/L. Therefore, the agreed first tier assessment do not show significant impact on the exposure to the groundwater compartment for UC 4.

For a qualitative assessment, the following aspects should be considered. In the UC 4 the creosote-treated wood is placed not above ground but in ground and therefore, for example in case of transmission poles the creosote-treated wood is in closer vicinity of the groundwater level than in UC 3. On the one hand, the leaching rates in UC 4 have been derived from experimental data UC 4b (in direct contact with surface water, study by Berbee, 1989; Doc III A2.10.2/07) and for the original initial approval of the active substance it was agreed in principle that these results were tentatively extrapolated to UC 4a (direct contact with soil) and the results of this leaching study are still valid for the current risk assessment for renewal of the approval. On the other hand, such an extrapolation may be considered unrealistic worst-case assumption, because of the different leaching conditions and the leaching rates may vary significantly in UC 3, UC 4a and UC 4b, especially for an UVCB substance. However, such an extrapolation may not be considered a worst-case assumption for poorly water soluble constituents of creosote.

The test results for UC 4b show higher leaching compared to UC 3 and on this basis the higher leaching for UC 4a compared to UC 3 may be expected. However, soil type and moisture contribute to adsorption/desorption and mobility in soil. What is more, the leaching rates determined in those studies were not for creosote itself, but for its components, and the flux was calculated back for creosote as a whole based on an initial proportion of those determined creosote components. Most probably, different components of creosote show different leaching behaviour due to their physico-chemical properties (according to text in SE Doc II-B, section 8.3.1).

Overall, based on the currently available data, the UC 3 modelling result and in the absence of harmonised guidance, it may be concluded that the qualitative assessment of exposure to groundwater from in-service use of creosote-treated wood in UC4a does not raise significant concern.

Overall conclusion on the environmental risk assessment

Based upon leaching rate data provided in the original SE CAR extrapolated to Time 1 and Time 2 for retentions of 90 kg/m^3 (UC 3, UC 4a and UC 4b) and 150 kg/m^3 (UC 5), the conclusions are the following:

UC 3: The House scenario at Time 2 in-service gave the PEC/PNEC$_{soil}$ of 1.05, although at Time 1 the value was lower than 1. However, the Noise barrier scenario gave the PEC/PNEC$_{STP}$ of <<1 at both Time 1 and Time 2, as well as the Bridge over Pond scenario gave the PEC/PNEC$_{water}$<1 and the PEC/PNEC$_{sediment}$<1 at both Time 1 and Time 2.
Tier 1 porewater screening identified possible exceedances of the trigger value. However, Tier 2 groundwater assessment using the railway sleepers scenario in FOCUS PEARL v.4.4.4 simulation model at 20 years in service results in the predicted levels which do not exceed the trigger value of 0.1 µg/l in groundwater. For groundwater the FOCUS modelling covers retention rate up to 400 kg/m^3.

UC 4a: The Transmission Pole scenario gave the PEC/PNEC$_{soil}$ of >1 at both Time 1 and Time 2. The Vineyard scenario at Time 2 in service gave the PEC/PNEC$_{soil}$ of >1.
In the absence of harmonised guidance, an agreed Tier 1 groundwater assessment for UC 4 is the one conducted for UC 3 (using the railway sleepers scenario), which resulted in the predicted levels not exceeding the trigger value in drinking water. Based on such modelling and currently available data, it may be concluded that the qualitative assessment of exposure to groundwater from in service use of creosote-treated wood in UC 4a does not raise significant concern. Hence also, exposure in soil may not be lowered by a removal of active substance further into groundwater.

UC 4b: The Jetty in the lake scenario at Time 2 in-service gave the PEC/PNEC$_{water}$ of >1, although at Time 1 the value was lower than 1, as well as the PEC/PNEC$_{sediment}$ lower than 1 at Time 1 and Time 2. The Sheet pilling in waterway scenario gave the PEC/PNEC$_{water}$ >>1 and the PEC/PNEC$_{sediment}$ >>1 at both Time 1 and Time 2.

UC 5: The Harbour wharf scenario gave the PEC/PNEC$_{seawater}$ >>1 and the PEC/PNEC$_{seasediment}$ >1 at both Time 1 and Time 2.

Creosote is an UVCB substance containing PBT and vPvB constituents. Therefore, the quantitative risk assessment method currently available (PEC/PNEC comparison) does not provide sufficient confidence that the environmental compartments are sufficiently protected.
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.
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 RAR 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. These estimated effects on the environment may not be the only elements for concluding which uses of creosote are supported but could still be of interest in the decision making phase (for instance regarding the relative level of risk between the assessed scenarios).

Based on the available data the classification as Aquatic Acute 1 (H400) and Aquatic Chronic 1, M-factor 10 (H410) remains applicable.

2.2.2.6. Assessment of endocrine disruptor properties

During the original evaluation of the dossier by SE eCA for active substance approval, it was concluded that creosote was a carcinogen (category 1B) and also a reproductive toxicant (category 1B fertility and category 2 development). The conclusion on reproductive toxicity was based on findings of post-implantation losses (developmental toxicity study) as well as reductions in litter size, live offspring and offspring viability (two generation reproductive toxicity study). All effects occurred in the presence of very mild maternal toxicity and hence were considered to be specific effects. No information was available at the time of the previous evaluation, nor for this renewal, with regard to the underlying mechanism of the effects on reproduction and development. It is possible that these treatment-related adverse effects are related to an endocrine mode of action; however, as sufficient information on the mode-of action is not available, a biologically plausible link cannot be established, and a conclusion cannot be made.

For the renewal, a review on endocrine disruption (ED) properties of the selected constituents of the European creosote composition, was submitted by the applicant (embedded in Appendix IIIC).

Literature screening of publications on relationship between the targeted PAH and ED endpoints on fertility, cancer, uterine/ovarian physiology etc, was reported. For this step 10 PAH, which are present in creosote composition were chosen: Naphthalene, Acenaphthene, Fluorene, Phenanthrene, Anthracene, Fluoranthene, Pyrene, p-Cresol, Benz(a)anthracene as well as 1-and 2-Methylnaphthalene (data on naphthalenes were combined). Total number of 31 publications was evaluated and compiled by contents on EATS (estrogenic, androgenic, thyroid-related, steroidogenic) mode of action (MoA) and level of the study (according to the OECD Conceptual Framework). For further steps the four PAH were chosen, i.e. Benz(a)anthracene (CAS 56-55-3), Fluoranthene (CAS 206-44-0) and Phenanthrene (CAS 85-01-8) as well as Naphthalene (CAS 91-20-3), 1- and 2-Methylnaphthalene (CAS 90-12-0 and 91-57-6), as for these PAH most of CF level and EATS MoA seemed covered by the available publications.

Lines of evidence for endocrine activity and adversity to investigate all EATS-mediated parameters were assembled for each of four PAH, assessed and reported.

For Naphthalene and 1- and 2-Methylnaphthalene the 6 published studies (4 *in vitro* assays and 2 *in vivo* studies) on EATS-mediated adverse effect combined with a general systemic toxicity classification indicate that these substances could be considered as not fulfilling the ED criteria.

For Fluoranthene the 4 published studies (3 *in vitro* assays and 1 *in vivo* study) on EATS-mediated adverse effects showed that the substance could be considered as not fulfilling the ED criteria.

For Phenanthrene the 6 published studies (5 *in vitro* assays and 1 *in vivo* study) on EATS-mediated adverse effects showed that the substance could be considered as having an endocrine activity but fails to fulfil the ED criteria.

For Benz(a)anthracene the 5 published studies (3 *in vitro* assays and 2 *in vivo* studies) on EATS-mediated adverse effects together with carcinogenicity and aquatic toxicity classification, biological plausibility is considered to support a possible risk to human health.

Based on the analyzed published studies, the four PAH chosen among the targeted constituents of creosote showed *in vitro* endocrine activities on steroidogenesis, estrogenicity and androgenicity. Based on other published studies, another constituent of creosote i.e. pyrene showed activity towards thyroid receptor. Benz(a)anthracene showed adverse effects on EATS-mediated parameters.

The review submitted by the applicant is limited by the selection of PAH and the number of publications screened.

Overall, no conclusion could be made on the endocrine disrupting properties of creosote for human and for non-target organisms with the available information.

2.2.2.7. Aspects concerning creosote treated wood in UC 4 including the new monitoring studies with determination of selected compounds in creosote treated wooden posts, soil and fruit samples

According to the intended uses defined in section 2.1.2, within the UC 4 the agricultural posts (e.g. tree stakes, orchard/vineyard posts and hop poles) are creosoted either by the vacuum pressure application method or by hot and cold open tank (bath) impregnation method.
The fully or partly creosoted wood elements are covered by the Transmission Pole scenario of emissions to soil during service life, however for uses in agriculture the posts are of other dimensions and their location is more dense. The possibility of potential creosote residues in food and feed resulting from the agricultural uses should be taken into account. For this reason, the new Vineyard scenario for use of creosote treated posts was provided by the applicant, however it concerns only the posts with creosoted bottom part. This scenario was accepted during the BPC WG ENV meeting March-April 2020.
In case of using only the bottom creosoted agricultural posts, the upper part of post is not creosote-treated and therefore creosote-treated wood is not in direct contact with fruit and plants.

No sufficient data is available to assess risk concerning the potential creosote residues in food or feed when creosote treated wood is used in agriculture, although two reports concerning the recent monitoring studies were submitted.
The former monitoring study (CCE 2018[1]) concludes that the levels of polycyclic aromatic hydrocarbons (PAH) were increased by 10 to 100 times in the fruit grown in direct contact with the creosoted posts in comparison to the detected levels in the fruit grown without such contact.
However, the number of chemically analysed samples was very limited so that a statistical analysis was not possible.
Only the selected PAH were determined, albeit the PAH markers included in this study were those mentioned in Commission Regulation (EU) No 835/2011[2] (i.e. benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene), which states the maximum level of total PAH 1 µg/kg in food for infants and young children. Among the selected PAH, that were chemically analysed in the collected samples, were benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, dibenz(a,h)anthracene, indeno(1,2,3-cd)pyrene and benzo(ghi)perylene, which are not determined in the creosote composition provided by the applicant (compare Table C1 in the confidential annex), as it was already mentioned in SE PAR (Addendum to product assessment report dated 1 July 2016: Residues and consumer risk assessment of products containing creosote, KEMI February 2017).The monitoring study reports that the sum of all PAH determined in fruit in contact with creosoted posts was between 225 and 2069 µg/kgww.
Ten selected PAH were determined using an accredited analytical method GC-HRMS with the limit of quantification (LoQ) of 0.5 µg/kgww in fruit picked at 1st campaign and its equivalent analytical method GC-MS/MS with the LoQ of 0.1 µg/kgww in fruit picked at 2nd campaign (but the provided proof of equivalency is not signed nor dated). Another eight PAH were determined in fruit and soil using similar methods, but the validation data for them are not complete. For determinations in wood samples the validation data are also not complete.
The storage conditions of collected samples are not reported; fruit – types apples and pears, wood – not defined but assumed to be post/stake and not tree fragments, soil – full sample prone to degradation.
The chosen sites of various soil types might not be representative since the justification in discussion of results states possible diffuse background depositions of some PAH (source of which might be road traffic).

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[1] Report titled 'Risk assessment on fruit grown in orchards constructed with creosote-treated stakes', Creosote Council Europe CCE, version 8, 20 November 2018

[2] Commission Regulation (EU) No 835/2011 of 19 August 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs (OJ L 215, 20.08.2011, p.4)

The latter monitoring study (CCE 2020[3]) was initiated to address a request of the former eCA (UK) to assess potential residue transfer into fruit from creosote-treated stakes in a commercially representative orchard setting. This study report concludes that the use of creosote-treated wooden stakes in orchards increases the creosote-specific PAH residues in the fruit, but does not have a significant measurable impact on PAH levels in the surrounding soils.
In this report the summary of results stated, that typically in the fruit the mid-range molecular mass PAH were determined and they were also present in the creosoted wood samples, whereas in the soil the higher molecular weight PAH were determined.
In this GLP study the chosen sites and samples are regarded as representative as well as the collected samples (apples not peeled and not washed, wood from creosoted post, full soil) were stored frozen until the analytical part in the dedicated laboratories, what is also recommended by the OECD TG 509 (2009).
In this study the sampling of fruits was by selection from quarters of a tree, hence the sampling is representative for a particular tree (instead of being representative for fruit having or not the contact with creosoted post, as it was in the former monitoring study).
The same selection of PAH for determination was in both monitoring studies. Ten selected PAH were determined in fruit and soil using accredited analytical methods. Another eight PAH were determined in fruit using similar methods, but only the indicative results are available and the validation data for them are not complete. The results of determinations in soil samples are given with an indication that stability period was exceeded (with no further explanation). For determinations in wood samples the validation data are also not complete.

The conclusions of the monitoring studies performed to date are limited by the selection of PAH determined in the samples as well as by the analytical method deficiencies. Among the non-analysed constituents of creosote is quinoline (which is a genotoxic carcinogen with harmonised classification as Carc. 1B, Muta. 2). The number of samples analysed is limited so that statistical analysis of results was not done and not reported. Both monitoring studies are the screening studies.
What is more, based on results of each of those two monitoring studies, the consumer dietary risk assessment conducted by the applicant refers to the tolerable daily intake value from a RIVM report (Baars et al, 2001). However, the value from the RIVM report (Baars et al, 2001) concerns petroleum hydrocarbons and is "for non-carcinogenic aromatics".
Also for the former consumer dietary risk assessment conducted by the applicant the assumption was that less than 0.36% fraction of fruit comes in contact with fully creosoted posts, but no assumption was for vineyard posts or hop poles usage.
Overall, the submitted assessments are not sufficient to refine the concern on consequences of contact between creosoted posts and the fruit.

What is more, the former monitoring study report (CCE, 2018[1]) stated, that the plant uptake from soil is not expected and in the applicant's view the published results on determinations of the hazardous reference PAH in fruit and vegetables are not specifically representing the relevant PAH profile of the EU creosote. Nevertheless, based on the submitted dossier, the incorporation of the creosote constituents into the plant biomass as an organic carbon source cannot be excluded, however the bioavailability of these compounds for plants from soil or water shall contribute to possible plant uptake (and may vary among crop species).
The soil is the primary receiving environmental compartment based on the service life exposure pathway concerning both the fully or the partly creosoted wood articles used for agricultural purposes. The laboratory and field studies on the leaching of creosote from the treated wood were submitted within the dossier. The original evaluation by SE (eCA 2010 Doc II B) indicated the interpretation difficulties due to the UVCB properties of creosote and the following assumption made by the applicant (Doc III A2.10.2/01-13). The leaching rates for creosote have been determined by extrapolating the results obtained for single creosote components, assuming that the ratio composition of these selected PAH in the leachate (i.e. of all known and unknown leachable components) was the same as the ratio composition of these selected PAH in creosote used for wood treatment.

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[3] Report titled 'Magnitude of the Residue Determination of Polycyclic Aromatic Hydrocarbons (PAH) Following the use of Creosote Treated Wooden Stakes on Fruit Trees in Belgium, Poland and the United Kingdom', [redacted], Creosote Council Europe CCE, 03 June 2020

The qualitative assessment of the groundwater exposure was done according to the outcomes of the BPC WG ENV meeting March-April 2020, and could not indicate removal from soil further into groundwater.
In conclusion, the bottom creosoted agricultural posts (e.g. tree stakes, orchard/vineyard posts and hop poles) have the upper part of post with no creosote and therefore the potential residue transfer into fruit and plant from creosote-treated part of post via direct contact is excluded. However, the potential residue transfer into fruit and plant from creosote-treated part of post via possible plant uptake from soil still remains.
The PEC/PNEC values are higher than 1 for soil (terrestrial compartment) identified at the service life of 20 years (Time 2) in the Vineyard scenario and Transmission Pole scenario, as assessed by the UK (the former eCA) and accepted during the BPC WG meeting March-April 2020. The available monitoring data are not reliable to refine the exposure assessment.

2.2.2.8. Measures to protect man, animals and the environment

Risk Mitigation Measures to protect man are based on data given in section 2.2.2.4.3 of the RAR. Furthermore, it is estimated that the exposure situation can be further improved by extra protective measures during work tasks where there is a risk of exposure. Protective measures not mentioned below can also be of importance and hence be applied as well:

- 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.

In addition:

- The working areas such as the treatment/equalisation hall shall be cleaned when judged necessary based on monitoring or inspections. Other areas such as changing and washing rooms, break rooms and control rooms shall be cleaned weekly. Relevant equipment and tools shall be cleaned in case of contamination.
- Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.
- After brushing, do not clean the brush and disposed it as hazardous waste.

It is estimated that the above mentioned protective requirements or measures would reduce the exposure substantially, and hence, lead to larger MOEs than those already obtained in the current risk assessment.

Risk Mitigation Measures to protect animals and the environment are based on data given in section 2.2.2.5.3 of the RAR.
Labelling and associated obligatory instructions must state that all 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), it 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).

Risk Mitigation Measures to protect man, animals and the environment concerning the use of creosote and creosote treated articles should also refer to REACH. The provisions given in REACH Annex XVII apply (Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII, OJ L 164, 26.06.2009), however the current status of the respective REACH legislation should be checked for any updates at the product authorisation stage. The current conditions of restriction are in the following three paragraphs:

1. Creosote shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood. Furthermore, wood so treated shall not be placed on the market.
2. By way of derogation from paragraph 1:
   (a) The substances and mixtures may be used for wood treatment in industrial installations or by professionals covered by Community legislation on the protection of workers for in situ retreatment only if they contain:
      (i) benzo(a)pyrene at a concentration of less than 50 mg/kg (0.005% by weight), and
      (ii) water extractable phenols at a concentration of less than 3% by weight.

   Such substances and mixtures for use in wood treatment in industrial installations or by professionals:
      - may be placed on the market only in packaging of a capacity equal to or greater than 20 litres,
      - shall not be sold to consumers.

   Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is visibly, legibly and indelibly marked as follows:
   "For use in industrial installations or professional treatment only".

   (b) Wood treated in industrial installations or by professionals according to subparagraph (a) which is placed on the market for the first time or retreated in situ may be used for professional and industrial use only, for example on railways, in electric power transmission and telecommunications, for fencing, for agricultural purposes (for example stakes for tree support) and in harbours and waterways.

   (c) The prohibition in paragraph 1 on the placing on the market shall not apply to wood which has been treated with *creosote* (i.a. *substances listed in entry 31 (a) to (i) in Annex XVII of REACH*) before 31 December 2002 and is placed on the second-hand market for re-use.
3. Treated wood referred to under paragraph 2(b) and (c) shall not be used:
   - inside buildings, whatever their purpose,
   - in toys,

- in playgrounds,
- in parks, gardens, and outdoor recreational and leisure facilities, where there is a risk of frequent skin contact,
- in the manufacture of garden furniture such as picnic tables,
- for the manufacture and use and any re-treatment of:
  - containers intended for growing purposes,
  - packaging that may come into contact with raw materials, intermediate or finished products destined for human and/or animal consumption,
  - other materials which may contaminate the articles mentioned above.

Taking into consideration the conditions of restriction for creosote and creosote-treated articles under REACH, and the fact that creosote meets the exclusion criteria, as well as a major concern is that a certain use pattern may pose a risk to human health (the user of a treated article or the general public) or the environment, labelling of treated articles should include prohibition of direct contact with food (art. 58(3) of the BPR and CA-Nov14-Doc.6.2-Final-Conditions on TA in approvals).

Risk mitigation measures are to be adjusted for the product at the product authorisation stage.

2.2.3. Public consultation for potential candidates for substitution and alternative substances or technologies

Creosote is an UVCB substance of the following properties: non-threshold carcinogen (Carc. 1B), toxic for reproduction (Repr. 2), persistent (P) and bioaccumulative (B) as well as very persistent (vP) and very bioaccumulative (vB). Therefore, the conclusion of risk assessment is that creosote meets the exclusion criteria of Article 5(1)(a), (c), (e) of the BPR. Creosote meets the criteria for substitution of Article 10(1)(a), (d), (e) of the BPR. This active substance can only be approved if at least one of the conditions of Article 5(2) of the BPR is met. In deciding whether the active substance may be approved the availability of suitable and sufficient alternative substances is to be considered.

