# Assimilated Regulation (EU) No 528/2012 (the GB Biocidal Products Regulation (GB BPR))

Evaluation of active substances

Renewal of approval

## Competent Authority Report

**Creosote**

**PT8**

Great Britain

CM: 2025/132508

November 2025

## Summary

| | |
|---|---|
| **Substance name** | Creosote |
| **CAS number** | 8001-58-9 |
| **EC number** | 232-287-5 |
| **Applicant** | Creosote Council Europe c/o REACH for Coal Chemicals (R4CC) |

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## 1. Statement of subject matter or purpose

### *Principles*

This assessment report describes the evaluation of the active substance creosote in product type 8 (wood preservatives) carried out for the possible renewal of the approval under assimilated Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (referred to in this document as 'GB BPR').

The conclusions of this assessment report shall be taken into account when evaluating creosote-based products under GB BPR. However, the data protection principles of GB BPR apply.

Where conclusions of this assessment report are based on data protected under GB BPR, they may only be used for the benefit of another applicant if the data owner has granted access to that applicant.

### *Roles*

Regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 appoints competent authorities for the purposes of Article 81 of GB BPR. These are, respectively, the Secretary of State (as regards England), the Scottish Ministers (as regards Scotland) and the Welsh Ministers (as regards Wales).

The Health and Safety Executive (HSE) acts on behalf of the competent authorities through agency agreements which came into force on 12 February 2021.

### *Background*

Creosote was first approved as an existing active substance in product type 8 for a period of 5 years under Commission Directive 2011/71/EU and included in Annex I of the Biocidal Products Directive (Commission Directive 98/8/EC) on 1 May 2013. This decision is supported by the assessment report from 2010 and will be referenced within this evaluation as 'original approval of creosote (2010)'.

The renewal of the approval was requested by the Creosote Council Europe on 27 October 2016.

On 14 February 2017, the European Chemicals Agency (ECHA) released the creosote dossier to HSE as the evaluating competent authority on behalf of the EU.

HSE accepted the dossier as complete for the purpose of the evaluation on 17 May 2017.

On the basis of the available information, HSE decided that a full evaluation of the application was necessary under Article 14(2). HSE informed the Commission of this decision on 14 July 2017. The Commission postponed the expiry date of approval of creosote from 30 April 2018 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).

On 14 March 2019, HSE submitted a copy of the draft renewal CAR to ECHA and the applicant.

An e-consultation was conducted in the Environment Working Group (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). HSE updated the draft renewal CAR to reflect the outcome and submitted the new draft to ECHA on 16 September 2019.

The UK left the EU on 31 January 2020 and began operating an independent regime for regulating biocides – GB BPR – following the end of the Transition Period on 31 December 2020. Any EU decisions that came into force during the Transition Period applied to the UK.

The EU continued to progress the renewal evaluation of creosote during the Transition Period, with a new evaluating competent authority (Poland), and the Commission decided to further postpone the expiry date of approval from 31 October 2020 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, 16.7.2020).

Under the transitional arrangements established by GB BPR, the Creosote Council Europe resubmitted their application for the renewal of creosote to HSE on 24 March 2021.

In October 2021, with the consent of the Devolved Governments, the Secretary of State decided to postpone the expiry date of approval of creosote in GB from 31 October 2021 to 24 July 2023 while HSE considered the priorities of the approximately 400 resubmitted active substance/product type combination applications within a wider programme of work.

Further to the additional data submitted to HSE by the applicant on 19 May 2022, on 14 November 2022, HSE contacted the applicant to request any further information/data that they considered would be relevant to completing the GB evaluation.

On 9 December 2022, the applicant submitted additional information and the application was considered ready to resume on 13 February 2023.

Technical difficulties with the IUCLID dossier delayed the continuation of the evaluation until July 2023.

In July 2023, with the consent of the Devolved Governments, the Secretary of State decided to further postpone the expiry date of approval of creosote from 24 July 2023 to 13 February 2025, following an assessment of the time needed to complete the remaining areas of the evaluation.

As creosote meets the exclusion criteria in Article 5(1) of GB BPR, the approval may only be renewed if any of the conditions in Article 5(2) are met. Additionally, creosote is

a candidate for substitution under Article 10(1). Under Article 10(3) HSE must consult on candidates for substitution and gather information on the availability of suitable and sufficient alternatives.

HSE launched a consultation on 24 September 2024 to gather information on the availability of suitable and sufficient alternatives and to determine if the conditions in Article 5(2) are still satisfied for each of the proposed uses of creosote. The consultation closed on 24 November 2024. The results of the consultation are published on the HSE website.

To allow sufficient time for the significant consultation response to be carefully analysed and for an opinion on the renewal of creosote to be developed, the Secretary of State, with consent from the Devolved Governments, decided to postpone the expiry date of approval from 13 February 2025 to 31 March 2026.

The final draft of the evaluation was peer reviewed across UK government departments between 20 June 2025 and 24 July 2025, ahead of preparing the final opinion.

# 2. Conclusion

## *2.1. Conclusions of the technical assessment*

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

This evaluation covers the use of creosote in product type 8.

The current mandatory classification and labelling for creosote according to assimilated Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (referred to in this document as GB CLP) is:

| | |
|---|---|
| **Hazard Class and Category Codes** | Carc. 1B, H350 |

***Labelling***

| | |
|---|---|
| **Pictogram codes** | GHS08 |
| **Signal Word** | Danger |
| **Hazard Statement Codes** | H350: May cause cancer |

***Specific concentration limits, M-Factors***

None

The (proposed) classification and labelling for creosote according to GB CLP is:

***(Proposed) Classification according to GB CLP***

| | |
|---|---|
| **Hazard Class and Category Codes** | Carc. 1B, H350<br>Repr. 1B, H360F<br>Repr. 2, H361d<br>Skin Sens. 1, H317<br>Skin Irrit. 2, H315<br>Eye Irrit. 2, H319<br>Aquatic Acute 1, H400 (M=1)<br>Aquatic Chronic 1, H410 (M=10) |

***Labelling***

| | |
|---|---|
| **Pictogram codes** | GHS07<br>GHS08<br>GHS09 |
| **Signal Word** | Danger |
| **Hazard Statement Codes** | H350: May cause cancer<br>H360Fd: May damage fertility. Suspected of damaging the unborn child<br>H315: Causes skin irritation<br>H317: May cause an allergic skin reaction<br>H319: Causes serious eye irritation.<br>H410: Very toxic to aquatic life with long lasting effects |

***Specific concentration limits, M-Factors***

M = 10

***Justification for the proposal***

The additional classification over and above that for carcinogenicity in the mandatory entry for effects on fertility, developmental toxicity, skin and eye irritation, skin sensitisation and aquatic environment is based on the evaluation of the available data performed for the purpose of the first approval under Directive 98/8/EC. No new information has become available since the original approval to justify a change in the proposal.

**b) Intended uses**

- 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 3 (UC3) according to EN Standard 335.

- Pressure impregnation: Preventive treatment of wood to be used as wood poles for overhead electricity and telecommunication, foundation timbers for wood poles, agricultural fencing, equestrian fencing, industrial and highways fencing, hop poles, industrial landscape retaining timbers, tree support posts (fruit, vineyards). Use class 4 (UC4) according to EN Standard 335.

- Pressure impregnation: Preventive treatment of wood to be used for marine installations. Use class 5 (UC5) according to EN standard 335.

- Surface treatment: Treatment of creosote impregnated wood (UC3 and UC4) 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).

- 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) UC4.

The specific use classes are defined as:

UC3: 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 (e.g., cladding, fence rails).

UC4: Situation in which the wood or wood-based product is in contact with the ground (UC 4a) or fresh water (UC 4b) and thus is permanently exposed to wetting (e.g., fence posts, decking in contact with soil).

UC5: Situation in which the wood or wood-based product is permanently exposed to sea water (e.g., marine piling, dock gates).

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

***Human health***

The table below summarises the exposure scenarios assessed.

| Scenario | Primary or secondary exposure and description of scenario | Exposed group | Conclusion |
|---|---|---|---|
| 1 | Vacuum/pressure treatment application.<br><br>Primary exposure –Application of Creosote to timber using solvent-based vacuum/pressure impregnation process | Industrial | Unacceptable risk |
| 2 | Hot and cold Impregnation<br><br>Primary exposure – automated dipping | Industrial | Unacceptable risk |
| 3 | Cleaning out dipping equipment<br><br>Primary exposure - cleaning out dipping tank, after use | Industrial | Unacceptable risk |
| 4 | Handling wet treated wood<br><br>Primary exposure - during handling of wet treated wood | Industrial | Unacceptable risk |
| 5 | Brush application<br><br>Primary exposure – Brush application (outdoors) | Professionals | Unacceptable risk |
| 6 | Cleaning paint brush<br><br>Primary exposure – Cleaning brush after application | Professionals | Unacceptable risk |

| Scenario | Primary or secondary exposure and description of scenario | Exposed group | Conclusion |
|---|---|---|---|
| 7 | Cutting/Sanding treated wood<br><br>Secondary exposure – Sanding surface of treated wood | Professionals | Unacceptable risk |
| 8 | Cutting/Sanding treated wood<br><br>Secondary exposure – Sanding surface of treated wood | General Public | Unacceptable risk |
| 9 | Laundering work clothes<br><br>Secondary exposure – Cleaning contaminated work clothes at home (following brush treatment) | General public | Unacceptable risk |
| 10 | Dermal and ingestion exposure from contact with treated wood<br><br>Secondary exposure [adult and toddler – contact treated poles or equestrian fences] | General public | Unacceptable risk |
| 11 | Inhalation volatilised residues<br><br>Secondary exposure –<br><br>Inhalation of volatilised residues indoors | General public | Unlikely to occur – Not considered |
| 12 | Exposure to livestock from agricultural fencing treated with creosote. | General public | Unacceptable risk |
| 13 | Evaluation of residues in fruit trees and consumer risk assessment | General public | Unacceptable risk |

***Overall conclusion***

Exposure from all the individual industrial and professional scenarios significantly exceeds the current DMEL and still exceeds when appropriate risk management measures (RMM'S) have been included. Whilst it can be assumed more than one task resulting in exposure could be completed in a working day this would be advised against because of the risk of exposure from the individual exposure assessments.

The risk for general public secondary exposure is demonstrated to be unacceptable for all scenarios.

The assessment of animal (livestock) exposure concludes that dietary intakes could be significant. In order to fully assess risks to livestock, an animal feeding study would be required (please consult HSE before setting up a study) and concurrently, data on a validated method of analysis must be generated. The data submission to meet this requirement should provide full details of the analytical method with suitable acceptable validation data (including recovery rates and the limit of quantification and detection for the active substance and residues), in relevant livestock matrices.

Regarding the proposed use of creosote on wooden posts used as supports for fruit trees (or other supports for food crops such as hops or grapevines) harmful effects on human health cannot be excluded.

***Environment***

The table below summarises the exposure scenarios assessed.

| **Scenario** | **Description of scenario including environmental compartments** | **Conclusion** |
|---|---|---|
| 1 – Use Class 3 - House | UC 3: pressure impregnation: Preventive treatment of wood according to EN Standard 335. This scenario is representative of non-residential cladding.<br><br>Wood above ground / not in contact with soil.<br><br>Relevant environmental compartments:<br><br>Soil and groundwater | Acceptable risk to soil (note that a marginal failure of tier 1 PEC/PNEC ratio for soil was derived based on the whole house scenario (**1.05**) and this is likely to be protective of non-residential cladding).<br><br>Acceptable risk to groundwater (based on higher tier modelling). |

| Scenario | Description of scenario including environmental compartments | Conclusion |
|---|---|---|
| 1 – Use Class 3 - Fence | UC 3: pressure impregnation: Preventive treatment of wood according to EN Standard 335. This scenario is representative of fencing (ie agricultural, equestrian etc) and cladding for non-residential buildings.<br><br>Wood above ground / not in contact with soil.<br><br>Relevant environmental compartments:<br><br>Soil and groundwater | Acceptable risks to soil.<br><br>Acceptable risk to groundwater (based on higher tier modelling). |
| 1 – Use Class 3 – Railway sleeper | UC 3: pressure impregnation: Preventive treatment of wood according to EN Standard 335.<br><br>Wood above ground / not in contact with soil.<br><br>Relevant environmental compartments:<br><br>Groundwater | Acceptable risk to groundwater (based on higher tier modelling). |
| 1 – Use Class 3 – Noise Barrier | UC 3: pressure impregnation: Preventive treatment of wood according to EN Standard 335.<br><br>Wood above ground / not in contact with soil.<br><br>Relevant environmental compartments:<br><br>STP | Acceptable risk to STP organisms. |

| Scenario | Description of scenario including environmental compartments | Conclusion |
|---|---|---|
| 1 – Use Class 3 – Bridge over pond | UC 3: pressure impregnation: Preventive treatment of wood according to EN Standard 335.<br><br>Wood above ground / not in contact with soil or water.<br><br>Relevant environmental compartments:<br><br>Surface water and sediment | Unacceptable risk to surface water.<br><br>Acceptable risk to sediment. |
| 2 – Use Class 4a – Transmission pole | UC 4a: pressure impregnation: Preventive treatment of wood according to EN Standard 335.<br><br>Wood in contact with soil.<br><br>Relevant environmental compartments:<br><br>Soil and groundwater | Unacceptable risk to soil and groundwater (tier 1 screening only – refinement with FOCUS modelling likely to resolve groundwater risk). |
| 2 – Use Class 4a – Fence posts | UC 4a: pressure impregnation: Preventive treatment of wood according to EN Standard 335.<br><br>Wood in contact with soil.<br><br>Relevant environmental compartments:<br><br>Soil and groundwater | Unacceptable risk to soil and groundwater (tier 1 screening only - refinement with FOCUS modelling likely to resolve groundwater risk). |

| Scenario | Description of scenario including environmental compartments | Conclusion |
|---|---|---|
| 2 – Use Class 4a – Vineyard stakes | UC 4a: pressure impregnation: Preventive treatment of wood according to EN Standard 335.<br><br>Includes 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)<br><br>Wood in contact with soil.<br><br>Relevant environmental compartments:<br><br>Soil and groundwater | Unacceptable risk to soil and groundwater (tier 1 screening only - refinement with FOCUS modelling likely to resolve groundwater risk). |
| 3 – Use Class 4b – Jetty on a lake | UC 4b: pressure impregnation: Preventive treatment of wood according to EN Standard 335.<br><br>Wood in contact with freshwater.<br><br>Relevant environmental compartments:<br><br>Surface water and sediment | Unacceptable risk to surface water.<br><br>Acceptable risk to sediment (considering TWA approach). |
| 3 – Use Class 4b – Sheet piling | UC 4b: pressure impregnation: Preventive treatment of wood according to EN Standard 335.<br><br>Wood in contact with freshwater.<br><br>Relevant environmental compartments:<br><br>Surface water and sediment | Unacceptable risk to surface water and sediment. |

| Scenario | Description of scenario including environmental compartments | Conclusion |
|---|---|---|
| 4 – Use Class 5 – Harbour wharf | UC 5: pressure impregnation: Preventive treatment of wood according to EN Standard 335.<br><br>Wood in contact with marine water<br><br>Relevant environmental compartments:<br><br>Marine water and marine sediment | Unacceptable risk to marine water and marine sediment. |