For that reason, the information submitted by interested third parties are to be taken into account by the BPC in the opinion making process. In order to collect the information on alternatives the public consultation was coordinated by ECHA as foreseen under Article 10(3) in order to gather elements on potential alternatives that can serve later in the decision making-process at Standing Committee level, and to facilitate the product authorisation stage if the active substance is eventually approved (in line with CA-Nov14-Doc.4.5 – Final). The public consultation lasted for 60 days and concerned applications for renewal of the approval of an active substance, as described respectively in Article 13 of the BPR.

For the public consultation if the submitter claims that suitable alternatives do not exist, explanations must be provided like technical limitations why there are no suitable alternatives or information on a substitution plan (according to the *Submission of information in the consultation on potential candidates for substitution under the Biocidal Products Regulation* by ECHA).

The public consultation was launched by ECHA from 23 October 2019 till 22 December 2019. The summary of the Public Consultation was compiled by ECHA and is attached in Appendix V of the RAR.

The information provided during the public consultation, the possible alternatives are identified and described in three tables below.

Certain advantages and limitations exist for each alternative material and some other advantages and limitations exist for creosoted wooden articles. Therefore, most of the entries state that an additional time is needed to enable 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.

In addition to the evaluation of the information submitted during the public consultations, the compilation of number of creosote containing biocidal products authorised in each market area (based on data in R4BP 3 as of 9 October 2020) as well as the overview of creosote containing biocidal products authorised in the EU, as a result of a survey conducted by ECHA among Member States is presented in Appendix VI.

The reports provided from Member States to the Commission justifying the conclusion, that there are no appropriate alternatives were analysed. Two separate compilations are in Appendix VII.
These reports indicated some disadvantages of named alternatives, but also indicated how the development of alternatives is promoted. These reports are made publicly available by the Commission.

Analysis of alternatives Applicability/ uses potentially covered: UC 3 RAILWAY SLEEPERS						
No.	**Alternative substance or technology**	**Technical feasibility**	**Economic feasibility**	**Availability**	**Advantages/ limitations/ notes/ remarks**	**Reference**
1.	Concrete, reinforced concrete	Replacing wooden with concrete sleepers requires significant reconstruction of part of the railway infrastructure, e.g. tunnels (enlargement), bridges, tracks with a small radius of curvature, etc. Sleepers of various type cannot always be mixed on the same track section.	Replacing sleepers is a track renewal operation (instead of regular maintenance), what poses an economic constraint for secondary tracks and low traffic lines Relative price comparison: wood:concrete = 1 : 1 concrete expected 100-150% higher price	Available Concrete manufacturing capacity exists, but the product is not fully developed as a potential replacement for wood sleepers in specific railway tracks (fastening system).	- Concrete sleepers break in the event of derailment and must be replaced immediately = derailment safety. - Tuned concrete by pre-cracking is of reduced stiffness. - Replacing concrete sleepers requires mechanization due to their weight and is not applicable in difficult terrain, i.e. in mountainous terrain, with large arches, curves, tunnels and bridges. - Railway sleepers infrastructure maintenance requires frequent cleaning and tamping of tracks, failure to comply with this requirement for concrete sleepers can lead to the destruction of sleepers and the entire track. - New lines (Austria) are made with concrete sleepers except for special areas and switching points. - Concrete sleepers have a worse ecological balance (e.g. use of the landscape in open-cast mining and high energy input in cement production). - Concrete sleepers are carbon intensive and energy consuming in production and installation process. - Concrete sleepers are heavier, more fragile, and hardly resistant to temperature and humidity fluctuations. The production of concrete sleepers is also associated with several times greater consumption of fossil fuels and water, and thus causes greater greenhouse gas emissions, affects more acid rain or smog. - Life Cycle Assessment (LCA) *data with no references given*: Concrete railway sleepers production: 1.8 times higher consumption of fossil fuels and 8.7 times higher water consumption. Concrete causes emissions: about 5.8 times more greenhouse gases, 68 times more acid rain, 2.3 times more smog, and 2.0 times more eutrophication (increasing soil fertility).	Finland, National Authority Sweden, National Authority Belgium, Industry or trade association Lithuania, Member State Austria, Member State Germany, Regional or local authority Estonia, Company-Downstream user Poland, National Authority Poland, Company-Manufacturer Poland, Company-Downstream user
2.	Steel	Replacing wooden with steel sleepers requires significant reconstruction of part of the railway infrastructure.	Relative price comparison: wood:steel = 1 : 2	Available	- Due to high costs steel sleepers are not used for the last 50 years in Austria. - Metal alternatives are heavier and suffer from large temperature and humidity fluctuations (service life). - Production is energy consuming (climate impact), not sustainable renewable material.	Austria, Member State Germany, Regional or local authority Poland,

		Sleepers of various type cannot always be mixed on the same track section.			- Production, installation and usage causes more noise. - Steel sleepers are made to order (not in stocks).	Company-Manufacturer Sweden, Company-Manufacturer
3.	Composite plastic **Recycled** polymer composite (plastic)	Service life 50 years. European standards for production of recycled plastic sleepers is in development. “ISO/FDIS 12856-2:2019 - Polymeric Sleepers and Bearers” provides the technical specification for railway sleepers made from plastic composites Plastic Composite Railway sleepers in tracks since 1996 in USA and since 2013 in Europe.	Relative price comparison: wood:plastic = 1 : 4 Recycled plastic expected 75-300% higher price (depending on supplier and source of the recycled material), Composite sleepers in Finland on test track since 2019, remarkably expensive. Initial unit cost of a plastic composite railway sleeper is more than that of an equivalent hardwood and softwood sleeper due to installation and maintenance costs, but longer service life.	Recycled plastic production capacity is limited. In Europe 5 established suppliers of polymer sleepers	- Although 6 types of plastic and synthetic sleepers are under testing (Germany), they are not able to cover the demand sufficiently to replace the wooden sleepers. - Plastic sleepers are oil-based and therefore cannot be produced sustainably. - Recycled plastic sleepers have equivalent climate impact to wooden sleepers and hazardous substances content was not identified at levels above 0,1% based on spot checks not yet representative for ensuring total production (not recycled from electronic waste). - Pure polyolefin materials contain no hazardous substances - *this applies only if sleepers are made of pure materials instead of the recycled composite plastic materials*. - Glasfibres and polyurethane used on long steel bridges only due to extremely high cost (3-4 -fold of wooden sleeper). - Composite sleepers more expensive and no bridge solutions sufficiently examined or considered safe (in ballastless bridges, switches and crossings). This assessment does not include the wider economic impact of utilising recycled plastics in such applications, either from the perspective of future carbon taxation initiatives or through wider savings to European governments in supporting the meeting of extremely challenging legal targets for plastic waste recovery and recycling. - Life Cycle Assessment (LCA) *data with no references given*: Plastic composites usage results in 2.5 times more fossil fuel consumption and 11 times more water consumption, emissions with the potential to produce 5.0 times more greenhouse gas emissions, 72 times more acid rain, and 1.1 times more smog. Creosote impregnated railway sleepers cause about 1.4 times more eutrophication than composite sleepers.	Austria, Member State Sweden, National Authority UK, Company-Manufacturer Germany, Regional or local authority Estonia, Company-Downstream user Netherlands, Company-Manufacturer Finland, National Authority Poland, Company-Manufacturer Poland, Company-Downstream user
3.1.	FFU syntehtic sleepers (made from glasfibres and polyurethane)	Since 1978 in Japan the product is used as substitution for wood in track, turnout and on steel bridges		For application like sleepers for turnouts, steel bridge and special track sleepers German Company-	In Europe more than 2.5 Million sleepers installed already - the product is used in 2004 first time.	Germany, Company-Manufacturer

				Manufacturer claims to be able to satisfy the market		
3.2.	Compact polymer sleepers which consist of secondary raw materials recyclate reinforced with fibres	Service life beyond 50 years (laboratory simulation tests only) Screw pull out force better than with wood		Available for track, turnout and bridge applications	- Highly resistant against environmental influences and chemicals. - Patented and approved for field testing in Germany.	Germany, Company-Manufacturer
4.	Copper-oil-based wood preservatives	Oil is hydrophobic additional protection; Copper-oil borne imply adaptations in standard treatment plant; Problem to extract water in the copper oil for treatment under 100° C (released water affect quality of treatment). No definitive process confirmed for any potential alternative.	Copper-oil expected 20% higher price, Copper-oil is expensive: 2 to 3 times the price of creosote.	Another 5 years to complete development phase or field trials, to prepare installations (technology) for production, to allow new certifications for sleepers impregnated with possibly alternative preservatives. Copper-oil investments to switch production (currently not used to make sleepers from pine wood). No industrial scale production is available in Europe today, only small trial plants.	- Lab tests suggest good behavior in water repellence and conductivity. - Limited efficacy due to resistance of fungi to copper biocides (because of continuous mutations). - Not available at large scale, hence the correct evaluation of hazards and risks is uneasy. - Potential negative environmental impact assessed to be lower for copper-oil sleepers than for creosoted sleepers (but awaiting long term field tests on leaching from sleeper containing below 0.5% copper per sleeper weight), as well as wooden sleepers cause lower carbon dioxide loads than concrete. - No copper-oil sleepers are to be installed in water protection areas, due to aquatic toxicity (Sweden). - Service life: quality of the wood determines the quality of the sleeper. - Creosoted wood has clearly defined disposal methods. such as combustion in authorized installations (energy recovery) and biological treatment (e.g. leaching bath in appropriate conditions with the participation of appropriate bacterial strains, resulting in a safe wood material and easily biodegradable emulsion). The disposal methods of hazardous waste from wood preserved by new agents under development are not known. Development of creosote alternatives can meet some difficulties due to the organization of the sector and the actual absence of market for « alternative sleepers »: - Chemical Industry cannot provide alternatives to the wood preservative industry because the wood industry cannot switch his treatment plant to another product for which there is currently no market, - Wood Preservation Industry cannot switch to another product if	Sweden, National Authority Sweden, Industry or trade association Spain, Company-Downstream user Poland, Company-Manufacturer Poland, Company-Downstream user France, Company-Downstream user

					this product is not ordered by Rail Infrastructure Managers, - Rail Infrastructure Managers want to have feedbacks with real scale tests before to homologate definitively new substances and create a market. But they cannot get sleepers in big quantity as no treatment plants (industrial or semi-industrial scale) use or produce these new substances. Since 2018 the start-up DURWOOD in the testing phase. 31 alternatives have been assessed - At this stage it is not possible to make a responsible choice; to replace the use of creosote with any of the potential alternatives currently under development.	
5.	Crude tall oil			Ongoing research programme AT-WOOD by UIC on feasibility of alternatives to creosote sleepers, hence gradual phasing out instead of a ban is postulated	- Tall oil cannot be used due to ignitability. *Mind major forces when using train brakes.* - Tall oil is a biobased by-product in the Kraft process of wood pulp manufacture, but do not provide sufficient protection in heavy-duty applications outdoors. - EU Horizon 2020 funded ERA-LEARN project CreoSub; Crude tall oil and impregnation with a copper-based preservative followed by vacuum drying in oil, according to the project's outlook may not live up to expectations or economically not viable. - LCA results: Environmental impact of creosote, a linseed oil-based product, as well as a tall oil based product was in the same range.	Finland, National Authority Norway, Industry or trade association Belgium, Industry or trade association
6.	Copper-based preservative followed by vacuum drying in oil			Time needed to complete development phase, to prepare installations (technology) for production, to allow new certifications for sleepers impregnated with possibly alternative preservatives.	- EU Horizon 2020 funded ERA-LEARN project CreoSub; Crude tall oil and impregnation with a copper-based preservative followed by vacuum drying in oil, according to the project's outlook may not live up to expectations or economically not viable. - LCA results: Environmental impact of creosote, a linseed oil-based product, as well as a tall oil based product was in the same range.	Belgium, Industry or trade association Sweden, Industry or trade association
7.	Copper-water-based chemical wood preservatives (e.g. Tanalith	Service life 15 years Horizontal sleeper position and cracks formation create access for water		Available	- Do not have a water repellent effect (as creosote does), what leads to crack formation and risk of decay but also to dimensional variations; impacts safety in railways. - Excessive conductivity of the copper water based preservative treated timbers.	Belgium, Industry or trade association Spain, Company-

	E)	and fungi inside the sleeper (with risk of premature failure) because of leakage of copper in water-borne formulations.			- Research project Bahnschwelle 2020 on water-based chemical wood preservatives; economic requirement of service life 30-35 years is not met by any. - Creosoted wood has clearly defined disposal methods. such as combustion in authorized installations (energy recovery) and biological treatment (e.g. leaching bath in appropriate conditions with the participation of appropriate bacterial strains, resulting in a safe wood material and easily biodegradable emulsion). The disposal methods of hazardous waste from wood preserved by new agents under development are not known.	Downstream user UK, Industry or trade association Norway, Industry or trade association France, Company-Downstream user Austria, Member State Estonia, Company-Downstream user Poland, Company-Manufacturer Poland, Company-Downstream user
8.	Non-treated tropical wood (e.g. azobe)	Service life 10 years	High price		- Hardwood (red ironwood; azobe) bend after long-term stress; limited usage in turnouts. - Non-treated tropical wood (azobe) as an alternative must originate from sustainable forestry, and transport costs occur if the scale beyond local. - For oak and beech sleepers availability limited, high price. - Siberian larch deteriorate within 20 years, too much resin to be saturated but not to prevent decay. - Use of hardwood and finewood is not ecologically sustainable and research is needed concerning standard rules to develop quality grading and stress rating of sawn timber.	Belgium, Industry or trade association Finland, National Authority

Analysis of Alternatives **Applicability/ uses potentially covered: UC 4** **OVERHEAD ELECTRICITY TRANSMISSION POLES**						
No.	**Alternative substance or technology**	**Technical feasibility**	**Economic feasibility**	**Availability**	**Advantages/ limitations/ notes/ remarks**	**Reference**
1.	Concrete	Service life 40 years	Expensive handling, maintenance and service of concrete poles.	Available	- Poles made of concrete are used near schools, kindergarten, recreational areas; wider uses are not economically reasonable due to high cost and short service life. - Alternative poles are only for critical places (gardens, playgrounds, protected areas, long pole distances, …) useful. At meadows, forests, mountains, in low- and middle voltage grids the creosote impregnated poles are the preferred for the energy provider and the land-owner. - Concrete poles are heavy, need more energy for transportation and have sometimes much less lifetime at cold climate (e.g. in Sweden). - Replacing concrete poles requires mechanization due to their weight and is not applicable in difficult terrain, i.e. power lines in forest and mountain areas. - Concrete production has greater impact on climate: consumption of fossil fuels and water consumption, causes greater emissions of greenhouse gases and smog.	Austria, individual Austria, Member State Sweden, Industry or trade association Austria, Industry or trade association Poland, Company-Manufacturer Poland, Company-Downstream user
1.1.	Wooden poles mounted on a concrete foundation	Concrete foundation is not feasible in mountain terrain. Replacements not into the same hole	Salt impregnated poles, founded in earth, are much more expensive because of the short lifetime.	Available	Available and used.	Austria, Member State
2.	Steel	Service life 40 years	High cost	Available	- Poles made of steel are used near schools, kindergarten, recreational areas; wider uses are not economically reasonable due to high cost and short service life. - Alternative poles are only for critical places (gardens, playgrounds, protected areas, long pole distances, …) useful. At meadows, forests, mountains, in low- and middle voltage grids the creosote impregnated poles are the preferred for the energy provider and the land owner. *- Additional safety precautions needed due to electrical insulation properties.* - Steel poles are made to order (not in stocks).	Austria, Member State Austria, Industry or trade association Sweden, Company-Manufacturer

3.	Fibre composite (GRP) polyethylene (PE) poles, plastic	Expected service life over 80 years Existing crews can install the poles with minimal training and standard equipment (nordic climbers can be used to ascend the pole safely).		Poles are also used for road and traffic applications where it typically replaces the steel pole.	- Easy to install, yet strong enough to cope with the most demanding of loads. - The pole is hollow; you have the option of routing cables internally. - No conductive, no risk of arcing. - Light weight. - Cannot rot. Resistant to vermin and insects. - Withstands freezing. - Crash safe, cannot corrode and is maintenance free. - For the composite pole, the production of polyethylene and the production of polyester are the two activities that contributes most to the total score for inhalation and for dermal, the production of glass fibre also contributes significantly to the score *(ProScale assessment Sept 2020 by IVL Swedish Environmental Research Institute Ltd.)*. ProScale score for inhalation up to 100 and the highest score is for polyester which is caused by the production of ethylene and the unit process for producing polyester. The reason for the high value for ethylene is because ethylene is produced from Naphtha. Naphtha has an OEL of 3.25 mg/m^3 and has the highest hazard classification (H350). ProScale score for dermal range up to 10 and the highest score is for ethylene. No plastic poles are used in Austria (MS).	Belgium, International NGO Sweden, Industry or trade association
3.1.	Composite plastic i.e. glass fibre reinforced polyester with outer protective layer of UV stable polythene and aluminium top cap	estimated service life beyond 80 years, lengths from 2m up to 24m	Finnish Utility Companies Federation assessed and compared costs of composite plastic poles, wooden poles and underground cable.	Production facilities in Sweden and Finland	- Reduced weight; easier transport and installation help to offset the difference in price. - Benefits of working with a clean inert pole. - Linesmen with a dust mask in addition to their normal PPE when drilling the poles. - Very good insulation properties as tested. - No rotting; could be designed to remain 60% of ultimate strength, vermin and woodpecker resistant. - Life Cycle Assessment (LCA) data *with no references given*: Plastic composites usage results in 2.5 times more fossil fuel consumption and 11 times more water consumption, emissions with the potential to produce 5.0 times more greenhouse gas emissions, 72 times more acid rain, and 1.1 times more smog.	Sweden, company-manufacturer Poland, Company-Manufacturer Poland, Company-Downstream user
4.	Wooden poles covered by plastics, Encapsulating wooden poles by extrusion of:				- Bolt insertions are susceptible to water intrusion into the wooden core of the pole = a defect difficult to detect at an HDPE encapsulated pole in service, - Surface of the HDPE-barriers is more slippery than a wood surface (transport, handling, climbing)	Norway, Industry or trade association

	- WPC (Wood Polymer Composite) - HDPE (High Density Poly Ethylene)				- Stiffness, static strength, dynamic strength are advantages, drilling patterns to improve impregnability are optimized - No disadvantages regarding electrical conductivity. - For the composite pole, the production of polyethylene and the production of polyester are the two activities that contributes most to the total score for inhalation and for dermal, the production of glass fibre also contributes significantly to the score (*ProScale assessment Sept 2020 by IVL Swedish Environmental Research Institute Ltd.*). ProScale score for inhalation up to 100 and the highest score is for polyester which is caused by the production of ethylene and the unit process for producing polyester. The reason for the high value for ethylene is because ethylene is produced from Naphtha. Naphtha has an OEL of 3.25 mg/m^3 and has the highest hazard classification (H350). ProScale score for dermal range up to 10 and the highest score is for ethylene. - Before phasing out creosote, environmental impacts of alternatives must be studied to avoid unknown risk of negative environmental and climate impact. - Energy supply through a robust and reliable power grid is important to meet EU energy and climate goals.	Sweden, Industry or trade association
5.	Salt based preserved wood poles Basic copper carbonate (CAS 12069-69-1) Copper oxide (CAS 1317-38-0) Granulated copper (CAS 7440-50-8) Copper hydroxide (CAS 20427-59-2) These Copper based active ingredients are formulated in combination with additional co-biocides for PT 8: Quaternary compounds (CAS 7173-51-5; CAS 68424-85-1) Triazoles (e.g. Tebuconazole, CAS	Service life 20-25 years	Costs of exchange and intensified use of timber may raise prices of wooden poles.	Available alternative products for the main application of creosote; authorised or under evaluation: - Tanalith E 3462, E 3473, E 8000, E 9000 Family - Impralit ACA protect • Bochemit Forte - Celcure M65 - Wolmanit CX-8, CX-8WB, CX-10 - Korasit KS 2, Korasit CC Not available stocks of alternatives ready to respond to 'wind damaged lines' where power and telecoms are required to be re-	- Do not have a water repellent effect (as creosote does). - Lower electrical insulation. - Evaluated product dossiers of these alternatives show acceptable risks for humans and the environment. - In populated areas the general public is exposed to the impregnated wood poles. - In low and medium voltage range, for last 30 years only salt based preserved wooden poles (with and without concrete foundation) or steel poles are used (Austria). - Copper based preservatives of relatively fast washing of the agent from wood (this is related to the work of the wood in changing weather conditions); after each replacement emission to the environment begins again what results in greater pollution. - Copper based preservatives of limited applicability due to resistance of soil fungi species (e.g. *Poria vaillantii*).	Austria, Member State Austria, individual Belgium, Industry or trade association Estonia, Industry or trade association Germany, individual Poland, Company-Manufacturer Poland, Company-Downstream user