***Overall conclusion***

Unacceptable risks have been identified in scenarios representing UC 4a (wood in contact with soil), UC 4b (wood in contact with freshwater) and UC 5. Some uses in UC 3 where timbers are not in contact with ground/soil can be considered as acceptable (such as potential application to non-residential cladding, fencing, railways sleepers and noise barriers) based on standard quantitative methods of environmental risk assessment. Note that no scenario directly representative of environmental barriers or industrial landscape retaining timbers is described in the PT8 Emission Scenario Document. But since these uses are likely to involve contact with soil and be classed as UC4a, unacceptable risks can be assumed based on the results of the other UC4a scenarios summarised above.

Due to unacceptable risks in and near water the following risk mitigation phrase is recommended:

*The biocidal product may only be applied to timber which will not be used above or adjacent to surface waters (with the exception of railway sleepers)*.

Application to railways sleepers is not expected to give rise to contamination of the soil compartment (as the ground under tracks is considered to be a technosphere) or surface water bodies (due to design of track on or near bridges preventing direct emissions). Groundwater is the only environmental scenario assessed for uses on railway sleepers according to the ESD.

Note that unacceptable risks to groundwater for all relevant scenarios was demonstrated on the basis of the standard tier 1 porewater screening approach. Acceptable refined assessments using the higher tier FOCUS PEARL 4.4.4. model were available for the UC3 house (and by read across the fence scenario) and railway sleeper scenarios. Based on the scale of soil exposure, similar FOCUS modelling would be expected to resolve the tier 1 porewater risks for all UC4 scenarios.

Therefore risks to groundwater may be considered acceptable. However creosote may be referred to as a dense non-aqueous phase liquid (DNAPL). These chemicals are

immiscible in water, but also more dense than water and may be prone to vertical transport through subsurface soil layers and into groundwater, depending on the quantity released and the residual capacity of the soil. The standard higher tier groundwater model recommended for biocide assessments (FOCUS PEARL 4.4.4) is based on the assumption of equilibrium partitioning between the substance and the soil organic carbon content, and simulates more classical leaching via chromatographic flow. The assumptions in the FOCUS models are not necessarily appropriate for complex mixtures of DNAPL chemicals such as creosote. In the absence of alternative models that may be better able to simulate the leaching risk of creosote, the standard FOCUS modelling approach has been applied. However HSE notes the validity of the modelling in this case is subject to a degree of uncertainty.

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, it can be assumed that storage places are sealed to prevent any direct release to the environment (local waterways, STP and ground). This is likely to be particularly important to mitigate risks to groundwater from large scale losses to soil at treatment sites. Labelling and associated literature 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). Any losses of the product must be collected for reuse or disposal as hazardous waste in accordance with local requirements.*

In addition with regards handling of freshly treated timber labelling and associated literature must state the following:

*Freshly treated timber must 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 must be collected for reuse or disposal as hazardous waste in accordance with local requirements.*

In addition, calculations have not been carried out to assess environmental risks from application by brush treatment of wood components used in UC 3 and UC 4 that have been modified (e.g. cut) after standard vacuum pressure treatment. According to the OECD ESD (2013), during brush application in situ any product losses due to spills and drips will likely end-up in the soil compartment, if soil is not protected with an appropriate impermeable covering. Therefore labelling and associated literature must also state the following:

*During in situ brush application treatments, the soil adjacent to the treated surface must be protected with an impermeable cover and any spillage should be collected to avoid emissions to soil and disposed of as hazardous waste in accordance with local requirements.*

Finally, it should be noted that creosote is a UVCB substance containing PBT and vPvB constituents. As such, the standard quantitative approach to environmental risk assessment may not provide sufficient confidence that the environmental compartments are adequately protected and the presence of PBT and vPvB constituents leads to

additional uncertainty in the estimation of risks to the environment. Therefore, based on the currently available risk assessment methodologies it cannot be demonstrated that there are no unacceptable effects to the environment for any of the proposed uses.

## 2.2. Exclusion, substitution and POP criteria

### 2.2.1. Exclusion and substitution criteria

The tables below summarise the relevant information with respect to the assessment of exclusion and substitution criteria:

***CMR properties***

| Property | Conclusions |
|---|---|
| Carcinogenicity (C) | Carc. 1B (H350) (mandatory classification under GB CLP) |
| Mutagenicity (M) | No classification required |
| Toxic for reproduction (R) | Repr. 1B (H360F) and 2 (H361d) (proposed) |

Creosote fulfils criteria (a) and (c) of Article 5(1) and criteria (a) of Article 10(1).

***PBT and vPvB properties***

| Property | Conclusions |
|---|---|
| Persistent (P) or very Persistent (vP) | Creosote is described as a substance containing P constituents |
| Bioaccumulative (B) or very Bioaccumulative (vB) | Creosote is described as a substance containing B constituents |
| Toxic (T) | Creosote is described as a substance containing T constituents |

Creosote fulfils criterion (e) of Article 5(1) and criteria (a) and (d) of Article 10(1).

No new information has been made available as part of the creosote renewal application. Therefore creosote should still be described as a substance containing

PBT constituents as concluded in the original approval of creosote (2010).

### *Endocrine disrupting properties*

No additional endocrine disruption (ED) data has been submitted as part of this renewal.

In terms of human health, creosote is classified in the mandatory list for carcinogenicity 1B (H350) and it therefore meets one of the exclusion criteria specified in Article 5 of the GB BPR, for which a non-threshold approach has been assumed. As a result, any potential endocrine effects that may be identified through submission of new data, would not be expected to affect the regulatory outcome, including the risk assessment. Similarly, identification of potential endocrine effects is unlikely to have a significant impact on the socioeconomic assessment. This is because the carcinogenic properties and associated risks are likely to dominate any negative impacts associated with any continued use of creosote under Article 5(2)(c).

Any additional risks associated with potential ED properties are likely to be small by comparison. This is because firstly, to the extent that the ED properties are typically associated with reprotoxicity effects, any associated monetised impacts will be much smaller relative to the carcinogenic impacts. Furthermore, as carcinogenicity is the leading health effect used for the risk characterisation of creosote and as no threshold is assumed for this effect, the carcinogenic risks associated with any exposures will always be greater than any ED risks for which thresholds of effects can be postulated. Finally, minimisation of the carcinogenic risks of creosote in the risk assessment most likely will lead to acceptable ED risks.

From an ecotoxicology perspective, insufficient data are available to conclude on the ED potential of creosote with regards to wild mammals, birds, reptiles, fish or amphibians. However, as above, any potential endocrine effects that may be identified via submission of new data, noting that the data required to conclude on ED activity/adversity constitutes vertebrate data, would not affect the overall outcome based on the concerns over carcinogenicity for human health.

Therefore, HSE do not consider it appropriate to request further information regarding endocrine disrupting properties.

Overall, no conclusion can be made on the endocrine disrupting properties of creosote, and therefore, no conclusion can be made on whether creosote fulfils criterion (d) of Article 5(1).

### *Respiratory sensitisation properties*

Creosote does not fulfil criteria (b) of Article 10(1).

No classification required.

### *Concerns linked to critical effects*

Creosote does fulfil criterion (e) of Article 10(1). It is a non-threshold carcinogen, so there are concerns for human health even when applying restrictive risk mitigation measures.

***Proportion of non-active isomers or impurities***

Not applicable to a UVCB substance. Creosote does not fulfil criterion (f) of Article 10(1).

***Overall conclusion***

Consequently, the following is concluded:

Creosote does meet the exclusion criteria laid down in Article 5(1)(a), (c) and (e) of GB BPR.

Creosote does meet the conditions laid down in Article 10(1)(a), (d) and (e) of GB BPR and is therefore considered as a candidate for substitution.

The assessment of whether creosote meets the substitution criteria has not included consideration of Article 10(1)(c) as not all of the existing active substances in product type 8 have yet been assessed for approval. This follows the principles in CA-Nov14-Doc.4.4 - Final - Further guidance on Art10(1).

*2.2.2. POP criteria*

In the absence of confirmation that all major components of creosote rapidly degrade in air so do not have the potential for long range transport, it may be prudent to consider the active as a substance *potentially* containing POP constituents. HSE acknowledges that this approach is precautionary in the absence of scientific certainty over the presence of POP constituents.

## *2.3. Requirement for further information*

Sufficient data have been submitted to conclude on the evaluation. The following requirements have been identified where additional data would be required for specific uses or future renewals.

These requirements for further information are based on the full technical evaluation. The final requirements linked to the overall renewal decision will be provided in the HSE GB opinion.

**Information requirements annex points 2.9, 2.10 and 2.11 (of GB BPR Annex II, Title 1)**

The specification of creosote should be re-considered at the next renewal.

**Information requirements annex points 5.2.1 (of GB BPR Annex II, Title 1)**

Validation data in accordance with Guidance on the BPR: Volume I Parts A+B+C for the method of analysis proposed as a monitoring method for the determination of residues in soil must be submitted. Validation data must be provided for the soil matrix. The method should be validated for a suitable number of creosote components (and/or metabolites) linked to a proposed residue definition.

These data are to be made available no later than 2 years after the renewal if creosote is renewed.

**Information requirements annex points 5.2.3 (of GB BPR Annex II, Title 1)**

Validation data in accordance with Guidance on the BPR: Volume I Parts A+B+C for the method of analysis proposed as a monitoring method for the determination of residues in water and sediment must be submitted. Validation data must be provided for the matrices sediment, marine water and marine sediment. The method should be validated for a suitable number of creosote components (and/or metabolites) linked to a proposed residue definition.

These data are to be made available no later than 2 years after the renewal date if creosote is renewed and there is expected exposure based on the renewed uses.

**Information requirements annex points 5.3 and 8.16 (of GB BPR Annex II, Title 1)**

If any of the uses; treatment of wood to be used as hop poles and tree support posts (fruit, vineyards), agricultural and equine fencing, are renewed the following data requirement would be required to be set.

The assessment of animal (livestock) exposure concludes that dietary intakes would be significant. In order to fully assess risks to livestock, an animal feeding study would be required (please consult HSE before setting up a study) and concurrently, data on a validated method of analysis must be generated. The data submission to meet this requirement should provide full details of the analytical method with suitable acceptable validation data (including recovery rates and the limit of quantification and detection for the active substance and residues), in relevant livestock matrices.

These data are to be made available for the next renewal assessment if creosote is renewed and the agricultural fencing uses are part of any onward approval.

**Information requirements annex points 5.3 (of GB BPR Annex II, Title 1)**

If the use; treatment of wood to be used as hop poles and tree support posts (fruit, vineyards) is renewed the following data requirement would be required to be set.

Sufficient residues data have been provided to enable an assessment of the exposure of the active substance in fruit trees; based on this a residue definition for risk assessment and for compliance and/or monitoring is not proposed and new MRLs are not being recommended at this time. The indicative dietary risk assessment (section A.6) shows high dietary intakes (exceedances) versus the reference value used for indicative chronic and acute dietary risk assessment. If there was a creosote use for plant based food exposure scenarios, there would be requirement for data on a validated monitoring method. The data submission to meet this requirement should provide full details of the analytical method with suitable acceptable validation data (including recovery rates and the limit of quantification and detection for the active substance and residues), in relevant plant matrices. HSE has provided details of a consideration of what a future monitoring method in food might cover in terms of residue definition, although a recommendation is not being made at this time (section

A.2).

These data are to be made available no later than 6 months after the renewal date if creosote is renewed and the treatment of wood to be used as hop poles and tree support posts (fruit, vineyards) uses continue.

# 3. Assessment Report

## 3.1. Summary presentation of the active substance

### 3.1.1. Identity of the active substance

***Main constituents***

| | |
|---|---|
| **ISO name** | Creosote |
| **IUPAC name** | Creosote |
| **CAS number** | 8001-58-9 |
| **EC number** | 232-287-5 |
| **Index number in Annex VI of GB CLP** | 648-101-00-4 |
| **Minimum purity / content** | Not applicable to a UVCB substance.<br><br>Specification for creosote is based on the criteria in European Standard EN 13991:2003 |
| **Structural formula** | Not applicable to an UVCB substance |

### 3.1.2. Intended uses and effectiveness

***Use of the active substance***

- 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 3 (UC3) according to EN Standard 335.