	107534-96-3) Copper-HDO (CAS 312600-89) Didecylmethylpoly (oxyethyl)ammonium propionate (CAS 94667-33-1) Polymeric Betaine (CAS 214710-34-6)			connected in a matter of days.		
6.	Copper-oil alternatives under evaluation, Bio-Oil	Shorter service life; more frequent replacements needed	Claimed to be more expensive than creosote. A planned scale up of new manufacturing plant and equipment; "operational costs need to be accommodated within regulatory electricity suppliers price control settlements" (UK)	Another 5 years to complete development phase or field trials, to prepare installations (technology) for production, to allow new certifications for poles impregnated with possibly alternative preservatives. Currently only non-industrial manufacture of copper-oil preservatives	- Mineral or bio-based oils in combination with copper and organic cobiocides have the greatest potential to substitute creosote *(project CreoSub 2014 – 2017; poles were installed at test sites in Norway, Germany and USA in 2015 and 2016 to cover different soil and climate conditions)* - Do not exhibit the same properties or performance as creosote and as such are yet to be considered suitable and sufficient replacements as defined by the Regulations. - Wind can destroy networks of poles and posts, currently only wood can be used to rebuild networks quickly. Alternative wood preservatives available on the market do not meet expectancy for wood pole. - Bio-oil under Horizon 2020 in development phase, copper-oil preservatives in field testing and under evaluation (ongoing assessment of risks on surface condition of treated articles and leaching). - Other copper-based biocide and oil products are being developed and assessed, but these have yet to be authorised under the Regulations - Combinations as oil or copper-oil not yet authorized or accepted by pole users, respectively. - Creosoted wood has clearly defined disposal methods. such as combustion in authorized installations (energy recovery) and biological treatment (e.g. leaching bath in appropriate conditions with the participation of appropriate bacterial strains, resulting in a safe wood material and easily biodegradable emulsion). The disposal methods of hazardous waste from wood preserved by new agents under development are not known.	Norway, Industry or trade association Spain, Industry or trade association UK, Industry or trade association Finland, Company-Downstream user Spain, Company-Downstream user Poland, Company-Manufacturer Poland, Company-Downstream user
7.	Tanasote S40 (hot oil-based product)	Service life of 40 years (for 100-133 kg/m^3 impregnated wood)	For Tanasote cost per liter is more than creosote. Poles	Once evaluated and product authorization granted, will be available on the market.	- Contains Copper hydroxide, Penflufen, and DDA (didecyldimethylammonium carbonate), and currently is in evaluation for biocidal product authorization, - Effective against brown rots (*Fibroporia vaillantii*) and copper-tolerant fungi. The shelf life of Tanasote S40 is 24 months.	UK, Company-Manufacturer

			installation costs increase slightly by 3-6%.		- Applied at lower temperature using the same treatment equipment and similar processes as for creosote (less energy consuming). - Has improved explosive and oxidizing properties and has a low auto-ignition temperature of ca. 268ºC. Tanasote treatment plant will operate at ~110°C below the flash point. (Creosote flash point is ~75°C and treatment plants need to operate at 45°C above the flash point.) - Tanasote is a low viscosity liquid even at low temperatures and can be transported without the requirement for heated transport containers, reheating on receipt at the treatment facility, whereas creosote needs to be transported and stored warm. - Containing no VOCs (volatile organic compounds). - Tanasote S40 treated utility pole had the lowest impact in damage to ecosystems, damage to human health and damage to resources; when compared to cast concrete pole, fiberglass polyester pole, steel pole, spun concrete pole, and fiberglass epoxy pole by LCA ReCiPe method.	
8.	Copper/co-biocide formulation followed by separate treatment with an oil			5 years needed to demonstrate feasibility or not	- Pole users do not accept the technical feasibility of using poles treated with copper/co-biocide formulations for its 40 year-plus pole requirement.	UK, Industry or trade association
9.	Copper naphthenate Napthenic acid and copper hydroxide-based preservative	In use since 1930	Only hot oil-based preservative which is as cost effective and useful as creosote	Can be used by the same impregnation installation system without high investment		Germany, Company-Manufacturer
10.	CCA (copper chrome arsenic) and other chromium containing biocides (arsenic, zinc, fluorine, chromium, phenolates)			Withdrawn from the market	- Forbidden due to their toxicity,	Norway, Industry or trade association Poland, Company-Manufacturer

Analysis of Alternatives **Applicability/ uses potentially covered: UC 4** **EQUESTRIAN FENCING, AGRICULTURAL FENCING, AGRICULTURAL POSTS/STAKES, HOP POLES**						
No.	**Alternative substance or technology**	**Technical feasibility**	**Economic feasibility**	**Availability**	**Advantages/ limitations/ notes/ remarks**	**Reference**
1.	Concrete	Service life 40 years		Available	- Concrete agricultural poles incompatible with orchard designs, growers limit the number of supports used (i.e. extend the gap between poles) and when typically interconnected (by wires) a failure in one support has consequences for replacing the whole line and results in significant impact. The lifetime of an orchard is typically around 25 years and supports are required to last beyond. - Concrete alternative products on the market are heavier, less elastic, hardly resistant to abiotic conditions, especially not adapted to climatic storms. - Concrete production has greater impact on climate: consumption of fossil fuels and water consumption, causes greater emissions of greenhouse gases and smog. *Animal injuries more common with stiff concrete fences.*	UK, Industry or trade association Poland, Company-Manufacturer
2.	Steel, aluminium	Service life 40 years	Higher cost than creosoted wooden articles.	Available	- Metal agricultural poles incompatible with orchard designs, growers limit the number of supports used (i.e. extend the gap between poles) and when typically interconnected (by wires) a failure in one support has consequences for replacing the whole line and results in significant impact. The lifetime of an orchard is typically around 25 years and supports are required to last beyond. - Steel alternative products on the market are heavier, less elastic, hardly resistant to abiotic conditions, especially not adapted to climatic storms. - Steel or aluminium posts, stakes, poles are expensive, non-renewable, have a negative carbon dioxide impact at manufacture (high energy consumption process). - Steel or aluminium are made to order (not in stocks). *Animal injuries more common with metal fences*.	UK, Industry or trade association Poland, Company-Manufacturer Sweden, Company-Manufacturer
3.	Plastic Polyolefin material, Composite plastic i.e. glass fibre reinforced polyester with outer protective layer of UV stable polythene and	Expected service life over 80 years. Lengths from 2m.	Expensive, but maintenance free at long service life.	Available	- Pure polyolefin materials contain no hazardous substances - *this applies only if sleepers are made of pure materials instead of the recycled composite plastic materials*. - Reduced weight; easier transport and installation help to offset the difference in price. - Benefits of working with a clean inert pole/*post/stake*. - No rotting, vermin and woodpecker resistant.	Netherlands, Company-Manufacturer Sweden, company-manufacturer UK, Company-

	aluminium top cap				- Withstands freezing, cannot corrode. - Crash safe. - Less attractive to cattle for rubbing. - With severe environmental impact at manufacture. - For the composite pole/*post/stake*, the production of polyethylene, polyester contributes to inhalation and dermal exposure at manufacturing. This assessment does not include the wider economic impact of utilising recycled plastics in such applications, either from the perspective of future carbon taxation initiatives or through wider savings to European governments in supporting the meeting of extremely challenging legal targets for plastic waste recovery and recycling. Long-term Impact on the environment is not assessed.	Manufacturer
4	Copper salt based preserved wood poles	Shorter service life	Costs of exchange and intensified use of timber may raise prices of wooden poles. Replacement of pedestrian (beam, slab, arch, truss) bridges with timber deck (exposed to rain and moisture) for possibly any alternative is expensive.	Available	- Wooden poles used in agriculture and protected with other impregnation agents based on copper have a significantly shorter vitality and are exposed to copper-resistant fungi (e.g. *Pioria vaillantii*). - Shorter service life, due to the rapid washing out of the agent from wood. - Do not have a water repellent effect (as creosote does). - Insufficient evidence of copper salt preservatives on competitive use to creosote, sufficient service-life, better safety for people and the environment in comparison to creosote (but also salt agents like arsenic, zinc, fluorine, chromium and boron compounds were or are being withdrawn from the market). In 2017-2019 wooden bridges were found with crust fungus (*Rhodonia placenta*), rot fungus resistant to copper and other metals (Finland).	Poland, Company-Manufacturer Poland, Company-Downstream user Belgium, Industry or trade association Finland, National Authority
5.	Copper-oil Bio-oil		Cost of these alternatives will be uncertain until field testing is completed.	An industrial scale is not available today.	- Service life shorter due to the degradation that wooden poles/*posts/stakes/fences* suffer due to our climate and weather conditions. - Risks exist in these alternatives, particularly on surface condition of treated articles and leaching risk. As far as we have been informed, the industry is testing single and dual process techniques to reduce these risks.	Spain, Company-Downstream user Poland, Company-Manufacturer Poland,

					- Bio-oil under Horizon 2020 in development phase, copper-oil preservatives in field testing and under evaluation (ongoing assessment of risks on surface condition of treated articles and leaching). - Other copper-based biocide and oil products are being developed and assessed, but these have yet to be authorised under the Regulations - Creosoted wood has clearly defined disposal methods. such as combustion in authorized installations (energy recovery) and biological treatment (e.g. leaching bath in appropriate conditions with the participation of appropriate bacterial strains, resulting in a safe wood material and easily biodegradable emulsion). The disposal methods of hazardous waste from wood preserved by new agents under development are not known.	Company-Downstream user
6	Tanasote S40 (hot oil-based product)	Service life of 40 years (for 100-133 kg/m^3 impregnated wood)	For Tanasote cost per liter is more than creosote.	Once evaluated and product authorization granted, will be available on the market.	- Tanasote S40 is suitable for equestrian fencing as it does not induce cribbing.	UK, Company-Manufacturer
7.	Copper/co-biocide formulation followed by separate treatment with an oil			5 years needed to demonstrate feasibility or not	- Tests are also underway to assess the resistance to cribbing of equestrian fencing treated with copper/oil products, however copper/co-biocide treated wooden articles are not technically feasible for equestrian fencing owing to damage associated with cribbing. - Service life (beyond 15 years) of safety-critical animal and highway fencing treated with copper/co-biocide formulations has proven to be less predictable than when treated with creosote.	UK, Industry or trade association
8.	Non-impregnated wood (different types of wood)				*Not specified in public consultation entries.* *Bamboo agricultural stakes if from sustainable sources and the least energy consuming transportation (light weight).*	

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2.2.4. Condition for derogation set under Article 5(2) of the BPR

Creosote fulfils the criteria set in Article 5(1) of Regulation (EU) No 528/2012 and as such the overall conclusion is that creosote in product type 8 should not normally be approved, unless one of the conditions for derogation in Article 5(2) is met. The decision on Article 5(2) is not in the remit of the BPC and so it will not be part of the opinion. However, the UK (the former eCA) has carried out an evaluation according to Article 5(2)(c). The results of this evaluation can be found in Appendix IV to this document, but it should be noted that this contains the position of the UK only.

2.3. Overall conclusions

The outcome of the assessment for creosote in product-type 8 is specified in the BPC opinion following discussions at the 36th and 37th meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2.4. List of endpoints

The most important endpoints for the active substance, based on the original evaluation and the re-evaluation performed for the renewal of approval, are listed in Appendix I.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Name)	Creosote
Product-type	Wood preservative: fungicide, insecticide.

Identity

Chemical name (IUPAC)	Creosote
Chemical name (CA)	Creosote
CAS No	8001-58-9
EC No	232-287-5
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	Not applicable to a UVCB substance. Specification for creosote is based on the criteria in European Standard EN 13991:2003
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	The term impurities does not apply to an UVCB substance. European Standard EN 13991:2003 specifies maximum content for (Grade B and C): Water extractable phenols: max 3% Matter insoluble in toluene: max 0.4% Benzo[a]pyrene: max 50 ppm
Molecular formula	Not applicable to an UVCB substance
Molecular mass	Not applicable to an UVCB substance
Structural formula	Not applicable to an UVCB substance

Physical and chemical properties

Melting point (state purity)	Crystallization temperature: 0°C and 30°C (grade B and grade C respectively)
Boiling point (state purity)	Range: ≥ 210 °C – 400 °C (grade B) ≥ 260-400°C (grade C)
Thermal stability / Temperature of decomposition	> 400°C
Appearance (state purity)	Brown liquid with aromatic phenolic odour (purity not applicable)
Relative density (state purity)	1.08 – 1.10 (Grade B and Grade C)
Surface tension (state temperature and concentration of the test solution)	Not possible to determine for a complex mixture with a low solubility in water.

Vapour pressure (in Pa, state temperature)	Measurements in the range 164-255°C (Grade B) and 180-285°C (grade C). Extrapolated: 20 °C 0.4 Pa (Grade B) 0.3 Pa (Grade C) 25 °C 0.66 Pa (Grade B) 0.50 Pa (Grade C) 50 °C 4.88 Pa (Grade B) 3.41 (Grade C) 100 °C 120 Pa (Grade B) 72.6 Pa (Grade C)
Henry's law constant (Pa m^3 mol $^{-1}$)	Not possible to determine for the complex creosote mixture Range for single components (literature data for 18 PAHs): 0.007 (6 ring PAH) – about 150 (acenaphthylene) Pa$*$$m^3$/mol
Solubility in water (g/l or mg/l, state temperature)	For creosote expressed as TOC: At a loading of 100 mg creosote/l water: 2.25-8.11 mg/l (Grade B, Grade B-composite and Grade C) At a loading of 10 g creosote/l water: 191 mg/l (Grade B-composite) 30.3 mg/l (Grade B) 27.7 mg/l (Grade C) Range for single components (literature data for 18 PAHs): 0.26 µg/l (benzo[ghi]perylene) – 31.7 mg/l (naphthalene) Higher solubilities anticipated for the polar components (i.e. phenolics, N-, S- and O-heterocycles)
Solubility in organic solvents (in g/l or mg/l, state temperature)	Completely miscible in benzene or toluene, >99.5 % in acetone, soluble in quinoline
Stability in organic solvents used in biocidal products including relevant breakdown products	Not relevant as creosote is not used in any solvents
Partition coefficient (log P_{OW}) (state temperature)	Experimentally determined for US types creosote P1/13 and P2: 2.7 (o:w 8:1)-3.7 (o:w 1:1.25)

	o:w = octanol to water ratio *See Chapter 4 on adsorption/desorption.*
Dissociation constant	Not possible to determine for the complex creosote mixture Creosote is not anticipated to be significantly affected by pH, as the great majority of the components cannot dissociate.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No specific information due to complex mixture of aromatic compounds
Flammability or flash point	Flash point: >87 – >120 °C (Grade B and Grade C)
Explosives/ explosive properties	Not explosive
Flammable gases	Not applicable as creosote is not a gas
Flammable aerosols	Not applicable as creosote is not an aerosol
Oxidising gases	Not applicable as creosote is not a gas and is not oxidizing
Gases under pressure	Not applicable as creosote is not a gas
Flammable liquids	Creosote is a liquid with a flash point of > 80 °C, therefore it is not classified as flammable liquid
Flammable solids	Not applicable as creosote is not a solid
Self-reactive substances and mixtures	Not applicable, no chemical groups present in creosote are associated with self-reactive properties
Pyrophoric liquids	Not applicable, creosote does not fall under the definition of pyrophoric liquids
Pyrophoric solids	Not applicable, creosote is not a solid
Self-heating substances and mixtures	Not applicable
Substances and mixtures which in contact with water emit flammable gases	Not applicable
Oxidising liquids	Not applicable, due to technical origin and chemical structure creosote is not oxidising
Oxidising solids	Not applicable, creosote is not a solid
Organic peroxides	Not applicable, creosote does not fall under the definition of organic peroxides
Corrosive to metals	Not applicable, experience in use shows that creosote is not corrosive to metal
Auto-ignition temperature (liquids and gases)/ Auto-ignition or relative self-ignition temperature	≥450 °C (Grade B and C)
Relative self-ignition temperature for solids	Not applicable, creosote is not a solid
Dust explosion hazard	Not applicable

Classification and proposed labelling

with regard to physical hazards	None
with regard to human health hazards	H350: Carc. 1B H360F: Repr. 1B H361d: Repr. 2 H315: Skin irrit. 2 H317: Skin sens. 1 H319: Eye irrit. 2
with regard to environmental hazards	H400: Aquatic acute 1 H410: Aquatic chronic 1 M=10

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	GC-FID Able to quantify 106 components in the creosote under evaluation
Impurities in technical active substance (principle of method)	Not relevant as the term impurities does not apply to an UVCB-substance. The methods for the relevant components of creosote are given in European Standard EN 13991:2003

Analytical methods for residues

Soil (principle of method and LOQ)	Sediment 24 PAHs in sediment SEC for isolation and GC-MS for analysis. LOQ not stated. LOD: 1-4 ng/g dry sediment (i.e. µg/kg) for low-molecular weight PAH and 0.3-0.5 ng/g dry sediment (i.e. µg/kg) for high-molecular weight PAH. However, the reporting and the validation data are not sufficient. Soil No specific method has been submitted. Soxhlet extraction in combination with e.g. GC-FID analysis has been proposed. Validation data had been provided in support of the proposal during product family authorisation. Another study: GC-MS. 16 EPA PAH and 1-methylnaphthalene, 2-methylnaphthalene
Air (principle of method and LOQ)	11 PAHs in air GC-FID. LOQ: 19.1-25.8 µg/air sampling tube. Another study for slightly different PAHs indicated LOQs of 1.6-10.2 mg/m^3

Water (principle of method and LOQ)	16 PAHs in surface and drinking water: GC-FID or HPLC-UV/FD (US EPA method 610) LOQ not stated. LOD: Naphthalene, acenaphthylene, acenaphthene: 1.8-2.3 µg/l, Fluorene-pyrene, chrysene: 0.15-0.66 µg/l, remaining PAHs: 0.017-0.076 µg/l (LOD for benz(a)pyrene is above the EU-drinking water limit (98/83/EC)) 6 PAHs in drinking water HPLC-FD (DIN 38407-8), LOQ: 0.005 µg/l Components of creosote in water (deionized) GC-FID, able to quantify 68 components of creosote, LOD: 1 µg/l, LOQ: 3 µg/l
Body fluids and tissues (principle of method and LOQ)	Urine and faeces 1-OH-pyrene in urine HPLC-FD, LOQ: 8.73 µg/l Phenanthrene, pyrene and chrysene and corresponding OH-metabolites in urine and faeces GC-FID/MS, LOQ not stated, LOD: 0.1 ng injected Blood and tissues 10 PAHs in blood HPLC-FD, LOQ: 76 ng/l-10 µg/l. However, the reporting and the validation data are not sufficient 24 PAHs in tissues SEC for isolation and GC-MS for analysis. LOQ not stated, LOD: 5-50 ng/g dry tissue (i.e. µg/kg) for low-molecular weight PAH and 0.5-3.5 ng/g dry tissue (i.e. µg/kg) for high-molecular weight PAH. However, the reporting and the validation data are not sufficient.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Fruits GC-HRMS, 16 EPA PAH + 2 PAH
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required due to the use pattern of creosote