- Pressure impregnation: Preventive treatment of wood to be used as wood poles for overhead electricity and telecommunication, foundation timbers for wood poles, agricultural fencing, equestrian fencing, industrial and highways fencing, hop poles, industrial landscape retaining timbers, tree support posts (fruit, vineyards). Use class 4 (UC4) according to EN Standard 335.

- Pressure impregnation: Preventive treatment of wood to be used for marine installations. Use class 5 (UC5) according to EN standard 335.

- Surface treatment: Treatment of creosote impregnated wood (UC3 and UC4) 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).

- 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) UC4.

***Effectiveness of the active substance***

| | |
|---|---|
| **Function** | A PT8 active used to prevent the destruction of softwood and hardwood by wood rotting fungi, soft rot fungi and wood destroying marine organisms. For use classes 3, 4 and 5. |
| **Organisms to be controlled** | Wood rotting basidiomycetes (brown rot and white rot fungi)<br><br>Soft rot fungi<br><br>Wood destroying marine organisms |
| **Limitation of efficacy including resistance** | Resistance management strategies proposed at product level |
| **Mode of action** | Creosote has antimicrobial, antifungal and insecticidal properties. Generally, the mode of action involves disrupting cellular processes and damaging cell membranes |

*3.1.3. Classification and labelling*

3.1.3.1. Classification and labelling for the active substance

***Physical hazards***

No applicable physical hazards identified.

***Human health hazards***

| Hazard class / property | Proposed classification |
|---|---|
| Acute toxicity via oral route | None |
| Acute toxicity via dermal route | None |
| Acute toxicity via inhalation route | None |
| Skin corrosion / irritation | Skin Irrit. 2, H315 |
| Serious eye damage / eye irritation | Eye Irrit. 2, H319 |
| Respiratory sensitisation | None |
| Skin sensitisation | Skin Sens. 1, H317 |
| Germ cell mutagenicity | None, inconclusive |
| Carcinogenicity | Carc. 1B, H350 |
| Reproductive toxicity | Repr 1B, H360Fd |
| Specific target organ toxicity-single exposure | None |
| Specific target organ toxicity-repeated exposure | None |

| Hazard class / property | Proposed classification |
|---|---|
| Aspiration hazard | None |

***Environmental hazards***

| Hazard class / property | Proposed classification |
|---|---|
| Hazardous to the aquatic environment | H400 – Aquatic acute 1 (M=1)<br>H410 – Aquatic chronic 1 (M=10) |
| Hazardous to the ozone layer | None |

***Current classification according to GB CLP***

| Hazard class and category | Hazard statements |
|---|---|
| Carc. 1B | H350: May cause cancer |

***Current labelling according to GB CLP***

| Pictograms | Signal word | Hazard statements | Supplementary hazard statements |
|---|---|---|---|
| GHS08 | Danger | May cause cancer | None |

***Proposed classification according to GB CLP***

| Hazard class and category | Hazard statements |
|---|---|
| Carc. 1B, H350<br>Repr. 1B, H360F<br>Repr. 2, H361d<br>Skin Sens. 1, H317<br>Skin Irrit. 2, H315<br>Eye Irrit. 2, H319<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 | H350: May cause cancer<br>H360Fd: May damage fertility. Suspected of damaging the unborn child<br>H315: Causes skin irritation<br>H317: May cause an allergic skin reaction<br>H319: Causes serious eye irritation.<br>H410: Very toxic to aquatic life with long lasting effects |

***Proposed labelling according to GB CLP***

| Pictograms | Signal word | Hazard statements | Supplementary hazard statements |
|---|---|---|---|
| GHS07<br>GHS08<br>GHS09 | Danger | H350: May cause cancer<br>H360Fd: May damage fertility. Suspected of damaging the unborn child<br>H315: Causes skin irritation<br>H317: May cause an allergic skin reaction<br>H319: Causes serious eye irritation.<br>H410: Very toxic to aquatic life with long lasting effects | None |

3.1.3.2. Classification and labelling for the representative product(s)

The representative product is identical to the active substance.

***Proposed classification according to GB CLP***

| Hazard class and category | Hazard statements |
|---|---|
| Carc. 1B, H350<br>Repr. 1B, H360F<br>Repr. 2, H361d<br>Skin Sens. 1, H317<br>Skin Irrit. 2, H315<br>Eye Irrit. 2, H319<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 | H350: May cause cancer<br>H360Fd: May damage fertility. Suspected of damaging the unborn child<br>H315: Causes skin irritation<br>H317: May cause an allergic skin reaction<br>H319: Causes serious eye irritation.<br>H410: Very toxic to aquatic life with long lasting effects |

***Proposed labelling according to GB CLP***

| Pictograms | Signal word | Hazard statements | Supplementary hazard statements |
|---|---|---|---|
| GHS07<br>GHS08<br>GHS09 | Danger | H350: May cause cancer<br>H360Fd: May damage fertility. Suspected of damaging the unborn child<br>H315: Causes skin irritation<br>H317: May cause an allergic skin reaction<br>H319: Causes serious eye irritation.<br>H410: Very toxic to aquatic life with long lasting effects | None |

***Packaging of the biocidal product***

| Type of packaging | Size / volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, general public) |
|---|---|---|---|---|
| Bulk container for transport by road, rail or sea | 250 - 700 000 L | Stainless steel | | Industrial / professional |

| Type of packaging | Size / volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, general public) |
|---|---|---|---|---|
| IBC container | 250 - 1000 L | Stainless steel | Chemical resistant sealing (Teflon or Vitron) | Industrial / professional |
| Drums | 25 - 250 L | Stainless steel | Steel | Industrial / professional |
| Cans | > 20 L | Metal cans | Steel | Industrial / professional |

## 4. Summary of the human health risk assessment

No new toxicological information has become available since the first approval. The conclusions from the original approval of creosote (2010) remain the same.

***Summary of the assessment of effects of human health***

| Endpoint | Brief description |
|---|---|
| Toxicokinetics | Oral absorption is rapid, but an accurate value could not be established. A value of 100% was assumed. A human dermal absorption value of 10% was estimated based on a weight-of-evidence approach. Information about the distribution and accumulation of creosote in tissues is scarce. The PAH components of creosote are oxidised to form epoxides which are subsequently hydrolysed or conjugated with glutathione. Excretion of 2-3 ring aromatic metabolites occurs mainly in urine, whilst excretion of 4-6 ring aromatic metabolites occurs mainly in faeces. |
| Acute toxicity | Creosote is of low acute toxicity by the oral, dermal and inhalation routes in rats |
| Corrosion and irritation | Based on animal data, creosote is a skin irritant and should be classified as Skin Irrit. 2 (H315). Based on human evidence, creosote is irritating to the eye and should be classified as Eye Irrit. 2 (H319) |
| Sensitisation | Creosote is a skin sensitiser based on a M & K guinea pig test and should be classified as Skin Sens. 1 (H317) |
| Repeated dose toxicity | In dermal and inhalation short-term toxicity studies, only mild effects were observed. No data via the oral route are available for this endpoint. |

| Endpoint | Brief description |
|---|---|
| Genotoxicity | Positive evidence in vitro, but inconclusive evidence in vivo. However, since creosote contains many genotoxic compounds, a non-threshold mechanism is assumed. |
| Carcinogenicity | Creosote is carcinogenic in animals. In a mouse dermal cancer bioassay, a dose-dependent increase in several tumour types was noted. The epidemiological data do not indicate an increased risk of cancer in creosote workers. Creosote is classified as Carc. 1B (H350) in the GB mandatory classification list. |
| Reproductive toxicity | Creosote caused post-implantation loss in rats and rabbits in presence of mild maternal toxicity. Classification with Repr. 2 (H361d) is proposed. Creosote also impaired fertility (reduction of live offspring, decrease in litter size and offspring viability) in a 2-generation study in the absence of significant parental toxicity. Classification with Repr. 1B (H360F) is proposed. |
| Neurotoxicity | Creosote has no neurotoxic potential. |
| Immunotoxicity | No specific data are available, but it is unlikely creosote has immunotoxic potential. |
| Disruption of the endocrine system | An assessment is not required since creosote already meets one of the exclusion criteria for approval for which a non-threshold approach is taken. |
| Other effects | No information available |

***Reference values***

Since creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded, AELs cannot be derived. A systemic DMEL (Derived Minimal Effect Level) for workers based on its carcinogenic effects has been established ((ECHA (2008): REACH Guidance on information requirements and chemical safety assessment, Chapter R.8). To facilitate a quantitative risk assessment for the consumer, an oral DMEL for the general population has been established by HSE. In addition, a systemic DMEL for the general public has also been established by HSE. This is detailed further in part C of this document.

| **Reference value** | **Study** | **NOAEL / LOAEL** | **Overall assessment factor** | **Value** |
|---|---|---|---|---|
| $AEL_{short\text{-}term}$ | NA | NA | NA | NA |
| $AEL_{medium\text{-}term}$ | NA | NA | NA | NA |
| $AEL_{long\text{-}term}$ | NA | NA | NA | NA |
| $DMEL_{systemic_workers}$ | Mouse dermal cancer bioassay | $T25_{corrected}$ = 210 mg/kg bw/d | 25000 | 8.4 µg/kg bw/d |
| $DMEL_{systemic_general\ public}$ | Mouse dermal cancer bioassay | $T25_{corrected}$ = 75 mg/kg bw/d | 250000 | 0.3 µg/kg bw/d |
| $DMEL_{oral_consumers}$ | Mouse dermal cancer bioassay | $T25_{corrected}$ = 75 mg/kg bw/d | 250000 | 0.3 µg/kg bw/d |

NA = Not applicable

***Risk characterisation***

***Summary of scenarios***

| Scenario number | Scenario (e.g. mixing / loading) | Primary or secondary exposure and description of scenario | Exposed group (e.g. professionals, general public, bystanders) |
|---|---|---|---|
| 1. | Vacuum/pressure treatment application | Primary exposure –Application of Creosote to timber using solvent-based vacuum/pressure impregnation process | Industrial |
| 2. | Hot and cold Impregnation | Primary exposure – automated dipping | Industrial |
| 3. | Cleaning out dipping equipment | Primary exposure - cleaning out dipping tank, after use | Industrial |
| 4. | Handling wet treated wood | Primary exposure - during handling of wet treated wood | Industrial |
| 5. | Brush application | Primary exposure – Brush application (outdoors) | Professionals |
| 6. | Cleaning paint brush | Primary exposure – Cleaning brush after application | Professionals |
| 7. | Cutting/Sanding treated wood | Secondary exposure – Sanding surface of treated wood | Professionals |
| 8 | Cutting/Sanding treated wood | Secondary exposure – Sanding surface of treated wood | General Public |
| 9. | Laundering work clothes | Secondary exposure – Cleaning contaminated work clothes at home (following brush treatment) | General public |

| Scenario number | Scenario (e.g. mixing / loading) | Primary or secondary exposure and description of scenario | Exposed group (e.g. professionals, general public, bystanders) |
|---|---|---|---|
| 10. | Dermal and ingestion exposure from contact with treated wood | Secondary exposure [adult and toddler – contact treated poles or equestrian fences] | General public |
| 11. | Inhalation volatilised residues | Secondary exposure – Inhalation of volatilised residues indoors | General public |
| 12. | Dietary Exposure | Secondary - Exposure to livestock from agricultural fencing treated with creosote. | General public |
| 13. | Dietary Exposure | Evaluation of residues in fruit trees and consumer risk assessment | General public |

***Conclusion of risk characterisation for industrial user***

| Scenario, Tier, PPE | Relevant reference value – DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / reference value (%) | Acceptable (yes/no) |
|---|---|---|---|---|
| 1, 1, gloves | 0.0084 | 2.09625 | 24955% | No |
| 1,2a, new gloves, coated coveralls | 0.0084 | 0.73525 | 8753% | No |

| Scenario, Tier, PPE | Relevant reference value – DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / reference value (%) | Acceptable (yes/no) |
|---|---|---|---|---|
| 1, 2b, new gloves, impermeable coveralls, RPE (APF 20), reduced no of treatment cycles. | 0.0084 | 0.2299 | 2737% | No |
| 2, 1, Gloves | 0.0084 | 2.09625 | 24955% | No |
| 2, 2a, new gloves, coated coveralls. | 0.0084 | 0.73525 | 8753% | No |
| 2, 2b / New Gloves, Impermeable coveralls, RPE (APF 20), reduced no. of treatment cycles. | 0.0084 | 0.2299 | 2737% | No |
| 3, 1, New Gloves, Impermeable coveralls, RPE (APF 20), reduced no. of treatment cycles. | 0.0084 | 0.23168 | 2758% | No |

| Scenario, Tier, PPE | Relevant reference value – DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / reference value (%) | Acceptable (yes/no) |
|---|---|---|---|---|
| 4, 1, New Gloves, Impermeable coveralls, RPE (APF 20), 1 treatment cycle. | 0.0084 | 0.2299 | 2737% | No |

***Conclusion of risk characterisation for professional user***

| Scenario, Tier, PPE | Relevant reference value - DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / reference value (%) | Acceptable (yes / no) |
|---|---|---|---|---|
| 5, 1, no PPE | 0.0084 | 4.1917 | 49901% | No |
| 5, 2a, gloves, coated coveralls. | 0.0084 | 0.49501 | 5893% | No |
| 5, 2b, new gloves, impermeable coveralls, RPE (APF 20), | 0.0084 | 0.20958 | 2495% | No |
| 5,2c, new gloves, impermeable coveralls, RPE (APF 20), reduced exposure duration/application area | 0.0084 | 0.052347 | 623% | No |

| Scenario, Tier, PPE | Relevant reference value - DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / reference value (%) | Acceptable (yes / no) |
|---|---|---|---|---|
| 6, 1, No PPE | 0.0084 | 0.2565 | 3054% | No |
| 6, 2a, gloves. | 0.0084 | 0.02565 | 305% | No |
| 6, 2b, new gloves. | 0.0084 | 0.0128 | 152% | No |
| 7, 1, no PPE. | 0.0084 | 0.9023 | 10742% | No |
| 7, 2a, reduced exposure time. | 0.0084 | 0.6287 | 7485% | No |
| 7, 2b, reduced exposure time, RPE (APF 20) | 0.0084 | 0.57673 | 6866% | No |
| 7, 2c, reduced exposure time, RPE (APR 20), gloves. | 0.0084 | 0.06013 | 716% | No |

***Conclusion of risk characterisation for general public user***

| Scenario, Tier, PPE | Relevant reference value - DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / reference value (%) | Acceptable (yes / no) |
|---|---|---|---|---|
| 8, 1, 1hr exposure time. | 0.0003 | 0.6287 | 209,567% | No |

***Conclusion of risk characterisation for indirect exposure***

| Scenario, Tier, PPE | Relevant reference value - DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / reference value (%) | Acceptable (yes / no) |
|---|---|---|---|---|
| 9, 1, no PPE | 0.0003 | 0.03399 | 11330% | No |
| 9, 2, no PPE, reduced exposure time | 0.0003 | 0.0068 | 2267% | No |
| 10, 1, Adult | 0.0003 | 0.06396 | 21320% | No |
| 10, 1, Toddler | 0.0003 (oral) | 1.078272 | 359424 % | No |

***Conclusion of risk characterisation for consumer for dietary risk assessment from livestock exposed by agricultural fencing.***

Consideration has been made as 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. Any use of creosote that leads to food residues should be considered unacceptable as

creosote is classified as a genotoxic carcinogen. There is no harmonised guidance for assessing the risk for animals, however, considering these assumptions it can be concluded that the risk to livestock from contact with creosote treated wood cannot be ruled out.

The assessment of animal (livestock) exposure concludes that dietary intakes could be significant. In order to fully assess risks to livestock, an animal feeding study would be required (please consult HSE before setting up a study) and concurrently, data on a validated method of analysis must be generated. The data submission to meet this requirement should provide full details of the analytical method with suitable acceptable validation data (including recovery rates and the limit of quantification and detection for the active substance and residues), in relevant livestock matrices.

***Conclusion of risk characterisation for consumer (oral) exposure arising from residues in crops, where creosote wooden posts are used as support structures (e.g. orchard fruit trees)***

Three fruit tree residues studies have been evaluated to consider residues arising from uses of creosotes wooden stakes as supports in food production. The studies covered pome fruits (apples and pears) and stone fruits (cherries and plums) and the evaluation and assessment of these studies is presented in full in Appendix VII.

Two out of the three studies were conducted to GLP, although they could be regarded as monitoring studies as the trials did not set out the mode or dose of applying the creosote to the wood posts. It is assumed that the posts were treated at the label recommended rate; this and other uncertainties are discussed in the detailed evaluation.

In all studies control sites were considered, where no creosote had been used. In all of these sites there are some soil residues of polycyclic aromatic hydrocarbons (PAHs), including some of the PAHs found in creosote, but also some wider PAHs found in the soil. The soil findings are therefore indicative of some background levels of PAHs from anthropogenic sources not including the uses of creosotes. There were some low level residues of PAHs in fruits taken from the control plots.

Wood analyses were performed to determine creosote components in each study (and to compare to the profiles suggested by the results for the fruit residue analyses).

In terms of fruit samples analysed for PAH residues, study 1 residues were evaluated in contact fruits, those that had come into contact with the creosote wooden stakes (and are unlikely to be of commercial harvest quality) and also in the non-contact fruits. The latter were taken from sampling that is not targeted to fruits that have been in contact with the wooden posts but are considered representative of a commercial harvest. Studies 2 and 3 only considered non-contact fruit samplings.

The main residues found in fruits are phenanthrene, fluoranthene and pyrene, all present in creosotes. Then, in terms of prevalence, followed by some other PAH constituents of creosotes.

Residues are much higher in the contact fruits compared to the non-contact fruits. In study 1, the total PAH levels (PAH18) in the non-contact fruits ranged from 29 to 128

µg/kg in fruits for the sites using creosoted wood stakes. The corresponding range for the contact fruits was 225 to 2069 µg/kg.

It is difficult to know the precise source of residues arising in the non-contact fruit. From the data overall it seems likely that there could be above ground transfer of residues from the parts of the trees that have had contact with the creosoted wooden stakes into the non-contact fruits, as well as there being low level uptake of the PAH residues from soil.

The residues in fruit determined in the fruits have enabled an indicative risk assessment to be performed. It is indicative, since a residues definition for dietary risk assessment is not being proposed as the residue findings are of concern (since creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded, see section 12.2 Reference values).

Whilst the consumer DMEL applied to the results of acute exposure assessment in the indicative exposure assessment is a conservative approach, the acute dietary intakes presented in the indicative risk assessment were all high, representing high exceedances of the consumer DMEL. The options presented for the various approaches and assessment of acute exposure of total PAH assessed in the studies (sum PAH 18) are all stated in the full residues evaluation (Appendix VII). The ranges for the highest dietary short term intakes (for the critical consumer group) for the non-contact fruits are 1800 to 17333 % of the consumer DMEL, so well above the consumer DMEL of 0.3 µg/kg bw/day.

The consumer DMEL is derived for the purpose of chronic dietary exposure assessment (oral intake) of 0.3 µg/kg bw/day. The results show that the consumer DMEL is even exceeded in the indicative risk assessment for the chronic exposure estimates representing sum of the PAHs in the untreated controls, but at a lower level (compared to the 'treated' samples). The UK total dietary intakes for UK toddlers based on untreated control fruits represented 116% of the consumer DMEL of 0.3 µg/kg bw/day (based on sum PAH18).

The highest dietary intakes were for the contact fruits, with highest UK total dietary (chronic) intakes for UK toddlers at 9771% of the consumer DMEL of 0.3 µg/kg bw/day (based on sumPAH18).

The applicant has explained how the non-contact fruit are regarded as representative of fruits that are harvested commercially (and not the 'contact fruits'). For these residues samples, the highest UK and EU total chronic dietary intakes for UK toddlers (UK model) and Dutch toddlers (EU model) represented 183% to 402% of the consumer DMEL of 0.3 µg/kg bw/day (based on sumPAH18).

When comparing to the consumer DMEL (0.3 µg/kg bw/day) the chronic and acute dietary intakes in this indicative dietary intake assessment far exceed this consumer DMEL. It is concluded that both assessment of chronic and acute dietary intakes indicate that an expectation of both long term and short term effects on health cannot be excluded arising from the assessment of the fruit tree uses of creosote.

It is not possible to propose risk mitigation measures that could bring dietary intakes within acceptable levels. Mitigation measures and uncertainties in the assessment are discussed in the detailed evaluation. As noted above creosote is considered to be a

genotoxic carcinogen. As such, for the proposed use of creosote on wooden posts used as supports for fruit trees (or other supports for food crops such as hops or grapevines) harmful effects on human health cannot be excluded.

## 5. Summary of the environmental risk assessment

***Fate and behaviour in the environment***

**Summary table on compartments exposed and assessed**

| Compartment | Exposed (yes / no) | Assessed (yes / no) |
|---|---|---|
| Sewage treatment plants (STP) | Y | Y |
| Surface water | Y | Y |
| Sediment | Y | Y |
| Marine water | Y | Y |
| Marine sediment | Y | Y |
| Soil | Y | Y |
| Groundwater | Y | Y |

**Summary table on relevant physico-chemical and fate and behaviour parameters of creosote**

| Parameter | Value | Unit | Remarks |
|---|---|---|---|
| Molecular weight | 200 | g/mol | Notional average of all grades (B + C) |
| Organic carbon/water partition coefficient (Koc) | 9333 | l/kg | Data from original approval of creosote (2010) |
| Water solubility | 8.11 | mg/l | Data from original approval of creosote (2010) (20 °C) |

| Parameter | Value | Unit | Remarks |
|---|---|---|---|
| Vapour pressure | 4.00E-1 | Pa | Data from original approval of creosote (2010) (20 °C) |
| $DT_{50}$ for biodegradation in surface water | 1000 | d (at 12 °C) | Decision from original approval of creosote (2010) |
| “k” rate for aquatic degradation | 6.93E-4 | $d^{-1}$ | Calculated rate |
| $DT_{50}$ for degradation in soil | 734 | d (at 12 °C) | Based on data from original approval of creosote (2010) with $DT_{50}$ of 387 d (20 °C). This was the longest value from 2 soils based on analysis of the PAH chrysene, taken as a worst case of the substances analysed. Note that normalisation was based on equation 28 from Vol IV part B+C and a longer value would be estimated if the latest activation energy was to be used in line with TAB ENV182. |
| “k” rate for soil degradation | 9.44E-4 | $d^{-1}$ | Calculated rate |
| Soil-water partitioning co-efficient ($K_{soil\text{-}water}$) | 2.80E+2 | $m^3/m^3$ | Calculated value |

| Parameter | Value | Unit | Remarks |
|---|---|---|---|
| Suspended matter-water partitioning co-efficient ($K_{susp\text{-}water}$) | 2.34E+2 | $m^3/m^3$ | Calculated value |

***Effects assessment***

**Summary table on calculated PNEC values**

| **Substance** | **$PNEC_{surface\ water}$ (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 |

To note, the $PNEC_{sediment}$ values are presented as normalised/non-normalised (to standard organic carbon content of the sediment).

***Exposure assessment***

**Summary table on calculated PEC values**

| **Scenario** | **$PEC_{STP}$ (mg/l)** | **$PEC_{water}$ (µg/l)** | **$PEC_{sed}$ ($mg/kg_{wwt}$)** | **$PEC_{seawater}$ (µg/l)** | **$PEC_{seased}$ ($mg/kg_{wwt}$)** | **$PEC_{soil}$ ($mg/kg_{wwt}$)** | **$PEC_{GW}$ (µg/l)** |
|---|---|---|---|---|---|---|---|
| 1 (UC 3 – House) : Time 1<br>1 (UC 3 – House) : Time 2 | - | - | - | - | - | 6.12E-2<br>3.15E-1 | **3.72E-1**<br>**1.91** |
| 1 (UC 3 – Fence) : Time 1<br>1 (UC 3 – Fence) : Time 2 | - | - | - | - | - | 5.09E-2<br>2.62E-1 | **3.09E-1**<br>**1.59** |
| 1 (UC 3 – Noise barrier) : Time 1<br>1 (UC 3 – Noise barrier : Time 2 | 2.06E-4<br>2.95E-5 | - | - | - | - | - | - |
| 1 (UC 3 Bridge-over-pond) : Time 1 [C at t]<br>1 (UC 3 Bridge-over-pond) : Time 2 [C at t] | - | 6.33E-2<br>4.39E-1 | 1.29E-2<br>8.95E-2 | - | - | - | - |
| 1 (UC 3 Bridge-over-pond) : Time 1 [TWA]<br>1 (UC 3 Bridge-over-pond) : Time 2 [TWA] | - | 3.18E-2<br>3.55E-1 | 6.47E-3<br>7.23E-2 | - | - | - | - |

| Scenario | $PEC_{STP}$ (mg/l) | $PEC_{water}$ (µg/l) | $PEC_{sed}$ ($mg/kg_{wwt}$) | $PEC_{seawater}$ (µg/l) | $PEC_{seased}$ ($mg/kg_{wwt}$) | $PEC_{soil}$ ($mg/kg_{wwt}$) | $PEC_{GW}$ (µg/l) |
|---|---|---|---|---|---|---|---|
| 2 (UC 4a – Transmission pole) : Time 1<br>2 (UC 4a – Transmission pole) : Time 2 | - | - | - | - | - | 9.34E-1<br>6.11 | **5.67**<br>**37.10** |
| 2 (UC 4a – Fence post) : Time 1<br>2 (UC 4a – Fence post) : Time 2 | - | - | - | - | - | 2.87E-1<br>1.88 | **1.74**<br>**11.40** |
| 2 (UC 4a – Vineyard stake) : Time 1 [partial]<br>2 (UC 4a – Vineyard stake) : Time 2 [partial] | - | - | - | - | - | 1.86E-1<br>1.90 | **1.13**<br>**11.60** |
| 2 (UC 4a – Vineyard stake) : Time 1 [whole]<br>2 (UC 4a – Vineyard stake) : Time 2 [whole] | - | - | - | - | - | 1.87E-1<br>1.91 | **1.14**<br>**11.64** |
| 3 (UC 4b – Jetty-on-a-lake) : Time 1 [C at t]<br>3 (UC 4b – Jetty-on-a-lake) : Time 2 [C at t] | - | 1.38<br>12.1 | 2.81E-1<br>2.47 | - | - | - | - |

| Scenario | $PEC_{STP}$ (mg/l) | $PEC_{water}$ (µg/l) | $PEC_{sed}$ (mg/$kg_{wwt}$) | $PEC_{seawater}$ (µg/l) | $PEC_{seased}$ (mg/$kg_{wwt}$) | $PEC_{soil}$ (mg/$kg_{wwt}$) | $PEC_{GW}$ (µg/l) |
|---|---|---|---|---|---|---|---|
| 3 (UC 4b – Jetty-on-a-lake) : Time 1 [TWA]<br>3 (UC 4b – Jetty-on-a-lake) : Time 2 [TWA] | - | 6.93E-1<br>9.79 | 1.41E-1<br>1.99 | - | - | - | - |
| 3 (UC 4b – Sheet piling) : Time 1<br>3 (UC 4b – Sheet piling) : Time 2 | - | 615.0<br>113.0 | 125.26<br>23.02 | - | - | - | - |
| 4 (UC 5 – Harbour wharf) : Time 1<br>4 (UC 5 – Harbour wharf) : Time 2 | - | - | - | 12.3<br>2.25 | 2.51<br>4.59E-1 | - | - |