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Considered as not relevant (impossible to assess, since creosote consists of several 100 compounds)
Rate and extent of dermal absorption:	10 %

Rate and extent of inhalational absorption:	100 % used
Distribution:	Pyrene (as model PAH): highest levels in liver, kidney and fat (transient peaks)
Potential for accumulation:	No evidence, reactive metabolites of certain PAH may react with DNA
Rate and extent of excretion:	Depending on compound: pyrene elimination rate constant (rat): 0.17 – 0.35/d, 70 – 80 % (6 d)
Toxicologically significant metabolite(s)	Epoxides, quinones, phenols

Acute toxicity

Rat LD_{50} oral	>3500 mg/kg
Rat LD_{50} dermal	>2000 mg/kg
Rat LC_{50} inhalation	>5000 mg/m^3 (aerosol)

Skin corrosion/irritation	Irritating

Eye irritation	Not irritating

Skin sensitisation (test method used and result)	Positive (Maximization) Negative (Buehler) Overall, concluded to be a skin sensitiser

Respiratory sensitisation (test method used and result)	Not tested

Repeated dose toxicity

Short term

Species / target / critical effect	No data
Relevant oral NOAEL / LOAEL	
Relevant dermal NOAEL / LOAEL	
Relevant inhalation NOAEC / LOAEC	

Subchronic

Species/ target / critical effect	Rat / liver hypertrophy / inflammation in nasal cavity (inhalation)
Relevant oral NOAEL / LOAEL	No data
Relevant dermal NOAEL / LOAEL	400 mg/kg bw/d (90 d)
Relevant inhalation NOAEC / LOAEC	22/128 mg/m3 (90 d)

Long term

Species/ target / critical effect	No data
Relevant oral NOAEL / LOAEL	
Relevant dermal NOAEL / LOAEL	
Relevant inhalation NOAEC / LOAEC	

Genotoxicity	Result	Creosote-type
Bacterial reverse mutation test (Ames test)	Negative (+/- S9)	EU (type B) <50 ppm BaP
Bacterial reverse mutation test (Ames test)	Positive (+ S9) Negative (- S9)	EU (type B; SNCF), but >50 ppm BaP (160 mg/kg)
In vitro mammalian chromosome aberration test (human lymphocytes)	Negative (+/- S9)	EU (type B) <50 ppm BaP
In vitro mammalian cell gene mutation test (mouse lymphoma L5178Y)	Positive (weak, + S9)	EU (type B) <50 ppm BaP
In vivo micronucleus assay (mouse, bone marrow)	Negative	EU (type B) <50 ppm BaP
Dominant-Lethal Test (rat)	Negative	US ~5000 ppm BaP

Carcinogenicity

Species/type of tumour	Mouse (dermal): skin tumors (papilloma and squamous-cell carcinoma)
Relevant NOAEL/LOAEL	CTP1 (BaP content 10 ppm): 3 mg (2x/wk) CTP2 (BaP content 270 ppm): 0.1 mg (2x/wk)

Reproductive toxicity

Developmental toxicity

Species/ developmental target / critical effect	Rat, rabbit/ embryonal / post-implantation loss
Relevant maternal NOAEL	50 mg/kg bw/d
Relevant developmental NOAEL	50 mg/kg bw/d

Fertility

Species/critical effect	Rat / fertility / decreased litter size in the high dose group, decreased live offspring, and decreased body weight of live pups during lactation (*the PL CA agrees with the note by UK CA that in the SE CAR (2010)*, a clear differentiation was not made between effects on fertility and effects on development in this two-generation study).
Relevant parental NOAEL	25 mg/kg bw/d

Relevant offspring NOAEL	25 mg/kg bw/d
Relevant fertility NOAEL	25 mg/kg bw/d

Neurotoxicity

Species/ target/critical effect	No data

Developmental Neurotoxicity

Species/ target/critical effect	No data

Immunotoxicity

Species/ target/critical effect	No data

Developmental Immunotoxicity

Species/ target/critical effect	No data

Other toxicological studies

No data

Medical data

Fatal cases after ingestion of creosote involve the amount of about 7 g for adults and 1-2 g for children.

Overall, the body of epidemiological data does not indicate an apparent elevated cancer risk for creosote workers.

Summary

	Value	Study	Safety factor
$AEL_{long-term}$	Creosote is classified for H350 Carc. 1B; an AEL cannot be set for substances that are genotoxic and/or carcinogenic unless a threshold mechanism has been clearly demonstrated, for a non-threshold carcinogen a semi-quantitative hazard characterisation has to be followed.	N/A	N/A
$AEL_{medium-term}$	Creosote is classified for H350 Carc. 1B; an AEL cannot be set for substances that are genotoxic and/or carcinogenic unless a threshold mechanism has been clearly demonstrated, for a non-threshold carcinogen a semi-quantitative hazard characterisation has to be followed.	N/A	N/A
$AEL_{short-term}$	Creosote is classified for H350 Carc. 1B; an AEL cannot be set for substances that are genotoxic and/or carcinogenic unless a threshold mechanism has been clearly demonstrated, for a non-threshold carcinogen a semi-quantitative hazard	N/A	N/A

	characterisation has to be followed.		
ADI[4]	By definition, ADI gives a safety level of daily intake of a substance via ingestion. Therefore, the setting of an ADI for creosote would be considered irrelevant, since creosote is used as a wood preservative (PT8). Furthermore, creosote is classified as H350 Carc. 1B. An ADI cannot be set for substances that are genotoxic and/or carcinogenic unless a threshold mechanism clearly has been demonstrated, for a non-threshold carcinogen a semi-quantitative hazard characterisation has to be followed.	N/A	N/A
ARfD	The setting of an ARfD for creosote which is used as a wood preservative (PT8) is considered not to be relevant.	N/A	N/A

T25 and DMEL

Study (*in vitro/vivo*), species tested	*In vivo* male mice
Formulation (formulation type and including concentration(s) tested, vehicle)	In the dermal carcinogenicity study CTP-1 (low BaP creosote) was used in treatment groups (0.3; 1; 3; 9 mg) and CTP-2 (high BaP creosote) was used in treatment groups (0.1; 0.3, 1, 3, 9 mg), vehicle was toluene
T25	260 mg/kg bw/day
CorrT25$_{\text{internal}}$	105 mg/kg bw/day for 50% dermal absorption in mice
DMEL	4.2 µg/kg bw/day for 50% dermal absorption in mice

Dermal absorption

Study (*in vitro/vivo*), species tested	*In vivo* rat X *in vitro* human/*in vitro* rat
Formulation (formulation type and including concentration(s) tested, vehicle)	Creosote
Dermal absorption values used in risk assessment	10%

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

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[4] If residues in food or feed.

<table>
<tr><td>Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)</td><td>Not applicable for creosote (PAH compounds not expected to be hydrolytically degraded).</td></tr>
<tr><td>Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites</td><td>Not applicable for creosote.
Direct photochemical transformation (latitude 40°N, midday, midsummer) for different PAH compounds in creosote:
<table>
<tr><th>Compound</th><th>DT_{50} (h)</th><th>Quantum yield x 10^3</th></tr>
<tr><td>Naphthalene</td><td>71</td><td>15±1</td></tr>
<tr><td>1,methylnaphthalene</td><td>22</td><td>18±1</td></tr>
<tr><td>2-methylnaphthalene</td><td>54</td><td>5.3±0.2</td></tr>
<tr><td>Phenanthrene</td><td>8.4</td><td>10±1.6</td></tr>
<tr><td>Anthracene</td><td>0.75</td><td>3.0±0.2</td></tr>
<tr><td>9-Methylanthracene</td><td>0.13</td><td>7.5±0.5</td></tr>
<tr><td>9,10-Methylanthracene</td><td>0.35</td><td>4.0±0.4</td></tr>
<tr><td>Pyrene</td><td>0.68</td><td>2.0±0.3</td></tr>
<tr><td>Fluoranthene</td><td>21</td><td>0.12±0.001</td></tr>
<tr><td>Chrysene</td><td>4.4</td><td>2.8±0.7</td></tr>
</table>
One major transformation product of PAHs seems to be quinone derivatives.</td></tr>
<tr><td>Readily biodegradable (yes/no)</td><td>No</td></tr>
<tr><td>Biodegradation in freshwater</td><td>Not applicable for creosote.
Mineralisation half-lives (at 22 °C) and total percentage mineralised of 14C-labelled PAHs after 56 days. Values in brackets for 2-methylnaphthalene and phenanthrene show estimated half-lives as given in the study report:
<table>
<tr><th></th><th>DT_{50}, days</th><th>% mineralised</th></tr>
<tr><td>Naphthalene</td><td>30.8</td><td>54.5</td></tr>
<tr><td>2-Methyl-</td><td>>56 (140)</td><td>18.8</td></tr>
<tr><td>phenanthrene</td><td>>56(126)</td><td>22.3</td></tr>
<tr><td>Pyrene</td><td>nd</td><td><0.2</td></tr>
</table>
nd = no mineralisation detected.</td></tr>
<tr><td>Non-extractable residues</td><td>Not applicable for creosote.
Between approx. 2% for naphthalene / methylnaphthalene to 7.5% for phenanthrene (56 days).</td></tr>
</table>

Distribution in water / sediment systems (active substance)	Not applicable for creosote. For naphthalene, methylnaphthalene, phenanthrene and pyrene: Between 3.1 and 8.4% was found in the water phase and between 8.2 and 75% was found in the sediment phase. (Measured as recovered 14C in the water and sediment phases, respectively, after 56 d)
Distribution in water / sediment systems (metabolites)	No data (polar metabolites of PAHs accounted for 0.1 to 6% of the original PAHs).

Route and rate of degradation in soil

Mineralization (aerobic)	No data
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Not applicable for creosote. For PAHs the following half-lives were determined (highest value of two soils) at 20 °C:

	DT_{50} (d)
Naphthalene	2.2
1-Methylnaphthalene	2.2
Phenanthrene	35
Anthracene	134
Fluoranthene	377
Pyrene	260
Benz[a]anthracene	261
Chrysene	387

	The kinetic calculations resulting in first order rate constants and half-lives gave r2 values ranging from 0.71-0.95 and 0.57-0.93 for the two soils, respectively
Field studies (state location, range or median with number of measurements)	No data
Anaerobic degradation	No degradation could be measured in anaerobic soil
Soil photolysis	No data
Non-extractable residues	No data
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	No data

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Data on log Kow and log Koc values for 42 single components present in creosote have been compiled and presented in the report. The log Kow and log Koc values for single components were weighted by their content in creosote (in percent), in order to estimate the corresponding partition coefficients for the different creosote oils, respectively.

Creosote Oil	Log K_{ow}	Log K_{oc}	Proportion of creosote used in the estimate [a]
Composite Grade B	4.12	3.67	61%
Grade B	4.43	3.97	58%
Grade C	4.63	4.17	53%

[a] The total sum of all analysed/identified compounds in the oils were approx. 65, 63 and 57% for 'composite Grade B', Grade B and Grade C, respectively (see Document III-A1-2).

No pH dependence of partition coefficients.

Creosote renewal (2018): further non-standard study data were submitted, investigating adsorption behaviour of PAHs in artificial soils (report A2.10.2/19b). Moraine soil from beneath SE railway sleepers was enriched with various concentrations of peat (as controlled increase of OM content) and Kd values for various PAHs were determined using the Equilibrium Recirculation column test.

It was concluded that at 2% peat content, Kd values for relevant PAHs were considered to be comparable to those derived by QSAR in the original SE CAR.

Fate and behaviour in air

Direct photolysis in air	No data
Quantum yield of direct photolysis	No data

Photo-oxidative degradation in air

Not applicable for creosote.

Half-lives of selected PAHs due to gas-phase reactions with hydroxyl (OH) radicals and nitrate (NO3) radicals for hypothetical summertime conditions in clean air:

	DT_{50} (OH)	DT_{50} (NO_3)
Naphthalene	4.0 h	10 years
1-Methylnaphthalene	2.4 h	5 years
2-Methylnaphthalene	1.9 h	3 years
1-Ethylnaphthalene	2.8 h	3 years
2-Ethylnaphthalene	2.4 h	5 years
Dimethylnaphthalen	1.2-1.7 h	0.1-3
Acenaphthylene	0.76 h	4.2 min
Acenaphthene	1.2 h	0.97 h
Fluorene	6.9 h	20 h
Phenanthrene	5.3 h	3.0 h

Volatilization

A laboratory study simulated emissions to air during storage of creosote treated timber. For this purpose, a climate–controlled enclosure was constructed into which test pieces of wood were placed. The air in the enclosure was circulated. There was constant supply of clean air and equal amount of air was extracted from the enclosure. The emissions were measured for their content of 21 PAHs by sampling the extracted air. The results showed that the loss rate of creosote (estimated from ΣPAH conc.) to air was approximately 8-74 mg/m² wood and day.

Reference value for groundwater

According to BPR Annex VI, point 68

“Polycyclic aromatic hydrocarbons” (PAHs) is a group name for several substances present in petroleum-based products such as coal tar. The drinking water standard of 0.1 µg/l applies for the sum of all these substances found within creosote (see Benzo(a)pyrene listed above for more information).

Monitoring data, if available

Soil (indicate location and type of study)	No data for creosote

PAH concentrations in soil at various depths and distances from creosote treated utility poles in service were determined in the USA (EPI, 1997; III-A2.10.2/12). The age of the poles ranged from less than 5 years to 40 years although most of the poles of the study were less than 20 years old. Twenty-two pole sites were investigated and from each site 40-44 samples were analysed for their content of 18 PAHs. Median ΣPAH concentrations of all maximum values at each distance (independent of depth) from each pole site:

Distance from the pole	Median creosote[1] concentration (mg/kg wet weight)
7.6 cm	3320
20.3 cm	973
45.7 cm	7.1
76.2 cm	4.0
122 cm	0.25 [2]

[1] Assuming that the proportion of the PAHs analysed was 40% of the creosote content.

[2] Background levels of ΣPAHs.

Creosote renewal (2018) : further monitoring data has been supplied in relation to PAH levels in soil around UK and SE fence posts (report A2.10.2/17) as well as SE utility poles (report A2.10.2/14). Similar to the USA report, EU data indicates that soil close to treated poles and posts contains significant concentrations of "priority" PAHs but levels in both horizontal and vertical directions drop quickly (i.e. < 1 m distance from wooden structure) to background levels.

In addition, monitoring data on PAH levels in ballast and subsoil below FR railway sleepers at over 100 locations (report A2.10.2/18) has also been submitted. It was concluded that levels of PAHs at most locations were equivalent to general background levels for FR soil and that similar levels of PAHs were found under creosote treated wooden sleepers and concrete sleepers.

Surface water (indicate location and type of study)	No data for creosote. In Sooke Basin, British Colombia, Canada, sea water concentrations of PAHs were measured with SPMD (semi-permeable membrane device) adjacent to underwater constructions (piling sites = dolphins) made of creosote treated wood (Goyette and Brooks, 1998 and 2002; III-A2.10.2/10). The highest water concentration of creosote (estimated from ΣPAH conc.) was 0.08 µg/l approx. 6 months after construction.
Sediment (indicate location and type of study)	In Sooke Basin, British Colombia, Canada, surface sediment concentrations of 16 PAHs were measured adjacent to underwater constructions (piling sites = dolphins) made of creosote treated wood (Goyette and Brooks, 1998 and 2002; III-A2.10.2/10). The following concentrations of creosote (estimated from Σ16PAH concentrations) were found (mg/kg wet weight):

Day from installation	Day 14	Day 384	Day 14	Day 384
Distance from site	*0.5 m*	*0.5 m*	*1.5 m*	*7.5 m*
Site-BMP*	12	31	1.5	6.3
Distance from site	*0.5 m*	*0.5 m*	*2 m*	*5 m*
Site-WP#	142	17	4.1	3.2

* Newly treated pilings

\# Weathered pilings

Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Test substance	Time-scale	Endpoint	Toxicity
Fish				
O. latipes (fresh water) *Pagrus major* (seawater)	creosote	96 h semi-static	LC_{50}	0.7 mg/l (measured conc. of 19 PAHs)

Brachydanio rerio	PAH-mixture	42 d	$\text{NOEC}_{\text{growth}}$	0.0021 mg Σ6PAHs/l (m)
Clupea pallasi	creosote from treated wood	9 d	$\text{NOEC}_{\text{hatching success}}$	0.001 mg creosote (Σ Aromatic compounds)/l
B. rerio	phenanthrene / fluoranthene	28/41 d	$\text{NOEC}_{\text{reproduction}}$	0.011/0.0044 mg/l (estimated/m)
P. promelas	anthracene	77 d	$\text{NOEC}_{\text{reproduction}}$	0.006 mg/l (m)
Invertebrates				
Daphnia magna	creosote	48 h	EC_{50}	1.14 mg/l (n)
Mysidopsis bahia	creosote	96 h	LC_{50}	0.018 mg/l (n)
Daphnia magna	anthracene, fluorene, phenanthrene	21 d	$\text{NOEC}_{\text{reproduction}}$	0.002, 0.015, and 0.018 mg/l
zooplankton community	creosote from treated wood	83 d	$\text{NOEC}_{\text{abundance}}$	0.011 mg creosote (Σ15PAHs)/l
Algae				
(*Desmodesmus subspicatus*)	creosote	72 h	E_rC_{50} NOEC	2.1 mg/l (measured TOC) 0.9 mg/l (measured TOC)
Sediment dwelling organisms				
Benthic community	creosote from treated wood pilings	1-4 years	NOEC abundance/ diversity	creosote (Σ15PAHs): 10 mg/kg dw = 22 mg/kg ww phenanthrene: 2 mg/kg dw = 4.4 mg/kg ww fluoranthene: 3 mg/kg dw = 6.5 mg/kg ww (in ww after conversion to TGD standard susp. matter)
Microorganisms				
Activated sludge	creosote	3 h	EC_{50} resp. inhibition	13 mg/l (TOC/creosote, estimated conc.)