***Risk characterisation***

**Summary table on calculated PEC / PNEC values**

| Scenario | PEC / $PNEC_{STP}$ | PEC / $PNEC_{water}$ | PEC / $PNEC_{sed}$ | PEC / $PNEC_{seawater}$ | PEC / $PNEC_{seased}$ | PEC / $PNEC_{soil}$ | PEC / $PNEC_{GW}$ |
|---|---|---|---|---|---|---|---|
| 1 (UC 3 – House) : Time 1<br>1 (UC 3 – House) : Time 2 | - | - | - | - | - | 2.04E-1<br>**1.05** | <<0.01<br><<0.01 |

| Scenario | PEC / $PNEC_{STP}$ | PEC / $PNEC_{water}$ | PEC / $PNEC_{sed}$ | PEC / $PNEC_{seawater}$ | PEC / $PNEC_{seased}$ | PEC / $PNEC_{soil}$ | PEC / $PNEC_{GW}$ |
|---|---|---|---|---|---|---|---|
| 1 (UC 3 – Fence) : Time 1<br>1 (UC 3 – Fence) : Time 2 | - | - | - | - | - | 1.70E-1<br>8.73E-1 | <<0.01<br><<0.01 |
| 1 (UC 3 – Railway sleeper) : Time 1<br>1 (UC 3 – Railway sleeper) : Time 2 | - | - | - | - | - | - | <<0.01<br><<0.01 |
| 1 (UC 3 – Noise barrier) : Time 1<br>1 (UC 3 – Noise barrier : Time 2 | 1.58E-3<br>2.27E-4 | - | - | - | - | - | - |
| 1 (UC 3 Bridge-over-pond) : Time 1 [C at t]<br>1 (UC 3 Bridge-over-pond) : Time 2 [C at t] | - | 6.33E-1<br>**4.39** | 6.45E-3<br>4.48E-2 | - | - | - | - |
| 1 (UC 3 Bridge-over-pond) : Time 1 [TWA]<br>1 (UC 3 Bridge-over-pond) : Time 2 [TWA] | - | 3.18E-1<br>**3.55** | 3.24E-3<br>3.62E-2 | - | - | - | - |

| Scenario | PEC / $PNEC_{STP}$ | PEC / $PNEC_{water}$ | PEC / $PNEC_{sed}$ | PEC / $PNEC_{seawater}$ | PEC / $PNEC_{seased}$ | PEC / $PNEC_{soil}$ | PEC / $PNEC_{GW}$ |
|---|---|---|---|---|---|---|---|
| 2 (UC 4a – Transmission pole) : Time 1<br>2 (UC 4a – Transmission pole) : Time 2 | - | - | - | - | - | **3.11**<br>**20.37** | **56.7**<br>**371.0** |
| 2 (UC 4a – Fence post) : Time 1<br>2 (UC 4a – Fence post) : Time 2 | - | - | - | - | - | 9.57E-1<br>**6.27** | **17.4**<br>**114.0** |
| 2 (UC 4a – Vineyard stake) : Time 1 [partial]<br>2 (UC 4a – Vineyard stake) : Time 2 [partial] | - | - | - | - | - | 6.20E-1<br>**6.33** | **11.3**<br>**116.0** |
| 2 (UC 4a – Vineyard stake) : Time 1 [whole]<br>2 (UC 4a – Vineyard stake) : Time 2 [whole] | - | - | - | - | - | 6.23E-1<br>**6.37** | **11.4**<br>**116.4** |
| 3 (UC 4b – Jetty-on-a-lake) : Time 1 [C at t]<br>3 (UC 4b – Jetty-on-a-lake) : Time 2 [C at t] | - | **13.8**<br>**121.0** | 1.41E-1<br>**1.24** | - | - | - | - |

| Scenario | PEC / $PNEC_{STP}$ | PEC / $PNEC_{water}$ | PEC / $PNEC_{sed}$ | PEC / $PNEC_{seawater}$ | PEC / $PNEC_{seased}$ | PEC / $PNEC_{soil}$ | PEC / $PNEC_{GW}$ |
|---|---|---|---|---|---|---|---|
| 3 (UC 4b – Jetty-on-a-lake) : Time 1 [TWA]<br>3 (UC 4b – Jetty-on-a-lake) : Time 2 [TWA] | - | **6.93**<br>**97.9** | 7.05E-2<br>**1.00** | - | - | - | - |
| 3 (UC 4b – Sheet piling) : Time 1<br>3 (UC 4b – Sheet piling) : Time 2 | - | **6150**<br>**1130** | **62.63**<br>**11.51** | - | - | - | - |
| 4 (UC 5 – Harbour wharf) : Time 1<br>4 (UC 5 – Harbour wharf) : Time 2 | - | - | - | **615**<br>**112.5** | **12.6**<br>**2.3** | - | - |

Note : Higher tier FOCUS PEARL 4.4.4 modelling to refine the groundwater exposure was undertaken for HOUSE and FENCE and RAILWAY SLEEPERS scenarios – acceptable concentrations (<0.001µg/l) were noted in all 4 GB relevant FOCUS scenarios.

***Conclusion***

Based upon leaching rate data provided and 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 following ENV conclusions can be reached:-

**UC 3**: For the HOUSE scenario note that a marginal failure of tier 1 PEC/PNEC ratio for soil was derived based on the whole house scenario (PEC/PNEC = 1.05) and this is likely to be protective of non-residential cladding. Therefore acceptable risks to soil are expected for non-residential cladding and acceptable risks have also been identified for the FENCE scenario. It should be noted that a service life of 20 years has been set but suggest that use of creosote on non-residential cladding and fencing may give rise to

acceptable soil risk. Higher tier groundwater assessment was performed for the HOUSE scenario as a surrogate for the FENCE scenario (as part of the consideration of fencing panels and non-residential cladding). It is noted despite significant failures in porewater screening, negligible (and thus acceptable) groundwater levels are predicted in GB relevant scenarios based on higher tier modelling (noting that the applicability of the FOCUS models to complex mixtures such as creosote is associated with a degree of uncertainty – see Section 13.5 for details).

Acceptable risks were noted at both Time 1 and Time 2 when considering potential effects on micro-organisms at STP (NOISE BARRIER scenario) but failures were noted at Time 2 using ECHA modelling for surface water in the BRIDGE OVER POND scenario). As such, precautionary labelling is necessary:

*With the exception of railway sleepers, treatment must only be applied to timber which will not be used above or adjacent to surface waters.*

By contrast, application to railways sleepers is not expected to give rise to contamination of the soil compartment (as the ground under tracks is considered to be a technosphere) or surface water bodies (due to design of track on or near bridges preventing direct emissions). PEARL 4.4.4 modelling of groundwater concentrations under railway sleepers indicated that negligible risks would be posed to all GB-relevant scenarios in the model.

**UC 4a**: unacceptable risks to the terrestrial compartment were identified at Time 1 and Time 2 in the TRANSMISSION POLE scenario and at Time 2 in the FENCE POST scenario plus VINEYARD POST/FRUIT STAKE model. Note the standard exposure and risk assessment model is relatively conservative as it assesses the risk in the terrestrial environment immediately surrounding treated timbers in contact with soil. Tier 1 porewater screening had identified concerns in all cases but, due to unacceptable risks already being identified in soil, higher tier groundwater modelling using PEARL 4.4.4 has not been applied to reassess porewater failures.

However, the level of refinement afforded by the FOCUS models in comparison to the tier 1 screening approach was large, where for example the tier 1 PECgw value for the House scenario was reduced from 1.9 µg/l down to <0000001 µg/l in all 4 GB relevant scenarios using FOCUS PEARL 4.4.4. Therefore it would be expected that higher tier FOCUS modelling would demonstrate acceptable risks from all UC4a scenarios where the highest tier 1 concentration of 37.1 µg/l was predicted for the TRANSMISSION POLE scenario (noting the general uncertainty in the applicability of the FOCUS models to complex mixtures such as creosote).

**UC 4b**: unacceptable risks to the aquatic compartment (water phase) were identified at Time 2 in the JETTY models and at Time 1 and Time 2 for the SHEET PILING scenarios. That alone would indicate that UC 4 b risks are unacceptable regardless of varying impacts on

sediment dwelling organisms across these two standard scenarios.

**UC 5**: unacceptable risks to the marine environment (sediment and seawater) were identified at Time 1 and Time 2 in the HARBOUR WHARF scenario, even when using refinements based upon TWA in the water phase and deriving sediment PNEC from the normalised freshwater PNECsediment value.

Although risks in UC 4a, UC 4b and UC 5 indicate that all uses would be unacceptable, some uses in UC 3 can be considered as acceptable (such as potential application to non-residential cladding, fencing, railways sleepers and noise barriers).

## 6. Assessment of exclusion, substitution criteria and POP

| | |
|---|---|
| **Conclusion on exclusion criteria** | Creosote does meet the exclusion criteria laid down in Article 5(1)(a), (c) and (e) of GB BPR. |
| **Conclusion on CMR** | Carc. 1B (H350) (mandatory classification under GB CLP)<br><br>Not classified as Muta. Cat. 1A or 1B.<br><br>Repr. 1B (H360F) and 2 (H361d) (proposed) |
| **Conclusion on ED assessment** | Conclusion cannot be made with available data |
| **Conclusion on PBT and vP/vB criteria** | Creosote is described as a substance containing PBT constituents |
| **Conclusion on substitution criteria** | Creosote does meet the conditions laid down in Article 10(1)(a) and (d) of GB BPR and is therefore considered as a candidate for substitution. |
| **Conclusion on LRTAP / POP assessment** | In the absence of confirmation that all major components of creosote rapidly degrade in air so do not have the potential for long range transport, it may be prudent to consider the active as a substance *potentially* containing LRTAP / POP constituents. HSE acknowledges that this approach is precautionary in the absence of scientific certainty over the presence of POP constituents. |

# Part A – Assessment of intrinsic properties and effects of the active substance

## 1. General substance information

### *1.1. Identification of the substance*

***Summary table on substance identity***

| | |
|---|---|
| **Common name (ISO name, synonyms)** | Creosote |
| **Chemical name (EC name, CA name, IUPAC name)** | Creosote |
| **CAS number** | 8001-58-9 |
| **EC number** | 232-287-5 |
| **Other CAS numbers (e.g. deleted, related, preferred, alternate)** | None |
| **Molecular formula** | Not applicable to an UVCB substance |
| **SMILES notation** | - |
| **Molar mass** | Not applicable to an UVCB substance |

***Structural formula***

| |
|---|
| Not applicable to an UVCB substance |

***Origin of the natural active substance or precursor(s) of the active substance***

| |
|---|
| Please refer to Appendix VIII for the origin of the active substance. |

***Method of manufacture***

Please refer to Appendix VIII for the method of manufacture.

## *1.2. Composition of the substance (reference specifications)*

***Specification of the different sources of the active substances***

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

**Specification for creosotes**

| **Normative parameters according to EN 13991:2003** | **Unit** | **Creosote Grade B (EN 13991)** | **Creosote Grade C (EN 13991)** |
|---|---|---|---|
| Density (20 °C) (DIN 51757) | g/mL | 1.02-1.15 | 1.03-1.17 |
| Water content (DIN 51777) | % | 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):<br><br>Distillate to 235 °C | % | max. 20 | - |

| **Normative parameters according to EN 13991:2003** | **Unit** | **Creosote Grade B (EN 13991)** | **Creosote Grade C (EN 13991)** |
|---|---|---|---|
| Boiling range (EN 13991):<br><br>Distillate to 300 °C | % | 40-60 | max. 10 |
| Boiling range (EN 13991):<br><br>Distillate to 355 °C | % | min. 70 | min. 65 |
| Benzo[a]pyrene (EN 1014-3) | ppm | max. 50 | max. 50 |
| Flash point Pensky-Martens (EN 22719) | °C | min. 61 | min. 61 |

Please refer to Appendix VIII for the batch data relating to the sources of creosote.

### 1.3. Physical and chemical properties of the active substance

No new information is available since the original approval and the conclusions remain the same. 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. The ambient temperature storage stability for creosote products will be addressed at product authorisation/renewal stage.

### 1.4. Physical hazards and respective characteristics

### 1.5. Hazard identification for physico-chemical properties

No new information is available since the original approval and the conclusions remain the same. Physical hazards data has been updated according to GB CLP in the list of endpoints.

### 1.6. Analytical methods for detection and identification

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 certificates of analysis (CoA) by all applicants, HSE is 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.

The specification of creosote should be re-considered at the next renewal.

**Analysis of the active substance as manufactured**

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

**Formulation analysis**

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

**Residue analysis**

Methods for food analysis were submitted with the residue studies on fruit trees (see Appendix VII). The information provided gave an overview rather than full details of methods, and associated validation data (including recovery data) to support LOQs were not provided.

Aside from the above (residues in food), no new information is available since the original approval and therefore further information is required (see section 2.3) to fulfil the deficiencies in the studies identified during the original approval of creosote (2010).

## 2. Effects against target organisms

### *2.1. Function and field of use envisaged*

Creosote is used as a preventative wood treatment for use in railway sleepers, fencing, marine installations and other safety critical uses when a long service life is required.

### *2.2. Intended uses*

**Summary table of intended uses**

| | |
|---|---|
| **Product Type** | Product Type 8: Wood preservatives |
| **Product description** | Creosote is used to prevent the destruction of softwood and hardwood by wood rotting fungi, soft rot fungi and wood destroying marine organisms. |
| **Target organisms (including development stage)** | Wood rotting basidiomycetes (brown rot and white rot fungi)<br>Soft rot fungi<br>Wood destroying marine organisms |
| **Description of use(s)** | For use by professional only in use classes 3, 4 and 5 applied by pressure process or superficial treatment. |
| **Mode of action** | Please refer to Section 2.3.2 |

| | |
|---|---|
| **Objects to be protected** | The objects to be protected are wood used for railway sleepers, fence panels. Electricity poles, agricultural tree stakes when long service life is required. |
| **Concentration of product in the in-use formulation/product** | The biocidal product is 100% creosote |
| **Concentration of active substance in the in-use formulation/product** | The biocidal product is 100% creosote |
| **Application rate(s)** | Use class 3: Pressure impregnation Softwood 70-185 kg/m³, Hardwood: 160-185 kg/m³<br><br>Use class 3: surface treatment 1 L/5m²<br><br>Use class 4: Pressure impregnation Softwood: 100 – 195 kg/m³, Hardwood: 160 – 210 kg/m³.<br><br>Use class 4: Surface treatment: 1 L/5m²<br><br>Use class 5: Pressure impregnation Softwood 240 – 400kg/m$^3$, Hardwood 240 – 290kg/m$^3$ |
| **Frequency of application** | One application before the wood goes into service |
| **Season/period for use (where relevant)** | N/A |

| | |
|---|---|
| **Field of use (indoors/outdoors)** | Indoors and outdoors. |
| **Category(ies) of user(s)** | Professional only |
| **Instruction for use** | N/A |

## *2.3. Summary on efficacy*

### *2.3.1. Efficacy*

**Experimental data on the efficacy of the active substance against target organism(s)**

| Study Details | Test method and conditions | Test results |
|---|---|---|
| **Study reference:** [redacted] (2020c)<br>Report number 32/18/10197/07A<br><br>**Product type:** PT8 – wood preservative.<br><br>**Test substance:** Creosote type C | EN113 (after accelerated ageing according to EN73)<br><br>Wood species tested: Scots pine (*Pinus sylvestris*)<br><br>Concentrations tested: 2.22%, 4.68%, 6.65%, 9.42% and 14.46% | *G. trabeum*<br>Upper toxic value: Concentration: 4.68% Retention: 27.52 kg/m³<br><br>Lower toxic value: Concentration: 2.22% Retention: 13.02 kg/m³<br><br>Mid toxic value: Concentration: 3.45% Retention: 20.27 kg/m³ |

| | | |
|---|---|---|
| **User:** Professional<br><br>**Use area:** Preventative wood preservative for wood in use classes 3 and 4.<br><br>**Label claims:** N/A<br><br>**Test organism(s):** *G. trabeum, L. lepideus, A. vaillantii, S. himantioides* | | *L. lepideus*<br>Upper toxic value: Concentrations: 4.68% Retention: 27.63 kg/m³<br><br>Lower toxic value: Concentration: 2.22% Retention: 13.02 kg/m³<br><br>Mid toxic value: Concentration: 3.45% Retention: 20.325 kg/m³<br><br>*A. vaillantii*<br>Minimum effective dose at or below lowest test concentration: <2.22% concentration, <13.17 kg/m³<br><br>*S. himantioides*<br>Minimum effective dose at or below lowest test concentration: <2.22% retention: <13.18 kg/m³<br><br>The biological reference value is the mid toxic value of the most tolerant fungus: 20.27 kg/m³ |
| **Study reference:** [redacted] (2020b) | EN113 (after accelerated ageing according to EN84) | *G. trabeum*<br>Minimum effective dose at or below lowest test Concentration: <2.22% Retention: 13.13 kg/m³ |

| | | |
|---|---|---|
| Report number 32/18/10197/06A<br><br>**Product type:** PT8 – wood preservative.<br><br>**Test substance:** Creosote type C<br><br>**User:** Professional<br><br>**Use area:** Preventative wood preservative for wood in use classes 3 and 4.<br><br>**Label claims:** N/A<br><br>**Test organism(s):** *G. trabeum, L. lepideus, A. vaillantii, S. himantioides* | Wood species tested: Scots pine (*Pinus sylvestris*)<br><br>Concentrations tested: 2.22%, 4.68%, 6.65%, 9.42% and 14.46% | <u>*L. lepideus*</u><br>Upper toxic value: Concentration: 4.68% Retention: 27.63 kg/m³<br><br>Lower toxic value: Concentration: 2.22% Retention: 13.02 kg/m³<br><br>Mid toxic value: Concentration: 3.45% Retention: 20.33 kg/m³<br><br><u>*A. vaillantii*</u><br>Upper toxic value: Concentration: 4.68% Retention: 27.51 kg/m³<br><br>Lower toxic value: Concentration: 2.22% Retention: 12.98 kg/m³<br><br>Mid toxic value: Concentration: 3.45% Concentration: 3.45% Retention: 20.25 kg/m³<br><br><u>*S. himantioides*</u> |

| | | |
|---|---|---|
| | | Minimum effective dose at or below lowest test Concentration: <2.22% Retention: 12.98 kg/m³<br><br>The biological reference value is the mid toxic value of the most tolerant fungus: Retention: 20.33 kg/m³ |
| **Study reference:** [redacted] (2019c)<br>**R**eport number 32/18/10197/04<br><br>**Product type:** PT8 – wood preservative.<br><br>**Test substance:** Creosote type C<br><br>**User:** Professional<br><br>**Use area:** Preventative wood preservative for wood in use classes 3 and 4.<br><br>**Label claims:** N/A | EN49 (after accelerated ageing according to EN73)<br><br>Wood species tested: European oak<br><br>Concentrations tested: 0.00%, 1.22%, 3.65%, 8.52%, 13.63% and 18.49% | Minimum effective dose at or below lowest test concentration (<1.22% concentration, <4.83 kg/m$^3$)<br><br>Upper toxic value: Concentration: 1.22% Retention: 4.83 kg/m³<br><br>Lower toxic value: Concentration: 0.00% Retention: 0.00 kg/m³ |

| | | |
|---|---|---|
| **Study reference:** [redacted] (2020a)<br>Report number 32/18/10197/03<br><br>**Product type:** PT8 – wood preservative.<br><br>**Test substance:** Creosote type C<br><br>**User:** Professional<br><br>**Use area:** Preventative wood preservative for wood in use classes 3 and 4.<br><br>**Label claims:** N/A<br><br>**Test organism(s):** *Anobium punctatum* | EN49 (after accelerated ageing according to EN84)<br><br>Wood species tested: European oak<br><br>Concentrations tested: 0.00%, 1.22%, 3.65%, 8.52%, 13.63% and 18.49% | Upper toxic value: Concentration: 3.65% Retention: 14.50 kg/m³<br><br>Lower toxic value: Concentration: 1.22% Retention: 5.02 kg/m³<br><br>Mid toxic value: Concentration: 2.44% Retention: 9.76 kg/m³ |

| | | |
|---|---|---|
| **Study reference:** [redacted] (2019b)<br>Report number 32/18/10197/02<br><br>**Product type:** PT8 – wood preservative.<br><br>**Test substance:** Creosote type C<br><br>**User:** Professional<br><br>**Use area:** Preventative wood preservative for wood in use classes 3 and 4.<br><br>**Label claims:** N/A<br><br>**Test organism(s):** *Hylotrupes bajulus* | EN47 (after accelerated ageing according to EN73)<br><br>Wood species tested: Scots pine (*Pinus sylvestris*)<br><br>Concentrations tested: 0.00%, 0.97%, 2.90%, 6.76%, 10.81% and 14.67% | Upper toxic value: Concentration: 10.81% Retention: 57.10 kg/m³<br><br>Lower toxic value: Concentration: 6.76% Retention: 35.60 kg/m³<br><br>Mid toxic value: Concentration: 8.79 % Retention: 46.35 kg/m³ |
| **Study reference:** [redacted] (2019a) | EN47 (after accelerated ageing according to EN84) | Upper toxic value: Concentration: 6.76% Retention: 35.23 kg/m³ |

| | | |
|---|---|---|
| Report number 32/18/10197/01<br><br>**Product type:** PT8 – wood preservative.<br><br>**Test substance:** Creosote type C<br><br>**User:** Professional<br><br>**Use area:** Preventative wood preservative for wood in use classes 3 and 4.<br><br>**Label claims:** N/A<br><br>**Test organism(s):** *Hylotrupes bajulus* | Wood species tested: Scots pine (*Pinus sylvestris*)<br><br>Concentrations tested: 0.00%, 0.97%, 2.90%, 6.67%, 10.81% and 14.67% | Lower toxic value: Concentration: 2.90% Retention: 14.82 kg/m³<br><br>Mid toxic value: Concentration: 4.83 % Retention: 25.03 kg/m³ |
| **Study reference:** [redacted] (2019d)<br><br>Report number 32/18/10197/05 | EN20 (after accelerated ageing according to EN73)<br><br>Wood species tested: European oak | Upper toxic value: Concentration: 4.09% Retention: 15.54 kg/m³ |

| | | |
|---|---|---|
| **Product type:** PT8 – wood preservative.<br><br>**Test substance:** Creosote type C<br><br>**User:** Professional<br><br>**Use area:** Preventative wood preservative for wood in use classes 3 and 4.<br><br>**Label claims:** N/A<br><br>**Test organism(s):** *Lyctus brunneus* | Concentrations tested: 0.00%, 1.36%, 4.09%, 9.54%, 15.26% and 20.71% | Lower toxic value: Concentration: 1.36% Retention: 4.90 kg/m³<br><br>Mid toxic value: Concentration: 2.73 % Retention: 10.22 kg/m³ |

*2.3.2. Mode of action*

The mode of action remains the same as for the previous approval.

*2.3.3. Resistance*

Resistance issues have previously been addressed and no new data is required.

## *2.4. Conclusion on efficacy*

The studies submitted demonstrate the innate activity of the active substance when used against fungi and wood boring beetles. HSE notes that while the data package submitted for the renewal of creosote is sufficient more data will be needed at the product stage. The data should be produced according to the current Guidance.

## 3. Assessment of effects on human health

No new toxicological information has become available since the first approval. The conclusions from the original approval of creosote (2010) remain valid.

## 4. Environmental effects assessment

### *4.1. Fate and distribution in the environment*

Creosote is an UVCB (ie unknown or variable composition) substance consisting of hundreds of constituents. The available data are almost exclusively related to polycyclic aromatic hydrocarbons (PAH), which are among the principal constituents of creosote. For the main environmental fate and distribution endpoints such as abiotic degradation, biodegradation, distribution and accumulation no new data has been submitted to support substance renewal. Therefore the summaries below are based on the assessment supporting the original approval of creosote (2010).

#### *4.1.1. Degradation*

##### 4.1.1.1. Abiotic degradation

***Hydrolysis***

**Value used in the risk assessment – Hydrolysis**

| | |
|---|---|
| **Value / conclusion** | No data submitted |
| **Justification** | PAH compounds are not expected to degrade hydrolytically due to the absence of hydrolysable groups. The justification was accepted in the original approval of creosote (2010). |

***Phototransformation in water***

**Value used in the risk assessment – Photolysis in water**

| | |
|---|---|
| **Value / conclusion** | Not applicable for creosote. |
| **Justification** | 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. |

***Estimated photo-oxidation in air***

**Value used in the risk assessment – Photo-oxidation in air**

| | |
|---|---|
| **Value / conclusion** | Not applicable for creosote. |
| **Justification** | 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. |

4.1.1.2. Biotic degradation

***4.1.1.2.1. Biodegradability (ready / inherent)***

**Value used in the risk assessment – Biodegradation studies (ready / inherent)**

| | |
|---|---|
| **Value / conclusion** | Not applicable for creosote. |
| **Justification** | Creosote is an UVCB (ie unknown or variable composition) substance consisting of hundreds of constituents. The mixture is not expected to be ready or inherently biodegradable |

4.1.1.3. Rate and route of degradation including identification of metabolites and degradation products

***4.1.1.3.1. Biodegradation in freshwater***

***Water / sediment degradation test***

**Value used in the risk assessment – Freshwater / sediment degradation**

| | |
|---|---|
| **Value / conclusion** | 1000 d (at 12 °C) |

| | |
|---|---|
| **Justification** | As per the original approval of creosote (2010).<br><br>Mineralisation half-lives (DT50 values) in sediment-water systems can be summarised as follows: For non-alkylated PAHs with two rings; DT50 ≈ 30 d, for alkylated PAHs with 2 rings and PAHs with 3 rings; DT50 = >60 d and finally, for PAHs with four rings, DT50 ≈ several years - ∞ (all at 22 °C). The rate of aerobic and anaerobic degradation of creosote components 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.<br><br>Dissipation half-life in the water phase of all PAHs (and creosote) was estimated to one month. The dissipation of creosote components from the water can most likely be ascribed to a combination of removal processes like volatilisation, adsorption, uptake by biota, photolysis and biodegradation. |

#### *4.1.1.3.2. Biotic degradation in soil*

##### *4.1.1.3.2.1. Laboratory soil degradation studies*

***Aerobic biodegradation***

**Value used in the risk assessment – Aerobic biodegradation in soil**

| | |
|---|---|
| **Value / conclusion** | 734 d (12 °C) |
| **Justification** | As per the original approval of creosote (2010), data with $DT_{50}$ of 387 d (20 °C).<br><br>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. The value of 387d was the longest value from 2 soils based on analysis of the PAH chrysene, taken as a worst case of the substances analysed. Note that normalisation was based on equation 28 from Vol IV part B+C and a longer value would be estimated if the latest activation energy was to be used in line with TAB ENV182.<br><br>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. |

*4.1.2. Distribution*

4.1.2.1. Adsorption onto / desorption from soils

**Value used in the risk assessment – Adsorption / desorption**

| | |
|---|---|
| **Value / conclusion** | 9333 l/kg |
| **Justification** | As per the original approval of creosote (2010). |

*4.1.3. Bioaccumulation*

***Measured aquatic bioconcentration***

**Value used in the risk assessment – Measured aquatic bioconcentration**

| | |
|---|---|
| **Value / conclusion** | Naphthalene: ~70 – 1000<br>1-methyl-naphthalene: ~100<br>2-methyl-naphthalene: ~140 – 4300<br>Phenanthrene: ~1600<br>Anthracene: ~750 – 5000<br>Fluoranthene: ~380<br>Fluorene: ~540 |
| **Justification** | As per the original approval of creosote (2010) |

*4.1.4. Monitoring data*

New information submitted to support the renewal of creosote summarised environmental monitoring performed either at limited numbers of European 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). The majority of newly submitted information does not provide results that can reliably be used to refine the emissions assessment. However information is briefly summarised in the table below, supported by more detailed information in individual RSSs.