Effects on earthworms or other soil non-target organisms

	Test substance	Endpoint/toxicity (mg/kg)
Acute toxicity to:	PAH- or creosote-contaminated soil	LC_{50} (14d): 286-1354 (ΣPAH) (ww)

earthworms (*E. fetida*)	1-/2-methylnaphtha-lene isomer mixture	LC_{50} (14d): 42 (ww)
springtails (*F.candida*)		
		LC_{50} (14d): 51.2/56.6 (ww)
earthworms (*E. fetida*)	fluorene/phenol	LC_{50} (14d): > 301 (ww)
	chrysene	(after conversion to standard TGD soil)
Long-term toxicity to: springtails (*F. candida*)	creosote Grade B	NOEC$_{\text{mortality}}$ (28d): 10 (dw) = 3 (ww)
	1-/2-methylnaphthalene isomer mixture	NOEC$_{\text{reproduction}}$ (28d): 56 (dw) = 16.8 (ww)
	phenanthrene	NOEC$_{\text{reproduction}}$ (28d): <75 (dw) = 22.6 (ww)
potworm (*E. crypticus*)	naphthalene, fluorene, fluoranthene, pyrene, carbazole, dibenzofuran	NOEC$_{\text{reproduction}}$ (28d): 11- 36 (dw) = 12- 40 (ww)
	anthracene	NOEC$_{\text{reproduction}}$ (28d): >897 (dw) = >690 (ww) (in ww after conversion to standard TGD soil)

dw = dry weight, ww = wet weight

Effects on soil micro-organisms

Nitrogen mineralization	creosote Grade B	NOEC (14 d): 316 (dw) = 373 (ww)
	1-/2-metylnaphthalene	NOEC (28 d): 1000 (dw) = 1180 (ww) NOEC (28 d): 100 (dw) = 80 (ww) (in ww after conversion to standard TGD soil)
Carbon mineralization	creosote Grade B	NOEC (28d): 1000 dw = 1180 ww (in ww after conversion to standard TGD soil)

dw = dry weight, ww = wet weight

Effects on terrestrial vertebrates

Acute toxicity to mammals	> 3500 mg creosote/kg (rat)
Acute toxicity to birds	No data
Dietary toxicity to birds	No data
Reproductive toxicity to birds	No data

Effects on honeybees

Acute oral toxicity	Not applicable
Acute contact toxicity	Not applicable

Effects on other beneficial arthropods

Acute oral toxicity	Not applicable
Acute contact toxicity	Not applicable

Bioconcentration

	Creosote substance	BCF
Bioconcentration factor (BCF)	naphthalene 1-methyl-naphthalene 2-methyl-naphthalene phenanthrene anthracene fluoranthene fluorene pyrene	~70 – 1000 ~100 ~140 – 4300 ~1600 ~750 – 5000 ~380 ~540 ~50 – 70
For estimated BCFs based on log Kow, see Doc II-A Table **Table 4.1.3.1-2**		
Depuration time (DT_{50})	naphthalenes anthracene fluoranthene	2 days (in oyster) 3 days (in oyster) 5 days (in oyster)
Depuration time (DT_{90})	Most PAHs in creosote	2-5 days (in fish)
Level of metabolites (%) in organisms accounting for > 10 % of residues	No data	

Summary

	Value	Study	Safety factor
$PNEC_{surface\ water}$	0.1 µg/l	Chronic toxicity to fish Chronic toxicity to invertebrates Growth inhibition in algae	10
$PNEC_{marine\ water}$	0.02 µg/l		50
$PNEC_{sediment}$	2 mg/kg ww		10
$PNEC_{STP}$	0.13 mg/l		100
$PNEC_{soil}$	0.30 mg/kg ww		10

Summary table for proposed PNECS for creosote and some individual PAHs (from SE Doc IIA)

	PNEC$_{surface\ water}$ (µg/l)	**PNEC$_{marine}$ (µg/l)**	**PNEC $_{STP}$ (mg/l)**	**PNEC$_{sediment}$ (mg/kg ww)**	**PNEC$_{soil}$ (mg/kg/ww)**
Creosote	0.1	0.02	0.13	2/0.4*	0.30
1-/2-methylnaphthalene	-	-	-	-	0.34
Fluorene	0.3	0.03	-	-	0.55
Phenanthrene	0.22	0.022	-	0.4/0.08*	0.45
Anthracene	0.042	0.0042	-	-	0.30
Fluoranthene	0.044	0.0044	-	0.6/0.12*	0.33
Pyrene	-	-	-	-	0.24

* The PNEC values are presented as normalised/non-normalised (to standard organic carbon content of the sediment).

Chapter 6: Other End Points

Appendix II: List of studies submitted for the renewal of approval process

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.
Used in SE CAR used in SE PAR (07/2016) and PL PAR (12/2016)

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
A2.10.1/08 (IIB, 8.3.2.2.4)	DHV	2013b	Data information: Impregnation process [DHV 2013b_VDI_Impreg process_20130227_rev20130920(en_de).pdf]	Personal communication and VDI 2012	--	7.10.5	Schaeferhenrich 2012_Creosote exposure_steeping impregnation	Data incorporated in the endpoint and in the attached background material: 01_DOCIIIA2.10.1-08_DHV_human exp_rev 20140317+KEMI COM.pdf
A2.10./08	Hebisch, R.; Holthenrich, D.; Karmann, J.; et al.	2009	Arbeitsplatzbelastungen bei der Verwendung von bioziden Produkten - Teil 4: Holzschutzmittel (German)	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) Dortmund	Projekt F 1809			01_DOCIIIA2.10.1-08_DHV_human exp_rev 20140317+KEMI COM.pdf DHV_Re-calculation of biomonitoring data_HH20140530.pdf
A2.10.1/08	Riechert, F.; Berger, M.; Kersten, N.	2011	Biomonitoring bei der Holzimprägnierung mit Steinkohlenteerölen - 1-Hydroxy-pyren im Urin als Marker für die innere Belastung mit polyzyklischen aromatischen Kohlenwasserstoffen	Zbl. Arbeitsmed., 61, 4 - 11	--			
A2.10.1/08	Schäferhenrich. A.; Hebisch, R.; Holthenrich, D.; et al.	2012	Messung von Hautbelastungen durch chemische Stoffe bei der Imprägnierung mit Holzschutzmitteln	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) Dortmund	Projekt F 2053			
A2.10.1/08	VDI	2012	Anforderungen an Hölzer nach ihrer Behandlung im Heiss-Kalt-Einstelltränkverfahren. (Draft), included in DHV 2013b	Verein Deutscher Ingenieure (VDI)	VDI-Richtlinie 3462			01_DOCIIIA2.10.1-08_DHV_human exp_rev 20140317+KEMI COM.pdf
A2.10.1/09	WPA	2013	Creosote: Brush Application, April 2013	Personal communication	--			Data incorporated in the endpoint and in the

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
A2.10.1/09	[redacted]	1994	Developing a method for measuring relative air emissions from creosoted timber (Engl. translation)	Stichting Hout Research (SHR)	Report 93.023., 22 Nov. 1994	7.10.5	WPA 2013_Exposure during cut-end treatment	attached background material: 02_DOCIIIA2.10.1-09_UK_brush 2013_human exp_rev 20140313.pdf
A2.10.1/10	Habert C, Guinot C, Fernandez G, Garnier R	2002	Evaluation de l’exposition aux hydrocarbures aromatiques polycycliques lors de l’usinage de traverses créosotées / 4ème trimestre 2002.	SNCF – Informations médicales	No 208	7.10.5	Habert 2002_Creosote exposure_crosstie mounting	Data incorporated in the endpoint and in the attached background material: 03_DOCIIIA2.10.1-10_SNCF_hum exp_rev20140317+20150109.pdf SNCF_Re-calculation of biomonitoring data_HH20140530.pdf
A2.10.1/10	[redacted]	2014	Additional Information about Biomonitoring in Workers Processing Creosoted Wood.	E-Mail communication with SNCF of 14 Feb. 2014	--	7.10.5		
A2.10.2/14	[redacted]	2012	Status Report on Soil Contamination in the Proximity of Creosote-Treated In-Service Utility Poles in Sweden., AB / 21 March 2012	Pöyry Swedpower	Project No. 3219500	5.5.2	[redacted] 2012_Field study_utility poles	Data incorporated in the endpoint and in the attached background material: 04_DOCIIIA2.10.2-14_Pole leaching study_SE.pdf
See IUC6, 5.5.2	CCE	2013	Creosote (PT8): Addendum DOCUMENT II B	Creosote Council Europe				SE pole study 2012_profile around poles_Addendum DOCIIB 2013.pdf ; SE pole study 2012_Addendum to Chap 4_Analyt meth_July 2014.pdf
A2.10.2/16 (IIB, 8.3.2.2.4)	DHV	2013a	Kreosot für die Verwendung im Agrar(Industrie-)bereich – Daten und Informationen / 13. Jan. 2013 Translation: Creosote for agricultural(industrial) applications – data and information / 13. Jan. 2013	Deutscher Holzschutzverband (DHV), Bingen/ Germany	--	5.5.2	+CCE 2013_Field studies_Vineyard model	Data incorporated in the endpoint and in the attached background material: DOC-IIB_ Addendum human and environ

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
A2.10.2/16 (IIB, 8.3.2.2.4)	DIN	1978	Imprägnierte Holzpfähle (included in DHV 2013a)	Deutsche Normen	68 810			xposure_rev.2015-05-11.pdf DOCIIIA2.10.2-16_DHV_agriculture_env exp_rev2_with KEMI comment
A2.10.2/17	Hudson N J, Murphy R J	1997	Losses of CCA Components and **Creosote** from treated timber to soil /1997	The International Research Group on Wood Preservation (IRG)	IRG/WP 97-50098	5.5.2	+Hudson et al 1997/Bergqvist et al 1994_Field study_creosoted posts	Data incorporated in the endpoint and in the attached background material: 06_DOCIIIA2.10.2-17_Fencing Appl_Environ_rev 20150313
A2.10.2/17	Bergqvist G and Holmroos S	1994	Analysis of creosoted posts after 40 years of exposure / 1994	The International Research Group on Wood Preservation (IRG),	IRG/WP 94-50035			
A2.10.2/18	Marechal B, Favre MC	2013	Impact des traverses créosotées sur les ballasts et les sols au droit des voies ferrées / 28 Feb. 2013	BG Ingénieurs Conseils SAS	FF0700.22-RN008	5.5.1	+Marechal, Favre 2013_Monitoring data_railway sleepers	Data incorporated in the endpoint and in the attached background material: 07_DOCIIIA2.10.2-18_SNCF environ exposure_rev
A.2.10.2/19a	Andersson-Sköld Y, Toomväli C, Larsson L, Nilsson P, Hemström K, Enell A	2008a	Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Ytutlakning av PAH från kreosotimpregnerade sliprar., Varia 587, Swedish Geotechnical Institute (SGI), Dnr Banverket S 05-3053/AL50, 05 May 2008 Translation: Creosoted sleepers and their role in migration of creosote to the ground – Leaching of PAH from the surface of creosoted sleepers. Varia 587, 2008	Statens Geotekniska Institute	Dnr Banverket S 05-3053/AL50	3.9.1	+Andersson-etal 2008a_Emissions from railway sleepers_lab test	Data incorporated in the endpoint and in the attached background material: 09_DOCIIIA2.10.2-19b_sleepers_adsorption from leachate_rev
A.2.10.2/19a	Andersson-Sköld Y, Toomväli C, Larsson L, Nilsson P, Hemström K, Enell A	2008b	Bilagor till: Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Ytutlakning av PAH från kreosotimpregnerade sliprar, Swedish Geotechnical Institute (SGI), Dnr Banverket S 05-3053/AL50, 05 May 2008 **Annex:** Methods and Results Tables	Statens Geotekniska Institute, Varia 587	Dnr Banverket S 05-3053/AL50			

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
A.2.10.2/19b	Enell A, Hemström K, Nilsson P, Andersson-Sköld Y	2008a	Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Fastläggnings- och desorptionstest av PAH. Swedish Geotechnical Institute (SGI), 2008, Dnr Banverket S 05-3053/AL50 Translation: Creosoted sleepers and their role in migration of creosote to the ground - Sorption and desorption tests of PAH. Varia 588, 2008	Statens Geotekniska Institute, Varia 588	Dnr Banverket S 05-3053/AL50	5.1.4	+Enell et al. 2008_Sorption and desorption of creosote components	Data incorporated in the endpoint and in the attached background material: 09_DOCIIIA2.10.2-19b_sleepers_adsorption from leachate_rev
A.2.10.2/19b	Enell A, Hemström K, Nilsson P, Andersson-Sköld Y	2008b	Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Fastläggnings- och desorptionstest av PAH Annex: Methods and Results Tables	Statens Geotekniska Institute, Varia 588	Dnr Banverket S 05-3053/AL50			
A7.2.2.1	Volkering F, Breure AM	2003	Biodegradation and general aspects of bioavailability, in: PAHs – An Ecotoxicological Perspective (ed. Douben PET),	Ecological & Environmental Toxicology Series, pp. 81-96, John Wiley & Sons Ltd., Chichester/UK	--	EPS 5.2.	Biodegradation	Data incorporated in the endpoint. No further background data attached (cited only).
A7.4.1.2/06 (IIA, 4.2.1.2)	Aniol S, Blum Th, Honnen W	2009a	Daphnia sp., Acute Immobilisation Test according to OECD 202 of Wash Oil, 18 March 2009	Steinbeis-Transferzentrum, Reutlingen/Germany	STZ 08-07-004	6.1.3	READACROSS_Aniol et al 2009_WO_daphnia,48 h,static-closed	Data incorporated in the endpoint. No further background data attached Submitted by CCE via R4BP file name: STZ 2007_GLP-Certificate.pdf
A7.4.1.2/07 (IIA, 4.2.1.2)	Aniol S, Blum Th, Honnen W	2009b	Daphnia sp., Acute Immobilisation Test according to OECD 202 of Anthracene Oil (BaP > 50 ppm), 25 March 2009	Steinbeis-Transferzentrum, Reutlingen/Germany	STZ 09-07-004	6.1.3	READACROSS_Aniol et al 2009_AO 06_daphnia,48 h,static-closed	Data incorporated in the endpoint. No further background data attached Submitted by CCE via R4BP file name: STZ 2007_GLP-Certificate.pdf

Lists of studies: Additions 2015/2016

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
DOC III A7.2.2.1			Environmental risk assessment – The route of degradation and identification of several metabolites	http://eawag-bbd.ethz.ch/	--	5	Environmental fate and pathways	Data incorporated in the additional information. No documents attached due to size of files. Link to database included
IUC6, EPS 5.5.2	CCE	2015	DOC-IIB_Addendum human and environ exposure_rev.2015-05-11	Environmental data: Utility poles in service -	See under “Title / Date”	5.5.2 EPS	Environmental data: Utility poles, posts and fences in service - evaluation	Included as attached document in 5.5.2 “CCE 2013_Field studies_Vineyard model”)
	CCE	2013	DOC-IIC_ Addendum human and environ RA_rev20131016	evaluation includes evaluation of fence-post/ fence model				Not included
IUC6, 5.5.2	CCE	2015	Use of wooden post/stakes in agriculture: vineyards, in: DOC-IIB_Addendum human and environ exposure_rev.2015-05-11	CCE 2013_Field studies_Vineyard model	DOC-IIB_add_ Chapter 8.3.2.2.4-4 / 2013-04-26	5.5.2	+CCE 2013_Field studies_Vineyard model	Data incorporated in the endpoint and in the attached background material: DOC-IIB_Addendum human and environ exposure_rev.2015-05-11.pdf
		2013	Environmental exposure data (field, vineyard) [in: DOCIIIA2.10.2-16_DHV_ agriculture_env exp_rev2]	CCE 2013_Field studies_Vineyard model	DOC-IIIA2.10.2/ 16			DOCIIIA2.10.2-16_DHV_agriculture_env exp_rev2_with KEMI comment
IUC6, 5.5.2	DHV	2013a	Kreosot für die Verwendung im Agra(Industrie-)bereich – Daten und Informationen; Translation: Creosote for agricultural(industrial) applications – data and information	Deutscher Holzschutzverband (DHV), Bingen/ Germany /	2013-01-20-			DOCIIIA2.10.2-16_DHV_ agriculture_env exp_rev2.pdf

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
IUC6, 5.5.2	CCE	2015	The use of hop poles, UC 4a	CCE 2015_Field studies_ use of hop poles_model	2015-05-11	5.5.2	CCE 2015_Field studies_ use of hop poles_model	Data incorporated in the endpoint and in the attached background material: CCE 2015_Hop pole_scenario_USES.pdf
	CCE	2013	Environmental exposure data (field, vineyard) [in: DOCIIIA2.10.2-16_DHV_agriculture_env exp_rev2.pdf]	CCE 2015_Field studies_ use of hop poles_model	DOC-IIIA2.10.2/16			DOCIIIA2.10.2-16_DHV_ agriculture_env exp_rev2.pdf
IUC6, 5.5.2		2016	Use Scenario – Timber Foundation Block for Steel-Utility Poles – UC 4a (CCE 2015, modified)	CCE 2016_Field studies_Timber foundation model(1)_SE	Revision date: 2016-10-22	5.5.2	+CCE 2016_Field studies_Timber foundation model(1)_SE	Data incorporated in the endpoint and in the attached background material: CCE 2015_Timber_Foundation UC4a_rev 20161022.pdf
		2016	Excerpt from DOC-IIB: (KEMI 2010) PEC – exposure to groundwater from in-service use	CCE 2016_Field studies_Timber foundation model(1)_SE	Revision date: 2016-10-22	5.5.2	+CCE 2016_Field studies_Timber foundation model(1)_SE	KEMI 2010_Groundwater_UC3+ UC4a.pdf
IUC6, 5.5.2		2016	Use Scenario – Timber Foundation Block for Wooden-Utility Poles – UC 4a	CCE 2016_Field studies_Timber foundation model(2)_UK	2016-10-06	5.5.2	+CCE 2016_Field studies_Timber foundation model(2)_UK	Data incorporated in the endpoint and in the attached background material: CCE 2016_Timber Foundation_wood pole_UC4a.pdf
		2015	Technical Report: Wood Pole Foundations (Creosote Registration under Biocidal Products Regulations)	Wood Protection Association (WPA)	2015-07-13			Borrie 2015_Pole foundations Report Vers 1-3_WPA.pdf
		2016	Excerpt from DOC-IIB: (KEMI 2010) PEC – exposure to groundwater from in-service use	CCE 2016_Field studies_Timber foundation model(2)_UK	Revision date: 2016-10-22			KEMI 2010_Groundwater_UC3+ UC4a.pdf

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
IUC6, 5.5.2		2016	Use Scenario – Noise Barrier – UC 3	CCE 2016_Field studies_noise barrier_model	2016-10-24	5.5.2	+CCE 2016_Field studies_noise barrier_model	Data incorporated in the endpoint and in the attached background material: CCE 2016_Use Scenario – Noise Barrier – UC 3.pdf
		2016	Excerpt from DOC-IIB: (KEMI 2010) PEC – exposure to groundwater from in-service use	CCE 2016_Field studies_Timber foundation model(1)_SE	Revision date: 2016-10-22			KEMI 2010_Groundwater_UC3+UC4a.pdf
IUC6, 5.5.2		2016	USE scenario - Landscape retaining wall from timber – UC 4a	CCE 2016_Field studies_landscape wall_model	2016-10-25	5.5.2	+CCE 2016_Field studies_landscape wall_model	Data incorporated in the endpoint and in the attached background material: CCE 2016_Landscape retaining wall from timber.pdf
		2016	Excerpt from DOC-IIB: (KEMI 2010) PEC – exposure to groundwater from in-service use	CCE 2016_Field studies_landscape wall_model	Revision date: 2016-10-22			KEMI 2010_Groundwater_UC3+UC4a.pdf
IUC6, 6.1.1	[redacted]	2009a	Fish, acute toxicity test according to OECD 203 of Wash Oil. Report No. STZ 08-07-003, 17 March 2009	[redacted]	STZ 08-07-003	6.6.1	STZ2009_WO_fish ,freshwater,key	Data incorporated in the endpoint, no AD
IUC6, 10, EPS	[redacted]	2015	Creosote - Efficacy and intended retentions, Rev. 3	Wood Protection Association (WPA), UK	2015-03-10	10	Effectiveness against target organisms_oil retention	Data incorporated in the end point summary. Full study in the attachments tab of EPS 2
DOC III B5.10 / **IUC6, 10.2**		2000	Marine performance of preservative treated southern pine panels, Part 1: Exposure in Newport, Oregon	31st Annual Meeting, Kona, Hawaii, 14th – 19th May 2000	IRG/WP 00-10368; 2000-05-14	10.2	Rhatigan/Zahora 2000_Field studies marine (6 years)	Data incorporated in the endpoint and in the attached background material: DOC-IIIB5_Rhatigan-Zahora 2000_Field tests UC5_HH 20150320.pdf
	[redacted]	2000	Marine performance of preservative treated southern pine panels, Part 2: Exposure at Mourilyan Harbour, Queensland, Australia	31st Annual Meeting, Kona, Hawaii, 14th – 19th May 2000	IRG/WP 00-10337; 2000-05-14		Rhatigan/Zahora 2000_Field studies marine (6 years)	

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
DOC III B5.10 / **IUC6, 10**		1975	Results of stake tests on wood preservatives (Progress report to 1974)	British Research Establishment (BRE), archived under IRG/WP 361	BRE CP 86/75; 1975-10-01	10.2	Purslow 1975_Longterm field studies	Data incorporated in the endpoint and in the attached background material: DOC-IIIB5_Purslow 1975_Field tests UC4_HH 20150317(val).pdf
DOC III A5.3.2 / **IUC6, 10 EPS**		1997	Sosnowe, dębowe i bukowe materiały drzewne nawierzchni kolejowej nasycane olejem impregnacyjnym / Title (Engl.): *Oil Impregnated Pine-wood, Oak-wood And Beech-wood Sleepers, Switch And Bridge Sleepers For Railways.*	PKN Polski Komitet Normalizacyjny / Poland	PN-D-95014	10 (EPS)	Effectiveness against target organisms_oil retention	Data incorporated in the end point summary. Full report in the attachments tab of EPS 2
DOC III A5.3.2 / **IUC6, 10 EPS**		1974	Materiały z okrągłego drewna sosnowego nasycone olejem impregnacyjnym metodą oszczędnościową */* Title (Engl.): *Materials made of round pine wood treated with impregnating oil by applying the empty –cell Rueping method*	Norma branżowa / Industry Standard Poland 1974	BN-74/9221-07	10 (EPS)	Effectiveness against target organisms_oil retention	Data incorporated in the end point summary. Full report in the attachments tab of EPS 2
DOC III A5.3.2 / **IUC6, 10 EPS**		2011 / 2014	Preservation of wood – Code of practice 2011 and A1.2014	The British Standards Institution	BS 8417, 2011	10 (EPS)	Effectiveness against target organisms_oil retention	Data incorporated in the end point summary. Full report in the attachments tab of EPS 2
DOC III A5.3.2 / **IUC6, 10 EPS**		2007	Imprägnierung von Eisenbahnschwellen aus Holz mit Kreosot (Steinkohlenteeröl) / Title (Engl.): *Impregnation of wood railway sleepers with creosotes (coal tar based oil)*	DIN Deutsches Institut für Normung e.V., Berlin	DIN 68811: 2007-01	10 (EPS)	Effectiveness against target organisms_oil retention	Data incorporated in the end point summary. Full report in the attachments tab of EPS 2
DOC III A5.3.2 / **IUC6, 10 EPS**		2011	Nordic wood preservation classes and product requirements for preservative-treated wood, Part 1: Pine and other permeable softwoods, NWPC Document No. 1	Nordic Wood Preservation Council (NPWC)	2011-01-01	10 (EPS)	Effectiveness against target organisms_oil retention	Data incorporated in the end point summary. Full report in the attachments tab of EPS 2
DOC III A5.3.2 / **IUC6, 10 EPS**		2015	Förteckning över godkända träskyddsmedel (Inventory of approved wood preservatives)	Nordic Wood Preservation Council (NPWC)	2015-01-19	10 (EPS)	Effectiveness against target organisms_oil retention	Data incorporated in the end point summary. Full report in the attachments tab. 2015_SPGodk…(of EPS 2)

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
IUC6, 9.3		2016	Screening of PAH residues on fruit grown in orchards constructed with creosote-treated stakes *New version of the report titled: Risk assessment on fruit grown in orchards constructed with creosote-treated stakes (CCE) version 8, 20/11/2018 (40 pages) [unpublished] – see under Addition 2020*	Creosote Council Europe	Final report 2016-06-02	9.3	CCE_Migration of residues into and their behaviour on food or feedingstuffs	Data incorporated in the endpoint and in the attached background material: CCE 2016_Creosote_key components in fruit.pdf

Lists of studies: Addition 2020

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
IUC REACH 9.3	[redacted]	2020	Magnitude of the Residue Determination of Polycyclic Aromatic Hydrocarbons (PAH) Following the use of Creosote Treated Wooden Stakes on Fruit Trees in Belgium, Poland and the United Kingdom (Arcadis (UK) Ltd, 3rd Floor, Charter House, 62-68 Hills Road, Cambridge, CB2 1LA, United Kingdom), 03 June 2020 (80 pages) [unpublished]	Performed by Arcadis (UK) Ltd. 3rd Floor, Charter House, 62-68 Hills Road, Cambridge, CB2 1LA, United Kingdom Sponsor: CCE	AUK-087-FINAL 2020-06-03	submitted by CCE via R4BP3	submitted by CCE via R4BP3, file name: Creosote Council Europe_AUK-087_PAH Residues_FINAL_Optimised.pdf	Attached documents submitted by CCE via R4BP3: 20200312 Consumer risk assessment Arcadis report.docx
IUC REACH 9.3 (plus EP-Summary)	Anonymus	2020	Consumer risk assessment for the Report, not dated	--	Unknown, received from CCE on 2020-06-04	submitted by CCE via R4BP3	submitted by CCE via R4BP3, file name: 20200312 Consumer risk assessment Arcadis report.docx	--

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
IUC REACH 9.2.1	[redacted]	2019	Livestock Exposure Assessment for Creosote, COVANCE, 17 September 2020 (6 pages) [unpublished]	Performed by COVANCE CRS (Switzerland) Ltd., Rheinstrasse 74,4414 Füllinsdorf, Switzerland Sponsor: CCE	RG61YB 2019-09-17	submitted by CCE via R4BP3	submitted by CCE via R4BP3, file name: RG61YB Tier I Livestock Assessment Exposure Creosote.pdf	--
IUC REACH 9.2.1	Anonymus	2020	Livestock: Residues in cattle (as model) after grass ingestion in the vicinity of creosote-treated fences, not dated (2 pages) [unpublished]	--	Unknown, received from CCE on 2020-06-04	submitted by CCE via R4BP3	submitted by CCE via R4BP3, file name: Point 6b_livestock residues.docx	--
IUC REACH 7.10.5	Anonymus	2020	Concerns: Dermal contact of general public to agricultural and equestrian fencing (including climbing children with parameters according to HEAdhoc recommendation No. 5 (2015), not dated [unpublished]	CCE	Unknown, received from CCE on 2020-06-04	submitted by CCE via R4BP3	Submitted by CCE via R4BP, file name: 20200604 Dermal contact of general public (Headhoc assessment).docx	--

Section No.	Authors	Year	Title / Date	Source	Report No. / date	Location Iuclid 6 (REACH complete TOC)	Location	Attached documents
IUC REACH 9.3 (plus EP-Summary)	CCE	2020	Risk assessment on fruit grown in orchards constructed with creosote-treated stakes (CCE) version 8, 20/11/2018 (40 pages) [unpublished]	CCE	Version 8, 2018-11-20	submitted by CCE via R4BP3	submitted by CCE via R4BP3 (CCE 2018_Final report fruit stake study v8c_20181120.pdf)	Attached documents submitted by CCE via R4BP3: 1. file name: Validation info fruit stake study Servaco.pdf 2. file name: Validation dossier PAH food Vito MS-MS def.pdf 3. file name: Translation keywords in English.docx 4. file name: Annex VIII Analytical method GC analysis (for wood extracts).pdf 5. file name: Annex VII.2 Analytical results PAH analysis on soil.pdf 6. file name: Annex VII.1 Analytical results PAH analysis on soil.pdf 7. file name: Annex VI.3 Recoveries of 1- and 2-methylnaphthalene.pdf 8. file name: Annex VI.2 Analytical method PAH analysis on soil.pdf 9. file name: Annex VI.1 Analytical method dry weight.pdf 10. file name: Annex V.1 Analytical results PAH analysis on fruit.pdf 11. file name: Annex IX.2 Analytical results PAH analysis on wood_calculated retentions.pdf 12. file name: Annex IX.1 Analytical results PAH analysis on wood_GC results.pdf 13. file name: Annex IV Reproducibilities and measurement uncertainties of PAH analysis on fruit.pdf 14. file name: Annex III.2 BELAC accreditation Servaco for PAH analysis on soil.pdf 15. file name: Annex III.1 BELAC accreditation Vito for PAH analysis on fruit.pdf 16. file name: Annex II Meeting report visit to fruit producer using creosoted stakes.pdf 17. file name: 20160531 Annex XII Bottom treated stakes.pdf 18. file name: Annex XI Alternative orchards geometries and additional info.pdf 19. file name: 20160318 Annex X Climatological data.pdf 20. file name: 20160219 Annex I Sampling and site data.pdf 21. file name: 20151215 Annex V.2 Analytical results PAH analysis on fruit growing season 2015.pdf
IUC REACH 6.6	CEHTRA	2018	Endocrine Disruption Assessment of Creosote under Biocides Product Regulation (EU) No 528/2012, Project No. CFR/CCE/BPR/1801, by CEHTRA, for Creosote Counsil Europe, 06/2018, Report CFR-18.066	CCE	Report CFR-18.066, 2018-06	submitted by CCE to the UK CA	submitted by CCE to the UK CA	--

Appendix IIIA: Additional modelling carried out to determine PECs (predicted environmental concentrations) for use in ENV risk assessment

New scenario outlined in A2.10.2/16 for use of creosote treated posts in vineyards and orchards (non-contact with fruit and plants)

Details of model dimensions (based upon principles found in the PT 8 ESD for transmission poles and fence posts) are outlined as follows :

Looking at the proposed model (provided as A2.10.2/16a) in detail, information provided by the German WPA states that the mean diameter of the end / line posts used in vineyards (and treated with creosote) is typically 9.36 cm^2 so, with a radius of 4.68 cm, the volume of a typical 2.25 m long post would be $\Pi \times 4.68^2 \times 225 = 15482\ cm^3$ ($0.01548\ m^3$). However, it is made clear that only 0.8 m of each post is treated with creosote (0.25 m above ground and 0.55 m below ground), representing only 5505 cm^3 ($0.0055\ m^3$).

Surface area of treated post above ground: $\Pi \times 9.36 \times 25 = 735\ cm^2$ ($0.0735\ m^2$)

Surface area of treated post below ground: $(\Pi \times 9.36 \times 55) + (\Pi \times 4.68^2) = 1686\ cm^2$ ($0.1686\ m^2$)

Volume of post below ground: $\Pi \times 4.68^2 \times 55 = 3784.5\ cm^3$

Volume of soil around the treated post at EU level is based upon a distance of 0.5 m (vertically and horizontally) from the post. Volume occupied by soil would be:

$[(\Pi \times (4.68 + 50)^2) \times (50 + 55)] - 3784.5 = 982500\ cm^3$ ($0.9825\ m^3$)

Appendix IIIB: Microsoft Excel calculation sheets for Use Classes 3, 4a, 4b and 5

UC3_creosote emissions.xlsx

UC4a_creosote.xlsx

UC4b_creosote.xlsx

UC others_creosote.xlsx

Appendix IIIC: Review on endocrine disruption (ED) properties of the selected constituents of the European creosote composition - submitted by the applicant

Creosote ED assessment from applicant.pdf

Appendix IV: Consideration of Disproportionate Impacts (BPR Art 5(2)(c)) as prepared by the UK (former eCA)

1. Background

Creosote was approved under the Biocidal Products Regulation (Regulation 528/2012/EU) (BPR) for use as a wood preservative (Product Type 8) on 1/5/2013 (Commission Directive 2011/71/EU). The original approval expiry date (30/4/2018) has been extended to 1/11/2020 (Commission Decision 2017/2334/EU).

Creosote meets the BPR Exclusion criteria in article 5(1)(a) and 5(1)(e). It has a harmonised classification in accordance with Regulation (EC) 1272/2008 as Carcinogenic Category 1B, and contains constituents that have Persistent, Bioaccumulative and Toxic (PBT) properties in accordance with the criteria set out in Annex XIII to Regulation (EC) 1907/2006.

Therefore, for the approval of creosote to be renewed, it is necessary to consider whether any of the conditions in article 5(2) are met. The article 5(2) (a) and (b) conditions are not considered to be relevant to creosote. Therefore, this report addresses the condition in article 5(2)(c) and evaluates whether not approving creosote would have a disproportionate negative impact on society when compared to the risk to human health, animal health or the environment arising from the use of creosote.

The evaluation is based on that provided by the UK CA for Biocides in August 2016 when considering the authorisation of the BPR product applications. This 2016 evaluation has been updated with new supplementary information provided to the UK CA by stakeholders, in advance of the article 10(3) consultation conducted by ECHA. A further update may therefore be required if new information is submitted on available substitutes during ECHA's consultation.

It is noted that in meeting the exclusion criteria, creosote also meets the criteria for a candidate for substitution under article 10(1)(a). Therefore, in accordance with article 10(4), if the renewal of the approval is deemed appropriate, the approval shall be for a period not exceeding 7 years.

In consideration of whether there are disproportionate negative impacts, no specific guidance has been developed under BPR to facilitate any assessment. The evaluation performed in this paper is thus based on the approach and guidance that is used for the socioeconomic assessment of impacts in the context of the REACH Regulation (1907/2006). Here, the disproportionate negative impacts criterion is operationalised in terms of whether the benefits of continued use exceed the risks of continued use of the substance[5]. The evaluation in this report is thus performed specifically in terms of whether the benefits of continued use of creosote biocidal products would exceed the risks of their continued use across the uses classes considered in the approval renewal application.

The disproportionate negative impacts evaluation covers the following use classes for which approval renewal is being sought:

- UC 3: pressure impregnation: Preventive treatment of wood to be used as railway sleepers, agricultural fencing, equestrian fencing, industrial and highways fencing,

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[5] See ECHA (2011), "Guidance on the preparation of socioeconomic analysis as part of an application for authorisation", available at: https://echa.europa.eu/documents/10162/13643/sea_authorisation_en.pdf as well as ECHA (2012), "The opinions of RAC and SEAC on Applications for Authorisation", available at: https://echa.europa.eu/documents/10162/13555/afa_note_rac_seac_opinions_en.pdf.

cladding for non-residential buildings, use class (UC) 3 according to EN Standard 335.
- UC 4: pressure impregnation: Preventive treatment of wood to be used as wood poles for overhead electricity and telecommunication, agricultural fencing, equestrian fencing, tree support posts, Use class (UC) 4 according to EN Standard 335.
- UC 5: pressure impregnation: Preventive treatment of wood to be used for marine installations. Use class (UC) 5 according to EN standard 335.
- Surface treatment (UC 3 and UC 4): Treatment of creosote impregnated wood (UC 3 and UC 4) after modifications such as sawing, cutting, shaping and machining. Preventive treatment. Surface treatment only applies where there has been machining of pressure treated wood after treatment (normally all machining to be done before treatment).
- UC 4: Whole wood - Hot and cold impregnation: Preventive treatment of wood to be used as tree support posts, posts/stakes for agricultural fencing, posts/stakes for equestrian fencing, Protection of wood corresponding to UC 4.

The report focuses on the following general use areas covered under these specific use classes for use: Railway sleepers; Transmission Poles (electric power transmission and telecommunications); Fencing; Wooden Poles/Stakes/Supports for use in the agricultural sector; Wood in Marine applications; Surface treatment of creosote impregnated wood after modifications.

The following information, most of which was submitted to the UK CA by the applicants in support of an application for mutual recognition of a national authorisation for biocidal products containing Creosote has been considered, as appropriate, in undertaking this evaluation:

- A socio-economic analysis of creosoted tree stakes. This document presents the findings of a socio-economic study of creosote as a preservative for tree stakes applications.
- A socio-economic analysis of creosoted fencing. This document presents the findings of a socio-economic study of creosote as a preservative for fencing applications.
- An analysis of the technical feasibility of substitution of creosote for the treatment of wood for poles, sleepers, fencing, agricultural uses (including tree stakes), fresh and sea water uses and professional use. This report is mainly based on information on and experience of wood uses in the UK.
- A socio-economic analysis. This document presents supplementary information submitted to the UK CA in October 2017 of a socio-economic study of creosote as a preservative for wood poles for power and telecommunication networks.
- Several lifecycle analyses.
- Information received during various public consultations regarding the availability of possible alternatives to creosote as well as experience from end users.
- Information on the hazards and risks associated with creosote.

The evaluation and conclusions reached are based on the information available to the UK Competent Authority at the time of writing (August 2016 – updated February 2018).

2. Disproportionate Impacts Evaluation: Do the costs of non-use of creosote as a biocidal products exceed the benefits (avoided risks) of non-use in the uses seeking approval?

☐ YES FOR ALL USES

☒ YES FOR SOME USES (PLEASE STATE WHICH USES: Railway sleepers; Transmission Poles (electric power transmission and telecommunications); Agricultural Fencing/Tree Stakes; ____)

☐ NO

Justification

Wood preservatives chemically protect wood from natural biodegradation that occurs when wood is attacked by bacteria, fungi, insects, or marine borers. The resulting protection depends on the type of preservative used and the achievement of proper penetration and retention of the chemicals. The wood preservative industry includes both industrial (primarily construction, transportation and communications sectors) and consumer markets (retail consumers). Creosote is one of the three major wood preservatives used in the industrial market only in those sectors permitted under REACH Annex XVII (31). The key function of creosote is to ensure the preservation of wood over relatively long service lives. Advantages of creosote are its toxicity to wood-destroying organisms, relative insolubility in water and low volatility that makes it fairly permanent under widely varying conditions, ease of application, ease of determining penetration depth, relative low cost, and record of satisfactory use.

Assessment of Impacts

In support of the contention that there would be a disproportionate negative impact on society from not approving creosote compared to the risks to human health, animal health or the environment from the authorisation and continued use of creosote, the applicants have submitted a package of documents that contain a variety of relevant qualitative and quantitative socioeconomic evidence, and upon which an evaluation by the UK CA can be made.

The documents contain information on the technical and economic feasibility of alternatives to creosote, in addition to some information on the risks associated with its use. This information can be used to assess the implications of not approving creosote across the different uses classes applied for. The negative impacts on society of this so-called 'non-use scenario' will depend on the reactions of manufacturers and users to the not approving, and in particular on the suitability and availability of alternatives to creosote. These negative impacts are typically assessed in terms of any additional economic costs faced by society as a result of no longer being able to use creosote in the use classes applied for. These costs can then be compared with the risks to human and animal health and the environment which are avoided as a result of not authorising creosote products. For some of the use classes applied for (Agricultural Tree Stakes, Fencing, Wood Pole applications), the applicant has submitted evidence which explicitly assesses the 'non-use scenario' and the associated costs and risks in a quantitative or semi-quantitative manner. However for the other use class cases, the information is more limited, such that it is only possible to make a more qualitative comparison and judgement of the costs and risks.

As mentioned earlier, in order to assess whether not authorising creosote products would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment, it is necessary to show that the costs of non-use exceed the avoided risks of non-use in the applied for use classes over the relevant analytical timeframe[6]. The analytical timeframe considered to be relevant in this case is 5

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[6] It should be noted that the analytical timeframe normally relates to the period sufficient to cover the lifecycle of all major impacts associate with the decision, which may or may not coincide with the decision making time horizon for which approval is sought. Given, that the approval period being sought is 7 years in the first instance, whilst the service life of creosote treated wood will typically be much longer, it is necessary, where appropriate, to properly account for this within the analysis. So, for example, capital investment costs may need to be annualized in order to be incorporated into analysis that is based on a shorter analytical timeframe than the life of the capital. Likewise, impacts associated with the carcinogenicity of creosote will typically involve impacts associated with long-term exposure and a period of latency between exposure and cancer occurring.

years[7], in line with the period of authorisation of the biocidal products. This is explicitly recognised but it is not clear whether and how it has been taken into account in the applicants' assessment for those use classes in which it undertook a fully quantitative or semi-quantitative assessment. Moreover, it was only implicitly assumed in the remaining use classes and again not clear how it was taken into account in the analysis. Nevertheless, for reasons which will become apparent later, any deficiencies in this respect do not affect the conclusions of the evaluation.

The assessment concerns impacts occurring to affected stakeholders within the UK (though in some cases broader impacts at EU level have been assessed by the analyses submitted), with the impacts being defined in terms of a non-use scenario in which biocidal products containing creosote can no longer be marketed and used in the use classes for which approval is sought. The non-use scenario is explicitly identified for the use classes concerning tree stakes, fencing and wood pole applications, whilst it is implicitly assumed for the remaining use classes (see costs section later). The non-use scenario should establish the least costly (in terms of both direct financial costs and overall economic viability) situation for the applicants and users of not being granted an authorisation. Likewise, the non-use scenario should establish the avoided risks and associated avoided health and environmental impacts of not being granted an authorisation. The extent that the costs and risks are considered and appropriately assessed is considered in more detail in the sections below. Overall, the assessments and analyses undertaken by the applicants vary in quality across the different use classes, with those for tree stakes, fencing and (to some extent) wood pole applications mostly conforming with standard practice for these types of assessments, whilst the picture for the remaining use classes is based on evidence that is somewhat partial, opaque and not presented coherently.