Three RSSs submitted summarise environmental monitoring and demonstrate some evidence of limited horizontal and vertical migration of polycyclic aromatic hydrocarbons (PAHs) such that measured levels quickly fall to background levels or show (in the case of railway networks and maintenance yards) that PAHs can 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 ESD.

A further study report (A2.10.2/19b), investigating the influence of creosote-treated sleepers on the migration of contaminants in ground, was also provided. It focussed on processes occurring when sleepers are in-use by analysing the fate of 16 priority PAH compounds from the leachate of freshly treated sleepers in moraine soil with different concentrations of artificially added organic matter (sand medium taken from an SE site was mixed with differing concentrations of peat in the laboratory: making up 0 %, 2 %, 5 % and 10 % of final “soil” medium). Sorption testing was then carried out according to a leaching test for determination on non-volatile, organic compounds from contaminated soils and follows the ER-H method (Equilibrium Recirculation column test for hydrophobic organic compounds). 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 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.

| 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). Limited support that main PAHs remain close to treated poles (horizontally and vertically) and soil levels quickly fall to background level. Not used in latest emissions model. |
| A2.10.2/16 | DHV, 2013 | Proposal for a vineyard post model to cover specific use pattern under UC 4a: original version submitted to RMS in 2013. No consideration made by HSE as newer 2015 version has also been submitted. |
| A2.10.2/17 | [redacted] 1997 + [redacted] 1994 | Monitoring data looking at PAHs around a small number of SE fence posts and UK wooden stakes (11 in total). Limited support that main PAHs remain close to treated posts / stakes (horizontally and vertically) and soil levels quickly fall to background level. Not used in latest emissions model. |

| Reference | Author | Conclusion |
|---|---|---|
| A2.10.2/18 | [redacted] 2013 | Monitoring data looking at PAHs in ballast and subsoil under FR railway sleepers at >100 specific SNCF locations. 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 model. |
| A2.10.2/19b | [redacted] *et al*, 2008 | Adsorption behaviour of PAHs in a range of artificially created soils from moraine extracted from subsoil beneath railway sleepers was investigated. Results obtained with 2% peat were comparable to values already obtained in original CAR by QSAR. Not used in latest emissions models. |

### *4.2. Effects on environmental organisms*

No new information has become available since the first approval. The conclusions from the original approval of creosote (2010) remain valid.

### *4.3. Endocrine disrupting properties*

**Conclusion used in the risk assessment – Endocrine disruption**

| | |
|---|---|
| **Conclusion** | Conclusion cannot be made with available data |
| **Justification** | From an ecotoxicology perspective, insufficient data are available to conclude on the ED potential of creosote with regards to wild mammals, birds, reptiles, fish or amphibians. However, as above, any potential endocrine effects that may be identified via submission of new data, noting that the data required to conclude on ED activity/adversity constitutes vertebrate data, would not affect the overall outcome based on the concerns over carcinogenicity for human health.<br><br>Therefore, HSE do not consider it appropriate to request further information regarding endocrine disrupting properties. |

### 4.4. Derivation of PNECs

Creosote

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Surface water | $PNEC_{surface\ water}$: 0.1 µg/L | Organism: Fish (*Clupea pallasi*)<br>Endpoint: $NOEC_{hatching\ success}$ (9 days) = 1 µg/L<br>Assessment factor: 10<br>Extrapolation method: Assessment factor<br>Justification: Since the three taxonomic groups (fish, invertebrates, algae) are covered with short-term and long-term toxicity data, an assessment factor of 10 is applied. |
| Marine water | $PNEC_{marine}$: 0.02 µg/L | Using the same dataset as for surface water but with an assessment factor of 50 applied to the lowest NOEC of 1 µg/L |
| STP (sewage treatment plant) | $PNEC_{STP}$: 0.13 mg/L | Organism: Activated sludge<br>Endpoint: $EC_{50}$ (3 hours) = 13 mg/L<br>Assessment factor: 100<br>Extrapolation method: Assessment factor<br>Justification: Since an $EC_{50}$ from an activated sludge growth inhibition test is available, an |

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| | | assessment factor of 100 is applied. |
| Sediment | $PNEC_{sediment}$: 2 mg/kg wet weight | Organism: Benthic community<br><br>Endpoint: $NOEC_{abundance/diversity}$ (1 – 4 years) = 22 mg/kg wet weight |
| Soil | $PNEC_{soil}$: 0.3 mg/kg wet weight | Organism: Springtails (*Folsomia candida)*<br><br>Endpoint: $NOEC_{mortality}$ (28 days) = 3 mg/kg wet weight<br><br>Assessment factor: 10<br><br>Extrapolation method: Assessment factor<br><br>Justification: Since three trophic levels are covered with short-term and long-term toxicity data, an assessment factor of 10 is applied. |

1-/2-methylnaphthlane

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Soil | $PNEC_{soil}$: 0.34 mg/kg wet weight | Organism: Springtails (*Folsomia candida)* |

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| | | Endpoint: $NOEC_{reproduction}$ (28 days) = 16.8 mg/kg wet weight<br><br>Assessment factor: 50<br><br>Extrapolation method: Assessment factor<br><br>Justification: Since two trophic levels are covered with short-term and long-term toxicity data, an assessment factor of 50 is applied. |

Fluorene

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Surface water | $PNEC_{surface\ water}$: 0.3 µg/L | Organism: Invertebrates (*Daphnia magna)*<br><br>Endpoint: $NOEC_{reproduction}$ (21 days) = 15 µg/L<br><br>Assessment factor: 50<br><br>Extrapolation method: Assessment factor<br><br>Justification: Since two taxonomic groups (fish and invertebrates) are covered with long-term toxicity data, an assessment factor of 50 is applied. |

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Marine water | $PNEC_{marine}$: 0.03 µg/L | Using the same dataset as for surface water but with an assessment factor of 500 applied to the lowest NOEC of 15 µg/L |
| Soil | $PNEC_{soil}$: 0.55 mg/kg wet weight | Assessment factor: 50 |

Phenanthrene

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Surface water | $PNEC_{surface\ water}$: 0.22 µg/L | Organism: Fish (*Brachydanio rerio)*<br><br>Endpoint: $NOEC_{reproduction}$ (28 days) = 11 µg/L<br><br>Assessment factor: 50<br><br>Extrapolation method: Assessment factor<br><br>Justification: Since two taxonomic groups (fish and invertebrates) are covered with long-term toxicity data, an assessment factor of 50 is applied. |

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Marine water | $PNEC_{marine}$: 0.022 µg/L | Using the same dataset as for surface water but with an assessment factor of 500 applied to the lowest NOEC of 11 µg/L |
| Sediment | $PNEC_{sediment}$: 0.4 mg/kg wet weight | Organism: Benthic community<br><br>Endpoint: $NOEC_{abundance/diversity}$ (1 – 4 years) = 4.4 mg/kg wet weight |
| Soil | $PNEC_{soil}$: 0.45 mg/kg wet weight | Organism: Springtails (*Folsomia candida)*<br><br>Endpoint: $NOEC_{reproduction}$ (28 days) = 22.6 mg/kg wet weight<br><br>Assessment factor: 50<br><br>Extrapolation method: Assessment factor<br><br>Justification: Since two trophic levels are covered with short-term and long-term toxicity data, an assessment factor of 50 is applied. |

Anthracene

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Surface water | $PNEC_{surface\ water}$: 0.042 µg/L | Assessment factor: 50 |
| Marine water | $PNEC_{marine}$: 0.0042 µg/L | Assessment factor: 500 |
| Soil | $PNEC_{soil}$: 0.3 mg/kg wet weight | Assessment factor: 50 |

Fluoranthene

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Surface water | $PNEC_{surface\ water}$: 0.044 µg/L | Organism: Fish (*Brachydanio rerio)*<br><br>Endpoint: $NOEC_{reproduction}$ (41 days) = 4.4 µg/L<br><br>Assessment factor: 100<br><br>Extrapolation method: Assessment factor<br><br>Justification: Since one taxonomic group (fish) is covered with long-term toxicity data, an assessment factor of 100 is applied. |

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Marine water | $PNEC_{marine}$: 0.0044 µg/L | |
| Sediment | $PNEC_{sediment}$: 0.6 mg/kg wet weight | Organism: Benthic community<br>Endpoint: $NOEC_{abundance/diversity}$ (1 – 4 years) = 6.5 mg/kg wet weight |
| Soil | $PNEC_{soil}$: 0.33 mg/kg wet weight | Assessment factor: 50 |

Pyrene

| Compartment | PNEC | Remarks / Justification |
|---|---|---|
| Soil | $PNEC_{soil}$: 0.24 mg/kg wet weight | Assessment factor: 50 |

**Summary table for proposed PNECS for creosote and some individual PAHs**

| Substance | $PNEC_{surface\ water}$ (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 |

To note, the $PNEC_{sediment}$ values are presented as normalised/non-normalised (to standard organic carbon content of the sediment).

# 5. Assessment of exclusion criteria, substitution criteria and POP

## 5.1. Exclusion criteria

### 5.1.1. Assessment of CMR properties

| Criteria (GB BPR Article 5 (1)) | Assessment |
|---|---|
| Active substances that have been classified in accordance with GB CLP as, or that meet the criteria to be classified as, carcinogen category 1A or 1B | Creosote meets the criteria to be classified as Carc. 1B (H350) (mandatory classification under GB CLP) |
| Active substances that have been classified in accordance with GB CLP as, or that meet the criteria to be classified as, mutagen category 1A or 1B | Active substance is not classified and does not meet the criteria to be classified as Muta. Cat. 1A or 1B. |
| Active substances that have been classified in accordance with GB CLP as, or that meet the criteria to be classified as, toxic for reproduction category 1A or 1B | Creosote meets the criteria to be classified as Repr. 1B (H360F) and 2 (H361d) (proposed) |

***Conclusion on CMR properties***

Creosote does meet the exclusion criteria laid down in Article 5(1)(a), (c) and (e) of GB BPR.

### 5.1.2. Assessment of endocrine disrupting properties

| Criteria | Assessment |
|---|---|
| Active substances that, on the basis of GB endocrine disrupting criteria, are considered as having endocrine-disrupting properties that may cause adverse effects in humans and to the environment. | Conclusion cannot be made with available data. An assessment is not required since creosote already meets one of the exclusion criteria for approval for which a non-threshold approach is taken. |

| Criteria | Assessment |
|---|---|
| Active substances that are classified in accordance with GB CLP as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2.<br>(Such substances shall be considered as having endocrine disrupting properties.) | Conclusion cannot be made with available data. An assessment is not required since creosote already meets one of the exclusion criteria for approval for which a non-threshold approach is taken. |
| Substances such as those that are classified in accordance with GB CLP as, or that meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs.<br>(Such substances may be considered as having endocrine disrupting properties.) | Conclusion cannot be made with available data. An assessment is not required since creosote already meets one of the exclusion criteria for approval for which a non-threshold approach is taken. |
| Active substances that are identified in accordance with GB endocrine disrupting criteria as having endocrine disrupting properties. | Conclusion cannot be made with available data. An assessment is not required since creosote already meets one of the exclusion criteria for approval for which a non-threshold approach is taken. |

***Conclusion on ED properties***

A conclusion cannot be made with the available data. An assessment is not required since creosote already meets one of the exclusion criteria for approval for which a non-threshold approach is taken.

*5.1.3. PBT Assessment (following Annex XIII to UK REACH)*

**Conclusion on P / vP properties**

Creosote is described as a substance containing P constituents

**Conclusion on B / vB properties**

Creosote is described as a substance containing B constituents

***Assessment of toxicity***

**Conclusion on T properties**

Creosote is described as a substance containing T constituents

***Summary and overall conclusions on PBT or vPvB properties***

**Overall conclusion:**

No new information has been made available as part of the creosote renewal. Therefore creosote should still be described as a substance containing PBT constituents as concluded in the original approval of creosote (2010).