Costs of Non-Use

The evaluation of the costs of non-use is based on evidence submitted by the applicant which differs across the different use classes for which approval is sought. In all cases the applicants have undertaken an analysis of alternatives in which they assess, to a greater or lesser extent, the economic feasibility of the alternatives. In the case of the tree stakes and fencing (and to a limited extent wood pole) use classes, this information is then used to formally develop cost estimates of the non-use scenario. For the remaining use classes, no formal assessment of costs is undertaken, but rather the applicant merely reports the rudimentary indications of cost expectations associated with the different alternatives contained in the economic feasibility assessment of the analysis of alternatives. An evaluation by the UK CA of the applicants' technical and economic feasibility assessment conducted as part of their analysis of alternatives is provided in Annex 1 of this report. This evaluation suggests that although the evidence is not always entirely convincing, the applicants claim that there are no appropriate alternatives is generally (if somewhat weakly), supportable for some of the use classes considered (see annex 1 for details).

Regarding the cost assessment conducted by the applicant for tree stakes and fencing, this follows established procedures for the calculation of the financial costs of switching to an alternative preservative or alternative material to wood. The evidence provided indicates that under the non-use scenario, the switch to alternative preservatives or alternative materials would result in users incurring additional direct costs. This is primarily due to the need to replace the wood more frequently (in the case of alternative preservatives being used) or as a result of the higher purchase price and installation costs associated with alternative materials. The applicants' analysis suggests that the costs are of the order of £50 million and £100 million (both present values) for Tree Stakes and Fencing respectively

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[7] In the case of the analysis provided for Wood Pole applications, the period of authorisation being sought is 10 years (even though the maximum legally permissible is 5 years, albeit renewable) , though it is not explicit to what extent the analysis uses this in assessing relevant impacts (see relevant section of the report).

over a 25 years period. These figures are EU wide costs rather than UK specific[8]. There are a number of deficiencies and uncertainties with the methodological approach and data used, such that the cost estimates noted above are rather speculative and cannot be relied upon as an accurate representation of costs. Nevertheless, the estimates can be considered to be indicative of the fact that users could potentially face additional costs of this order of magnitude in the event of non-approval. At the same time, as indicated in the analysis in annex 1, there is some evidence that alternatives are widely available and in use in agricultural fencing applications, though it is unclear to what extent such use is in areas with more limited service life specification requirements.

In the case of the socioeconomic analysis for wood pole applications, the applicant sets out the expected behaviours and associated costs of the non-use scenario in which creosote is not approved/authorised for use as a treatment for wood poles. The expected behavioural responses and associated impacts from the non-use of creosote are generated using a stakeholder consultation exercise, including discussions and structured questionnaires with relevant industry actors, associations and research bodies. The analysis is conducted on a sectoral basis across the relevant supply chain and includes the forestry sector, creosote manufacturers, wood pole treaters and end users of utility poles, and whilst cost estimates are included for some of the individual sectors, the approach is lacking in terms of methodological transparency and no aggregate estimate for the entire supply chain is calculated. Although the overall approach does not readily conform with a transparent and systematic methodological approach to socioeconomic assessment, the information is sufficient to conclude on the general plausibility of impacts for the sector. The temporal boundary of analysis is 60 years, which is consistent with the life expectancy of creosote treated wood poles (though the applicant appears to provide an alternative rationale). The geographic boundary covers impacts within the EU, including impacts related to non-EU sales. Although some impacts are reported for the forest sector (€4 million annual losses as well as potential loss of around 450 jobs), there are considered to be no direct impacts to creosote manufacturers (who are said to be able to divert the sales of creosote to other markets). It was not possible to scrutinise the validity of the impacts on the forest sector since no evidence was presented to substantiate the impact estimates. According to the analysis, the main impacts of a non-use scenario appear to be to wood pole treaters and the power and telecom network operators. For the wood pole treaters, the impacts are apparently of the order of €150 million annual losses, though it is unclear what this figure actually relates to (be it profits, turnover, additional investments required, etc, or some combination of these elements) or how exactly it was derived. It is clear that there would be considerable variation in impacts amongst the different wood treating companies, depending on the extent of their exposure (share of total output) to the wood pole sector versus other wood products, as well as the extent to which other types of preservatives are able to be used as substitutes for creosote for treatment of wood poles in the event of non-use of creosote. Although there does appear to be some degree of the use of other preservatives amongst those companies consulted, such that the distribution of impacts will vary across companies, the evidence from the technical feasibility assessment (see Annex 1) suggests that wood poles treated with other preservatives do not at this time have the life expectancy typically desired by end users (60 years), such that any move to using alternatives will have negative impacts on the demand for such treated products, or other impacts on end users (see below). In addition, conversion of plant to alternative treatments would apparently also require sizeable capital investments of the order of €2.5-5 million per treatment unit. Companies also reported impacts on their export markets for creosote treated wood poles, though it is not clear from the analysis what the exact motivation is for the loss of non-EU export markets. There were also impacts reported in terms of employment and the local economy. Although it is clear then that impacts would be felt by at least some companies and the local economy, due to the lack of transparency in the estimation of impacts for the wood treating sector, it is not possible to verify the magnitude

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[8] Assuming a proportionate relationship between these costs and GDP estimates, the UK share would be in the region of around £16 million and £8 million respectively (based on the UK GDP being roughly around 16% of EU GDP).

of impacts or the extent that they would be transitory and localised. The other main impacts associated with the non-use scenario relate to the end users in power and telecom network operations. Given the reduction in life expectancy of alternative wood preservatives noted by the study (asset life is assumed to be 20 years), impacts of around £0.75 billion are estimated for the power network operators. A more realistic option is considered to be the use of alternative pole materials, though even the most favourable option - composite poles - which are technically feasible, are not considered economically feasible (at least in the short term) given that they are around 3 times the price of comparable wood poles. Likewise for the telecom operators, a similar picture is painted in terms of impacts from the use of alternative materials or preservatives. The use of composite materials is again technically feasible, but their price remains high at 6 times the equivalent wood pole. Given this, the telecom operators indicate that alternative preservatives would be used to treat wooden poles, with the consequences that due to their reduced life expectancy (asset life of 30 years), additional costs of around €20-25 million per annum are expected. Although in the power and telecom cases, there is more transparency regarding the estimation of costs, the information provided is insufficient to fully scrutinise and assess the validity of impact estimates, particularly in respect of what the aggregate additional costs would be under the 'composite materials' non-use option. Despite the uncertainties over the nature and magnitude of the different cost elements estimated for the wood poles non-use scenario, it is clear that some aspects of the sectors responses are plausible and would likely imply additional costs either in the form of additional operating costs or capital expenditures for the sector as a whole.

The SEA for the wood pole sector also seeks to justify an authorisation for a period of 10 years. However, as noted in the SEA, approval can only currently be granted for a period of 5 years. Furthermore, given ongoing developments and testing of the efficacy of alternative wood preservatives and associated life expectancy of corresponding wood treated products (see Annex 1), an authorisation period of 10 years is not considered appropriate in any case.

As already mentioned, no formal cost assessment was undertaken for the remaining use classes (railway sleepers, marine applications and surface treatments), such that only the information from the economic feasibility assessment from the applicants' analysis of alternatives is available for evaluation. Although some cost information is presented by the applicants, for the most part this is not based on a systematic and methodologically robust approach to cost assessment (and one in which a serious attempt is made to fully estimate the expenditures related to the additional resource costs and losses in productive values as a consequence of the non-use scenario). Whilst a fully quantitative and robust estimation of costs is not available for these remaining use classes, the economic feasibility assessment does nevertheless indicate that additional costs, albeit of a highly speculative magnitude (but potentially even larger than those estimated for tree stakes and fencing), are likely to be incurred, particularly for the railway sleeper use classes (see annex 1 for further justification). In the case of marine applications, there is almost no information on costs, though as outlined in the evaluation of technical and economic feasibility for this use class, a justification for continued use could potentially be made on the grounds of preserving cultural heritage in certain circumstances. This justification is considered further in the comparison of costs and risks section.

In summary, the evaluation of costs has indicated that there are significant uncertainties with the assessment of costs of non-use across the use classes seeking authorisation. The uncertainty is such that any estimates of costs are speculative in their magnitude and should not be relied upon as being truly representative of costs. It should be noted that the uncertainties could be in either direction. Nevertheless, even if the magnitude of costs cannot be assessed with any degree of accuracy or robustness, it is clear from the analysis of alternative that in the event of non approval, switching to alternatives will not be a costless exercise, particularly in the case of railway sleepers, transmission poles and, notwithstanding some conflicting evidence, agricultural fencing/tree stakes.

Benefits (avoided risks) of Non-use

In order to assess whether the costs are disproportionate, it is necessary to consider the benefits of not approving creosote. Given that there are risks to human and animal health and the environment from the use of creosote products, the benefits of not granting an authorisation derive from the avoidance of those risks in each of the use classes concerned.

As was the case for the costs assessment, the applicants have submitted a formal economic assessment of the health and environmental risks for the tree stakes and fencing use classes, but no such evidence for the remaining use classes. For Tree Stakes and Fencing the applicants attempt a quantitative analysis using an impact assessment methodology based partly on an 'impact-pathway' type methodology. This is based on linking quantitative relationships between exposure and the health/environmental impacts of interest. Such approaches are considered state of the art in assessing the benefits of pollutants and are considered an appropriate methodology in the present case. According to the analysis conducted, the human health risks and associated monetised impacts from the use in both tree stake and fencing applications are negligible (< £1000). Although it has not been possible to monetise the environmental impacts, these are also expected to be negligible given that any release to soil over time would be localised to the vicinity of the site of use of each stake or fence pole. Whilst there are again some methodological and data uncertainties with the analysis undertaken by the applicant, the UK CA considers the estimates of health impacts to most likely be overestimated in any case, given the period of approval being sought and associated exposures and latency of any potential effects. The analysis conducted by the applicant is thus considered proportionate in assessing the risk related impacts, particularly in view of the Risk Considerations discussed in Annex 2.

For the use classes covering railway sleepers and transmission poles, although no formal impact evidence has been submitted, the UK CA considers the analysis undertaken for tree stakes and fencing to also be broadly relevant and applicable to these use classes. Moreover, as indicated in the Risk Considerations outlined in Annex 2, the risks can be considered to be controlled to a tolerable level given the risk mitigation and exposure circumstances in place across these use class areas. It is not clear however, the extent to which this analysis applies equally to any risks from marine applications and surface treatments.

In summary, the evaluation of the benefits of non-use has considered the avoided risks and impacts associated with non-use across the use classes seeking approval. Although the analysis submitted by the applicants is partial, in the sense of only covering some of the use classes, it is nevertheless considered to be applicable to some of the remaining use classes, namely railway sleepers. In accordance with the findings of this analysis, as well as the Risk Considerations described in Annex 2, the health and environmental impacts of using biocidal products containing creosote are considered to be at worst limited to some very localised environmental effects and most likely negligible in all other respects. This assessment relies on a qualitative judgement for those use classes for which a quantitative analysis was not undertaken by the applicants.

Comparison of Costs and Benefits of Non-Use

Overall, given the above characterisation of limited or even negligible levels of risks and associated impact to health and the environment across the main use classes for which approval is sought, the UK CA considers that any degree of modest costs would be sufficient to indicate that there are "disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product" as a result of not authorising the biocidal product. Whilst there are a number of uncertainties with the assessment of costs undertaken by the applicants such that the magnitude of impacts is speculative, there are nevertheless sufficient grounds for concluding that at least some level of modest (and potentially more significant) costs would be incurred across most of the various use classes seeking authorisation. In the case of marine applications and surface treatment no evidence on costs has been submitted, though there may be other potential justifications which apply in these cases and to which the UK CA has made reference in this report and associated annexes. Overall, whilst the uncertainties in the assessment of costs and benefits are such that the evaluation of disproportionate impacts often relies heavily on more qualitative evidence and judgements as to their nature, the conclusion that costs outweigh the benefits of non-use is considered to be robust for railway sleepers, transmission poles and agricultural fencing/tree stakes (though in the latter case, there is some dispute regarding the technical and economic feasibility of alternatives across all applications). In the case of marine applications and surface treatment, whilst a case could potentially be made for granting authorisation on the basis of disproportionate impact grounds, there is nevertheless a lack of evidence submitted at the time of writing to fully support this.

Conclusion

The UK CA concludes that not approving creosote would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product in the use classes indicated earlier. The material submitted by the applicants in support of this assessment is not fully robust and somewhat lacking from an analytical perspective, as well as being difficult to fully scrutinise and challenge, particularly due to a lack of detail and transparency, as well as some apparently contradictory evidence in some cases. Nevertheless, despite these deficiencies, there are at least credible qualitative grounds, in addition to some acceptable quantitative evidence to support the general conclusions.

Appendix V: Summary of the public consultation of Creosote (prepared by ECHA 2020)

Summary Public
Consultation by ECH

Appendix VI: Overview of creosote containing biocidal products authorised in the EU, based on a survey coordinated by ECHA 2020

Member State	Number of creosote containing biocidal products authorised (from R4BP 3 as of 9 October 2020)	1) Treatment of wood to be used as railway sleepers	2) Treatment of wood to be used as transmission poles (electricity, telecommunication)	3) Treatment of wood to be used as tree support poles in orchards and vineyards or other agricultural stakes (potential residues in food)	4) Treatment of wood to be used for fences (agricultural fencing, e.g. for horse stables and other fences)	5) Treatment of wood to be used in harbours and waterways	6) Other
France	6	YES (no alternatives are available for the moment)	NO	NO	NO	NO	NO
Austria	3	YES (no alternatives for railway sleepers for some uses)	YES (not enough suitable alternatives for electricity distribution network especially in low- and medium-voltage range)	YES: for orchards and vineyards; (not enough suitable alternatives to avoid upcoming resistances in orcharding and viniculture (copper-resistant fungi); restriction for the use of poles: impregnated section of the pole must always be slightly above the floor level. NO: for hop growing.	NO	NO (not applied for)	NO
Denmark	0	NO	NO	NO	NO	NO	NO
Germany	5	YES (No alternatives approved in accordance with German railway regulations)	NO	NO	NO	NO	NO
Latvia	7	YES: according to comparative assessment there are no sufficient alternatives	NO	NO	NO	NO	NO

		LV.pdf					
Norway	5	YES (According to the comparative assessment the availability of alternative biocidal products and non-chemical alternatives currently is insufficient. Not authorising products with this active substance will result in disproportionate negative consequences for society in comparison with the risk associated)	YES (According to the comparative assessment the availability of alternative biocidal products and non-chemical alternatives currently is insufficient. Not authorising products with this active substance will result in disproportionate negative consequences for society in comparison with the risk associated)	NO	Yes (for export only)	YES (According to the comparative assessment the availability of alternative biocidal products and non-chemical alternatives currently is insufficient. Not authorising products with this active substance will result in disproportionate negative consequences for society in comparison with the risk associated)	YES Used for construction of timber bridge structures (According to the comparative assessment the availability of alternative biocidal products and non-chemical alternatives currently is insufficient. Not authorising products with this active substance will result in disproportionate negative consequences for society in comparison with the risk associated)
Switzerland	2	YES (According to comparative assessment from 2017 by the Swiss authority, there are no sufficient alternatives for wooden railway sleepers.) (In Switzerland, as of 1st of June 2019 creosote treated wood can be used only as railway sleepers (regulated under Annex 2.4 of Ordinance on the Reduction of Risks relating to the Use of Certain Particularly Dangerous Substances, Preparations and Articles (Chemical Risk Reduction Ordinance, ORRChem)) CH.pdf	NO	NO	NO	NO	NO

Greece	6	NO	YES (It was authorised because of lack of viable alternatives) (The products were authorized following MRP. However, article 37 applied for those products by restricting their use in Greece only for the treatment of electricity transmission poles.)	NO	NO	NO	NO
Sweden	9	YES (no alternatives)	YES (no alternatives)	NO	NO	NO	NO
Estonia	0	NO	NO	NO	NO	NO	NO
Spain	4	YES (2 product families); no alternatives are available.	YES (2 product families); no alternatives are available.	NO	NO	NO	NO
Ireland	6	YES (no alternative currently available).	YES (no alternative currently available).	NO	YES (no alternative currently available).	YES (no alternative currently available).	YES (external cladding on non-residential buildings).
Netherlands	0	NO	NO	NO	NO	NO	NO
Portugal	2	YES (no alternatives available).	NO	NO	NO	NO	NO
Slovenia	5	YES (no alternatives available for the moment).	NO	NO	NO	NO	NO
Poland	9	YES (Creosote containing product was authorised, because apart from this product only one more was authorised in Poland as an alternative in UC3 effective against both fungi and insects. Currently, no updated analysis of alternatives is available (2020).)	YES (Creosote containing product was authorised, because apart from this product only one more was authorised in Poland as an alternative in UC4a, but only by vacuum-pressure method of application. No alternative was authorised in Poland and available in UC4b. Currently, no updated analysis of alternatives is available (2020).)	Yes (e.g. fruit tree, hop and vineyard stakes) Procedure concerning a change within this use is in progress.) See also 2).	Yes (e.g. fences, anti-hail curtains). See also 2).	NO	NO
Belgium	4	YES (as no alternatives are available).	YES (as no alternatives are available).	YES (as no alternatives are available).	YES (as no alternatives are available).	NO	NO
Croatia	7	YES (as no alternatives are available).	NO	NO	NO	NO	NO
Finland	5	YES (No other alternatives than concrete sleepers. Wooden ones are needed in old tracks for replacements.)	YES (No alternatives for replacement of single old wooden poles. New wooden poles are needed in sparsely populated areas.)	NO	YES (Not used in Finland, for export production only.)	NO	YES (wooden bridges and gluelams used in wooden bridges; No alternatives for wood material with equally long durability; Wood as a material in constructing bridges, especially in railroad

							and light traffic bridges, is supported by the Finnish Ministry of Economic Affairs and Employment as a sustainable building material.)
Czech Republic	0	YES (no feasible alternatives for the replacement of worn out railway sleepers)	YES (not enough suitable alternatives for electricity distribution network)	NO	YES (not enough suitable alternatives for treatment of wood to be used agricultural fences)	NO	NO
Hungary	2	YES (no alternatives are available)	YES (no alternatives are available)	NO	NO	NO	NO
Lithuania	0	NO	NO	NO	NO	NO	NO

Notes:
Estonia has a need to use the creosote treated wood for certain areas for railway sleepers and for transmission poles. However there is no need that the treatment of the wood takes place especially in Estonia. We see as a creosote meets the exclusion criteria set out in points (a) and (e) of Article 5(1) of Regulation (EU) No 528/2012, so we should not broaden the treatment facilities in Europe. We should not establish new treatment plants nor re-modify the wood treatment plants for the use of creosote. On the 27-05-2016 Estonia received the NA-MRS application which was rejected on the 10-11-2016 due to the absence of the creosote impregnation company in Estonia. On the 15-06-2017 the second attempt to submit the NA-MRS application was made. We are still not convinced that the selected treatment plant in Estonia will be in accordance with the requirements from human health and environmental point of view. We are of the opinion not to support the expansion of treatment plants for creosote. However the applicant has not agreed with our several explanations and for that reason this application is on hold until we receive the results of the market surveillance of the selected treatment plant.
Luxembourg: no application received.
Slovakia: one application received which was withdrawn.
Romania: no information received although 4 biocidal products are authorised according to R4BP 3 as of 9 October 2020.
Bulgaria: no information received although 3 biocidal products are authorised according to R4BP 3 as of 9 October 2020.

Appendix VII: Compilation based on reports provided from Member States to the Commission justifying the conclusion, that there are no appropriate alternatives

Uses supported or not supported by Member States

Member State *(report date)*	1) Treatment of wood to be used as railway sleepers	2) Treatment of wood to be used as transmission poles (electricity, telecommunication)	3) Treatment of wood to be used as tree support poles in orchards and vineyards or other agricultural stakes (potential residues in food)	4) Treatment of wood to be used for fences (agricultural fencing, e.g. for horse stables and other fences)	5) Treatment of wood to be used in harbours and waterways
Austria *(July 2016)*	Supported	Supported	Supported	Not supported	Not supported
Belgium *(March 2019)*	Supported	Not supported	Supported	Supported	Not supported
Finland *(February 2017)*	Supported	Supported	Only for export	Only for export	--
France *(April 2018)*	Supported	Not supported #	Not supported #	Not supported #	--
Germany *(2016)*	Phasing out earliest 2022	Supported for export.	Supported for export.	Not supported	Not supported
Greece *(February 2017)*	Not authorised, but may accept in future	Supported and authorised for internal market	Not authorised, but may accept in future	Not authorised, but may accept in future	Not authorised, but may accept in future
Ireland *(January 2019)*	Supported	Supported	May be not supported – art. 37.1 possible in future. Or supported if with realistic Risk Mitigation Measures	Supported	Not supported
Latvia *(June 2016)*	*supported*	--	--	--	--
Norway *(January 2019)*	Supported	Supported	No such authorised	No such authorised	Limited
Poland *(July 2016)*	Supported	Supported	Supported	Supported	Not supported
Slovenia *(≥ 2017)*	Supported	--	--	--	--
Spain *(September 2018)*	Supported	Supported	--	--	Not supported
Sweden *(July 2016)*	Supported	Supported	No such use authorised in SE	Not supported	Not supported
Switzerland *(March 2017)*	Supported	No such use authorised in CH	No such use authorised in CH	Not supported	Not supported
The United Kingdom *(July 2016)*	Supported	Supported	Supported	Supported equine fencing only	Supported but not convinced of no alternatives

 # if understood correctly

Information on alternatives based on the reports provided from Member States to the Commission

1) Treatment of wood to be used as railway sleepers	2) Treatment of wood to be used as transmission poles (electricity, telecommunication)	3) Treatment of wood to be used as tree support poles in orchards and vineyards or other agricultural stakes (potential residues in food)	4) Treatment of wood to be used for fences (agricultural fencing, e.g. for horse stables and other fences)	5) Treatment of wood to be used in harbours and waterways	6) Other
Creosote treated sleepers are still in use to maintain the existing wooden lines in Austria. Belgium for export: 70% railway sleepers. Only 12% main tracks and 75% side tracks are made of creosoted wooden railway sleepers. In Ireland for sleepers technical reasons (resiliency, impact resistance, lower weight). Sleepers of various type cannot always be mixed on the same section. Creosoted wooden sleepers used on clayey ground, in old tunnels, on metal structures, in stations, in narrow curves and on sections where there are switches and crossings. Allowed by Switzerland national law. Wood sleepers also reduce noise and vibration, as well as having electrical isolation properties (UK). No alternatives meet requirements for passenger and cargo safety critical applications in Norway.	Creosoted base pole and upper part impregnated with salts (chromium-copper and now chromium-free). Bandages at groundline zone with biocides (e.g. dazomet) = additional protection measure and salt based treated upper part. Treated wood is a sustainable, economical and effective pole material that requires relatively little energy to manufacture. Trees sequester carbon dioxide as they grow. The utilisation of alternative preservatives giving a lesser pole service life would require more frequent replacement of poles with increased tree harvesting requirements Wood adsorbs dynamic load, inherent flexibility but not buckling. Climbing easier than onto other material poles with no steps. Poland: only by vacuum pressure method of application in UC4a. Finland: only in sparsely populated areas.	Avoid upcoming resistances – mainly in orcharding and viniculture - of copper-resistant fungi. Fruit and winegrowing no longer the totally creosoted but creosoted base. Lightweight, easy to install regardless of soil type, provide the necessary flexibility to strong wind and damp Irish weather conditions, proven lifetime of at least 25 years. The use was not fully evaluated by SE in the PAR; highly unlikely that creosote scorched apples would enter into the food chain.	Belgium for export: 95% equestrian fencing. Horses chew and destroy wooden fencing, but will not chew creosoted fencing, which remain strong barrier and flexible to collision with farm animals and horses. Grant-aided project only for creosoted horse fencing. Metal, naturally resistant wood, plastics, concrete and fiberglass posts not viable alternatives in Ireland. Biosecurity – potential dangers to road users/railway passengers. No use of creosote treated fence posts in the agricultural sector due to the prohibition of this application by national law in Switzerland.	Not of relevance in big ports, as wood of short static and life period, but still for construction of spur dykes in coast protection (possibly stones, untreated tropical woods as used in North and Baltic Sea). The use of creosote treated poles in marine areas as construction material in piers and jetties is today limited due to REACH and alternatives are mainly used for larger commercial construction. For bridge only with a separate permit due to national pollution act in Norway Cultural heritage associated with historic marine structures in the UK.	Gluelams used in pole structures, Wooden bridges and gluelams used in wooden bridges – long durability. Wood is a constructing material in railroad and light traffic bridges – sustainable building material – supported by Finland. *Industrial fencing,* *Highway fencing,* *Brushing as a treatment following wood modification,* External Cladding for non-residential buildings allowed in Ireland

Non-chemical alternative materials: Concrete (partially with steel enforcement), Concrete sleepers not for super elevations in tight curves, old low tunnels, switching points, marshalling yards. Concrete sleepers energy-consuming both in the production and in the transport process and different ballast depth. In Switzerland concrete sleepers 35%,	Alternative materials available, like concrete, steel (hybrid), aluminium, or composite poles Concrete and steel poles are not technically feasible (too thick if high enough) for low-voltage and telecommunications in rural areas Concrete and steel poles are more expensive. Steel major producers are outside Europe. Mining and quarrying for raw materials have risks and toxic emissions. Concrete and steel poles are no alternatives for power lines located in difficult terrain (forest or mountain). Concrete, Metal poles are not safe (electrical insulation). One product may replace in Spain (not mentioned which one) Concrete bases for wooden poles, avoiding the direct contact to the ground (use class 4) Protection sheets around the lower part of the pole Concrete, steel poles have rigidity and fire retardancy, but costs.	Metal posts (steel, galvanised iron etc.) have disadvantages: they are not suitable to be used in steep slopes and they release zinc to the environment. Galvanised steel short good for vineyards, but not for hop and orchards; longer means thicker (heavy, expensive, reinforced supports, environment impact during production). Concrete or steel posts and stakes disadvantage of high secondary damage for pomiculture in case of breakdown of the scaffoldings to prevent damage by hail, but also they prevent using overarching machines due to the need for cross-bracing of such concrete/steel posts.	Tanalith 3462 (copper salt based) authorised under BPR in Austria. Copper azole and alkaline copper quaternary preservatives promote equestrian/cattle cribbing, biting, nibbling, scrubbing and hence exposure. Tantalised (treated with Tanalith by Lonza; copper+tebuconazole) is to be replaced every 8 years compared to creosoted 25 years.		
Modified steel sleepers (Y-shape) used in Switzerland. In Switzerland steel sleepers 21%	Underground power transmission lines and telecommunication lines	Concrete post are also routinely used in various agricultural sectors, but have a higher risk of fracture, are of heavy weight and are therefore not suitable for steep slopes.	Metal fencing injuries in animals, expensive, environment impact during production.		

		Concrete critical failure due to winds, heavy rain, soft soil; lack of flexibility; not for hop and hail protection requiring 6m length (concrete up to 4.8m); one post fails affecting area of plantation Concrete or steel posts and stakes disadvantage of high secondary damage for pomiculture in case of breakdown of the scaffoldings to prevent damage by hail, but also they prevent using overarching machines due to the need for cross-bracing of such concrete/steel posts. Concrete up to 4.8m not for hop and hail protection uses			
Plastic sleepers recently achieved marketability FFU glass fibre/polyurethane sleepers used in Japan for >30 years (Fiber Reinforced Foamed Urethane; Co.Sekisui). Recycled plastic (RPT Railway Plastic Tie made of recycled polyolefin, Co.PAV) (Germany). Plastic not sufficient strength in damp conditions (UK).	composites (fiberglass). Glass-fibre reinforced plastics not good alternatives (higher costs), but life-period is longer and less maintenance. Glass reinforced plastic (GRP) alternatives for utility poles no experience and hazards related to the used raw materials in the production of polymers associated with GRP. Fibreglass and composite poles require other ancillary equipment and fittings	Coniferous (pine) wood impregnated with chromium-copper but now chromium free preservatives – tests with QAC	Concrete - rotting due to weather, breaking of poles in fence when cattle pushes against and causing injuries.		
Untreated oak sleepers for open-track bridges. Oak sleepers impregnated with salt-based Wolmanit products and waxed (SleeperProtect, Co.Osmose) used in Italy. Oak trees are costly (climate,	Tanalith 3462 (copper salt based) authorised under BPR in Austria; might replace Creosote for the protection of wooden poles used for electric power transmission and telecommunications.	Untreated acacia wood (cost, handling, not like soft wood).	Paddock and fences: Non-creosoted wood combined with electrical fence (protects against damage by game animals).		

biodiversity).					
One product may replace in Spain (not mentioned which one)	The submitted life cycle analyses do not give a coherent picture of which of the alternative material or creosote treated wood has the least negative impact on the studied environmental and health factors	Recycled plastics – insufficient rigidity of posts.	Recycled plastic posts.		
		Mixture of creosote with linseed oil - Plant oils as “green” substances for wood protection; decrease by 70% of pure creosote retentions – research and development stage not yet an alternative. Also poles to position hail protection and plastic roof to limit the use of pesticides as fruits are less wet (less moulds).			

Appendix VIII: Exposure calculation for professionals during brushing or cleaning a brush

Brushing of small area after sawing, cutting or machining of the creosote (pressure) treated wood

	units	Tier 1	Tier 2
Active substance	%	100	
Body weight	kg	60	
Dermal penetration rate	%	10	
Potential dermal exposure			
Potential hand exposure			
Indicative value[1]	mg/m^2	0.5417	
Application area[2]	m^2	0.2	
Potential hand deposit	**mg**	**10.83**	
Penetration through gloves[3]	%	10	10
Actual hand deposit	**mg**	**1.083**	**1.083**
Potential body exposure			
Indicative value[1]	mg/m^2	0.2382	
Application area[2]	m^2	0.2	
Potential body deposit	**mg**	**4.76**	
Clothing penetration[3]	%	10	5
Actual body deposit	**mg**	**0.476**	**0.238**
Total dermal deposit	mg	1.559	1.321
Penetration through skin	mg	0.156	0.132
Exposure via dermal route	**mg/kg bw/d**	**0.0026**	**0.0022**
Inhalation exposure			
Indicative value[2]	mg/m^3	0.135	
Duration[2]	min	48	
Inhalation rate[1]	m^3/min	0.021	
Assigned protection factor		No	10
Inhaled a.s.	**mg**	**0.136**	**0.0136**
Exposure via inhalation	**mg/kg bw/d**	**0.0023**	**0.00023**
Total systemic exposure	**mg/kg bw/d**	**0.0049**	**0.00243**
Corr T25	mg/kg bw/d	105	
MoE		**21 428**	**43 209**

1. The model "Professional brush treatment" (based on Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006) according to Biocides Human Health Exposure Methodology (October 2015) – PT8 is used for the dermal and inhalation exposure estimation. Indicative value represents product with a.s. rounded to 1%.
2. Applicant's data.
3. HEEG opinion 9.Default protection factors for protective clothing and gloves.
4. Guidance on Information Requirements and Chemical Safety Assessment Chapter R.14: Occupational exposure assessment.

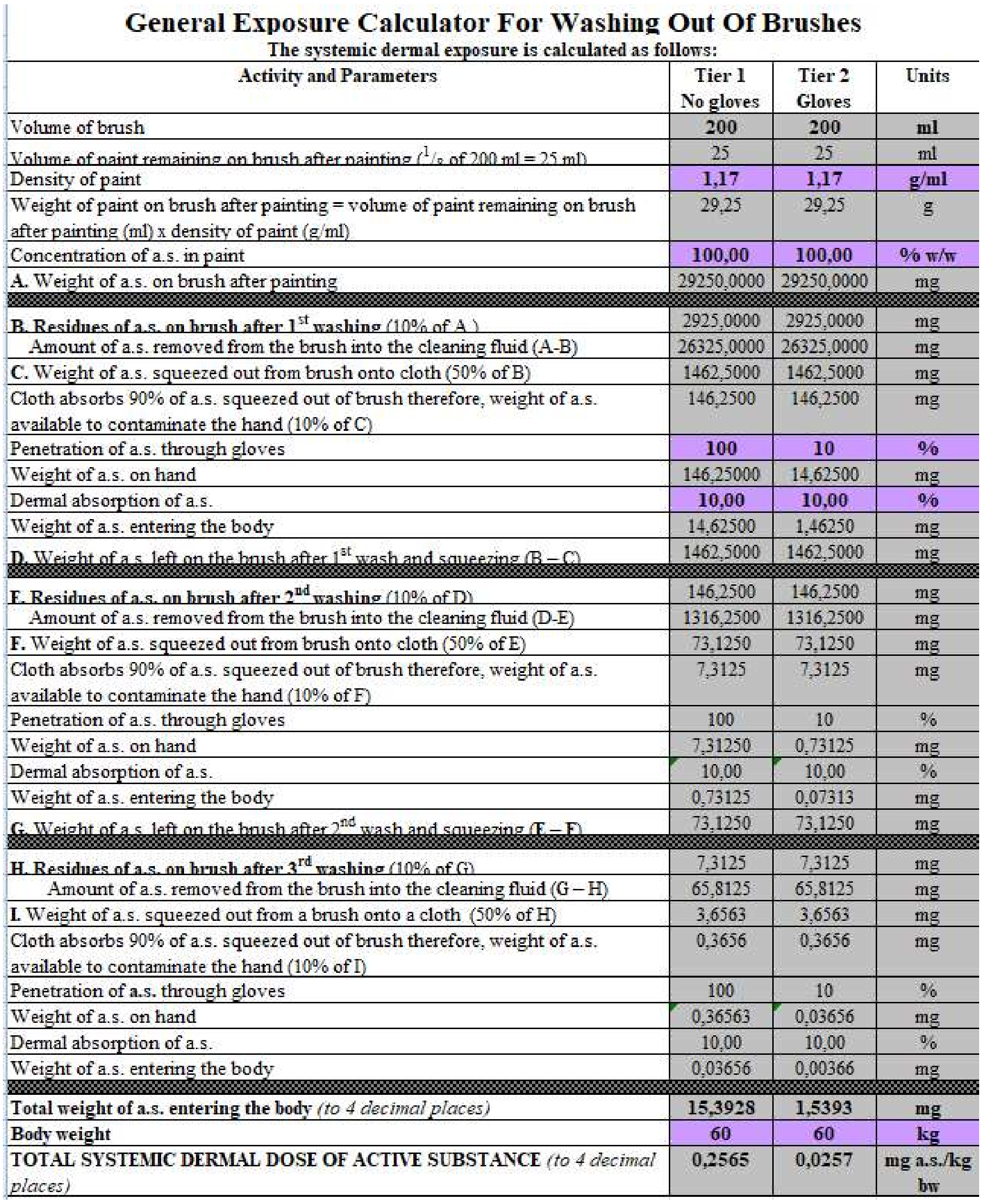
Tier 1. No RPE, PPE protection: Coated coverall 90%, gloves 90%
Tier 2. RPE protection 90%, PPE protection: Impermeable coverall 95%, gloves 90%

Brushing application according to scenario's parameters.

	units	**Tier 1**	**Tier 2**
Active substance	%	100	
Body weight	kg	60	
Dermal penetration rate	%	10	
Potential dermal exposure			
Potential hand exposure			
Indicative value[1]	mg/m^2	0.5417	
Application area[1]	m^2	31.6	
Potential hand deposit	**mg**	**1712**	
Penetration through gloves[3]	%	10	10
Actual hand deposit	**mg**	**171.2**	**171.2**
Potential body exposure			
Indicative value[1]	mg/m^2	0.2382	
Application area[1]	m^2	31.6	
Potential body deposit	**mg**	**753**	
Clothing penetration[3]	%	10	5
Actual body deposit	**mg**	**75.3**	**37.65**
Total dermal deposit	mg	246.5	208.9
Penetration through skin	mg	24.65	20.89
Exposure via dermal route	**mg/kg bw/d**	**0.411**	**0.348**
Inhalation exposure			
Indicative value[2]	mg/m^3	0.135	
Duration[1]	min	240	
Inhalation rate[1]	m^3/min	0.021	
Assigned protection factor		No protection	10
Inhaled a.s.	**mg**	**0.68**	**0.068**
Exposure via inhalation	**mg/kg bw/d**	**0.0113**	**0.00113**
Total systemic exposure	**mg/kg bw/d**	**0.422**	**0.3492**
Corr T25	mg/kg bw/d	105	
MoE		**248.8**	**300**

Brushing application according to applicant's parameters

	units	Tier 1	Tier 2
Active substance	%	100	
Body weight	kg	60	
Dermal penetration rate	%	10	
Potential dermal exposure			
Potential hand exposure			
Indicative value[1]	mg/m^2	0.5417	
Application area[2]	m^2	25	
Potential hand deposit	**mg**	**1354**	
Penetration through gloves[3]	%	10	10
Actual hand deposit	**mg**	**135.4**	**135.4**
Potential body exposure			
Indicative value[1]	mg/m^2	0.2382	
Application area[2]	m^2	25	
Potential body deposit	**mg**	**615.5**	
Clothing penetration[3]	%	10	5
Actual body deposit	**mg**	**61.55**	**30.78**
Total dermal deposit	mg	196.95	166.2
Penetration through skin	mg	19.7	16.62
Exposure via dermal route	**mg/kg**	**0.328**	**0.277**
Inhalation exposure			
Indicative value[2]	mg/m^3	0.135	
Duration[2]	min	420	
Inhalation rate[1]	m^3/min	0.021	
Assigned protection factor		No protection	10
Inhaled a.s.	**mg**	**1.191**	**0.1191**
Exposure via inhalation	**mg/kg**	**0.02**	**0.002**
Total systemic exposure	**mg/kg**	**0.348**	**0.279**
Corr T25	mg/kg bw/d	105	
MoE		**301.7**	**376.3**



General Exposure Calculator For Washing Out Of Brushes

The systemic dermal exposure is calculated as follows:

Activity and Parameters	**Tier 1** **No gloves**	**Tier 2** **Gloves**	**Units**
Volume of brush	**200**	**200**	**ml**
Volume of paint remaining on brush after painting ($^{1}/_{8}$ of 200 ml = 25 ml)	25	25	ml
Density of paint	**1,17**	**1,17**	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	29,25	29,25	g
Concentration of a.s. in paint	**100,00**	**100,00**	**% w/w**
A. Weight of a.s. on brush after painting	29250,0000	29250,0000	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	2925,0000	2925,0000	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	26325,0000	26325,0000	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	1462,5000	1462,5000	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of C)	146,2500	146,2500	mg
Penetration of a.s. through gloves	**100**	**10**	**%**
Weight of a.s. on hand	146,25000	14,62500	mg
Dermal absorption of a.s.	**10,00**	**10,00**	**%**
Weight of a.s. entering the body	14,62500	1,46250	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	1462,5000	1462,5000	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	146,2500	146,2500	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	1316,2500	1316,2500	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	73,1250	73,1250	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of F)	7,3125	7,3125	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	7,31250	0,73125	mg
Dermal absorption of a.s.	10,00	10,00	%
Weight of a.s. entering the body	0,73125	0,07313	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (E – F)	73,1250	73,1250	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	7,3125	7,3125	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	65,8125	65,8125	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	3,6563	3,6563	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of I)	0,3656	0,3656	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0,36563	0,03656	mg
Dermal absorption of a.s.	10,00	10,00	%
Weight of a.s. entering the body	0,03656	0,00366	mg
Total weight of a.s. entering the body *(to 4 decimal places)*	**15,3928**	**1,5393**	**mg**
Body weight	**60**	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE *(to 4 decimal places)*	**0,2565**	**0,0257**	**mg a.s./kg bw**