## *5.2. Substitution criteria*

| **Substitution criteria (GB BPR, Article 10)** | **Assessment** |
|---|---|
| One of the exclusion criteria listed in Article 5 (1) is met but AS may be approved in accordance with Article 5 (2). | Creosote fulfils criteria (a), (c) and (e) of Article 5(1). The approval may only be renewed if any of the conditions in Article 5(2) are met. |
| The criteria to be classified, in accordance with GB CLP, as a respiratory sensitiser is met. | Creosote does not fulfil criterion (b) of Article 10(1).<br><br>No classification required. |
| The acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario. | No assessment has been made of whether creosote fulfils criterion (c) of Article 10(1) as not all of the existing active substances in product type 8 have yet been assessed for approval. This follows the principles in CA-Nov14-Doc.4.4 - Final - Further guidance on Art10(1). |
| Two of the criteria for being PBT in accordance with Annex XIII to UK REACH are met. | Creosote is described as a substance containing PBT constituents. |

| Substitution criteria (GB BPR, Article 10) | Assessment |
|---|---|
| There are reasons for concern linked to the nature of the critical effects that, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures. | Creosote does fulfil criterion (e) of Article 10(1). It is a non-threshold carcinogen, so there are concerns for human health even when applying restrictive risk mitigation measures. |
| The AS contains a significant proportion of non-active isomers or impurities. | Not applicable to a UVCB substance. Creosote does not fulfil criterion (f) of Article 10(1). |

**Conclusion on substitution criteria**

Creosote does meet the conditions laid down in Article 10(1)(a) and (d) of GB BPR and is therefore considered as a candidate for substitution.

### *5.3. Assessment of long-range environmental transportation and impact on environmental compartments*

| Criteria | Assessment |
|---|---|
| The active substance or a degradation product is a persistent organic pollutant (POP) listed in Annex I of assimilated Regulation (EU) No 2019/1021 (GB POPs). | In the absence of confirmation that all major components of creosote rapidly degrade in air so do not have the potential for long range transport, it may be prudent to consider the active as a substance *potentially* containing POP constituents. HSE acknowledges that this approach is precautionary in the absence of scientific certainty over the presence of POP constituents. |

| Criteria | Assessment |
|---|---|
| Assessment of long-range transport potential (LRTAP):<br>• Vapour pressure <1000 Pa<br>**and**<br>• half-life in air > 2 days; **or**<br>• Monitoring data in remote area showing that the substance is found in remote regions; **or**<br>• Result of multi-media modelling. | In the absence of confirmation that all major components of creosote rapidly degrade in air so do not have the potential for long range transport, it may be prudent to consider the active as a substance *potentially* containing LRTAP constituents. |
| The active substance or a degradation product is vP/vB or T. | Creosote is described as a substance containing PBT constituents |

**Conclusion on LRTAP / POP assessment**

With regard to the LRTAP / 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 approval of creosote (2010) indicates that many components such as naphthalene, 1-methylnaphthalene, 2-methylnaphthalene, 1-ethylnaphthalene, 2-ethylnaphthalene, dimethylnaphthalene, acenaphthalene, acenaphthene, fluorene and phenanthrene all have predicted DT50 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.

However, 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 LRTAP / POP constituents. HSE acknowledges that this approach is precautionary in the absence of scientific certainty over the presence of POP constituents.

# Part B – Exposure assessment and effects of the active substance in the biocidal product(s)

## 6. General product information

The biocidal product is the active substance as manufactured and therefore the identity/composition/hazard information is the same.

## 7. Efficacy

The biocidal product is made up of 100% creosote (i.e. the representative biocidal product is entirely made up of the active). As efficacy has already been demonstrated for the active in part A, no further data is required for the representative product as this is the same as the active.

## 8. Human exposure assessment

Creosote is a solvent based wood preservative formulation, containing 100% w/w creosote as active substance. The product is intended for industrial use by vacuum pressure impregnation, hot & cold impregnation; and professional use via brush - further details are provided in the table below.

The product is to be used as a penetrative wood preservative (preventive fungicide and insecticide) for timber Use Classes (UC) 3, 4 and 5 (as defined under EN 335).

Timber is intended to be treated only once before use or installation

| Application | In-use concentration of creosote (% w/w) | Effective retention of creosote in treated wood |
|---|---|---|
| Vacuum pressure treatment:<br><br>Pressure process / vacuum impregnation<br><br>(Pressure impregnation)- Preventive treatment of wood to be used as railway sleepers, agricultural fencing, equestrian fencing, industrial and highways fencing, cladding for non-residential buildings, use class (UC) 3 according to EN Standard 335. | 100 | UC3:<br>Softwood: 70 - 185 kg/m3<br><br>Hard wood: 160-185 kg/m3<br><br>One cycle per batch |

| Application | In-use concentration of creosote (% w/w) | Effective retention of creosote in treated wood |
|---|---|---|
| Vacuum pressure treatment:<br><br>Pressure process / vacuum impregnation<br><br>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. | 100 | UC4:<br>Softwood: 100 - 195 kg/m3<br><br>Hard wood: 160 - 210 kg/m3<br><br>One cycle per batch |
| Vacuum pressure treatment:<br><br>Pressure process / vacuum impregnation<br><br>UC 5: pressure impregnation: Preventive treatment of wood to be used for marine installations. Use class (UC) 5 according to EN standard 335. | 100 | UC5:<br><br>Softwood: 240 - 400 kg/m3<br><br>Hardwood: 240 - 290 kg/m3<br><br>One cycle per batch |
| Brushing (outdoor)<br><br>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) | 100 | UC3/UC4: (1 litre/5 $m^2$ ) Single application. |

| Application | In-use concentration of creosote (% w/w) | Effective retention of creosote in treated wood |
|---|---|---|
| Vacuum pressure treatment:<br><br>Pressure process / vacuum impregnation<br><br>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. | 100 | UC4:<br>Softwood: 100 - 195 kg/m3<br><br>Hard wood: 160 - 210 kg/m3<br><br>One cycle per batch |

### *8.1. Identification of main paths of human exposure towards the active substance from its use in the biocidal product*

**Summary table – Relevant paths of human exposure – Primary (direct) exposure**

| Exposure path | Industrial use | Professional use | General public use |
|---|---|---|---|
| Inhalation | Yes | Yes | N/A |
| Dermal | Yes | Yes | N/A |
| Oral | N/A | N/A | N/A |

**Summary table – Relevant paths of human exposure – Secondary (indirect) exposure**

| Exposure path | Industrial use | Professional use | General public bystanders | Via food |
|---|---|---|---|---|
| Inhalation | N/A | Yes | Yes | N/A |
| Dermal | N/A | Yes | Yes | N/A |

| Exposure path | Industrial use | Professional use | General public bystanders | Via food |
|---|---|---|---|---|
| Oral | N/A | N/A | Yes | Yes |

## 8.2. List of scenarios

**Summary table – Exposure scenarios**

| Scenario number | Scenario (e.g. mixing / loading) | Primary or secondary exposure Description of scenario | Exposed group (e.g. professionals, general public users, bystanders) |
|---|---|---|---|
| 1. | Vacuum/pressure treatment application | Primary exposure – Application of creosote to timber using solvent-based vacuum/pressure impregnation process | Industrial |
| 2. | Hot and cold Impregnation | Primary exposure – automated dipping | Industrial |
| 3. | Cleaning out dipping equipment | Primary exposure - cleaning out dipping tank, after use | Industrial |
| 4. | Handling wet treated wood | Primary exposure - during handling of wet treated wood | Industrial |
| 5. | Brush application | Primary exposure – Brush application (outdoors) | Professionals |
| 6. | Cleaning paint brush | Primary exposure – Cleaning brush after application | Professionals |
| 7. | Cutting/Sanding treated wood | Secondary exposure – Sanding surface of treated wood | Professionals |

| Scenario number | Scenario (e.g. mixing / loading) | Primary or secondary exposure Description of scenario | Exposed group (e.g. professionals, general public users, bystanders) |
|---|---|---|---|
| 8 | Cutting/Sanding treated wood | Secondary exposure – Sanding surface of treated wood | General Public |
| 9. | Laundering work clothes | Secondary exposure – Cleaning contaminated work clothes at home (following brush treatment) | General public |
| 10. | Dermal and ingestion exposure from contact with treated wood | Secondary exposure [adult and toddler – contact treated poles or equestrian fences] | General public |
| 11. | Inhalation volatilised residues | Secondary exposure – Inhalation of volatilised residues indoors | General public |

In line with The Biocides Human Health Exposure Methodology Document. 2015, (p. 119 – 120) [abbreviated to BHHEM], and HEAdhoc Recommendation 6 (p.19 – 20), HSE has carried out an exposure assessment for human health based on a tiered approach. Body weights and inhalation rates are based on values stated in HEEG opinion 17; TM II, 2013. Default protection factors for clothing and gloves are based on values stated in HEEG Opinion 9. A dermal absorption value of 10.0 % for creosote has been used.

Creosote treated wood is for use outdoors only. The current label states creosote treated wood is not for use: 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, or other materials which may contaminate the articles mentioned above.

### *8.3. Industrial user exposure*

### *8.3.1. Scenario 1. Industrial use - Primary exposure during vacuum pressure treatment process*

**Description of Scenario (1)**

Primary exposure of an industrial user to creosote during its application by industrial vacuum pressure impregnation has been assessed using the Handling Model 1 (HEADhoc recommendation 6, v4; BHEEM, 10.4.1, p 300, 1st ed, 2015). The data used to derive the model relates to industrial timber treatment plants using “standard” vacuum pressure processes applying water-based or solvent-based formulations. As creosote is solvent based, the solvent-based indicative values have been used.

The model considers 3 cycles per day for vacuum pressure impregnation. The product is ready to use and dosed automatically so there is no mixing and loading. Inhalation time is 10 minutes per cycle.

| Tier | Parameters | Value |
|---|---|---|
| Tier 1 | In use concentration of creosote | 100 % w/w |
| Tier 1 | Hand Exposure (inside gloves) | 260 mg/cycle |
| Tier 1 | Dermal absorption of creosote | 10 % |
| Tier 1 | Potential body exposure | 158 mg/cycle |
| Tier 1 | Inhalation exposure | 0.6 mg /$m^3$ |
| Tier 1 | Inhalation rate | 1.25 $m^3$ |
| Tier 1 | Inhalation duration | 10 min/cycle |
| Tier 1 | Number of treatment cycles/day | 3 |
| Tier 1 | Operator body weight | 60 kg |
| Tier 2a | Hand Exposure (inside new gloves) | 130 mg/cycle |

| Tier | Parameters | Value |
|---|---|---|
| Tier 2a | Coated Coveralls | 10 % |
| Tier 2b | Clothing penetration (impermeable coveralls) | 5 % |
| Tier 2b | RPE (APF20) | 95 % |
| Tier 2b | Number of treatment cycles/day | 1 |

**Calculations for Scenario (1)**

An example calculation is presented for clarity. All remaining calculations can be found in Appendix II: Human exposure calculations and the findings summarised in the table – Scenario 1 - Systemic exposure from industrial uses.

Tier 1 assessment

3 Cycles

Dermal

Potential body exposure (mg) = potential body exposure indicative value (mg/cycle) x number of cycles = 158 mg/cycle x 3 cycles = 474 mg

Potential hand exposure = potential hand exposure indicative value (gloves worn) (mg/cycle) x number of cycles = 260 mg/cycle x 3 cycles = 780 mg

Total dermal exposure to the product (with gloves) = 474 mg + 780 = 1254 mg

Dermal exposure to active substance (mg/kg bw/day) = total dermal exposure to the product (mg) x active substance (% w/w) x dermal absorption (%) / body weight (kg)

Dermal exposure to creosote = 1254 mg x 100% x 10% / 60 kg = 2.09 mg/kg bw/day

Inhalation

Potential inhalation exposure = Indicative value (mg/m$^3$) x duration (h) x inhalation rate (m$^3$/h) = 0.6 mg/m$^3$ x 0.5 h x 1.25 m$^3$/h = 0.375 mg of inhaled product

Inhalation exposure to active substance (mg/kg bw/day) = total inhalation exposure to the product (mg) x active substance (% w/w) x inhalation absorption (%) / body weight (kg)

Inhalation exposure to Creosote = 0.375 mg x 100% x 100% / 60 kg = 0.00625 mg/kg bw/day

**Summary table – Scenario 1 - Systemic exposure from industrial uses**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
|---|---|---|---|---|
| Scenario 1 | 1 / Gloves | 0.00625 mg/kg bw/day | 2.09 mg/kg bw/day | 2.09625 mg/kg bw/day |
| Scenario 1 | 2a / Gloves(new),Coated coveralls (10%) | 0.00625 mg/kg bw/day | 0.729 mg/kg bw/day | 0.73525 mg/kg bw/day |
| Scenario 1 | 2b / Gloves (new), Impermeable coveralls(5 %) and RPE with APF 20 (95% removal)<br><br>1 treatment cycle instead of default of 3. | 0.000104 mg/kg bw/day | 0.2298 mg/kg bw/day | 0.2299 mg/kg bw/day |

**Further information and consideration on Scenario (1)**

Due to the biocidal product classification a local effects assessment was also considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

*8.3.2. Scenario 2. Industrial use - Primary exposure during Hot and Cold impregnation treatment process*

**Description of Scenario (2)**

Hot and cold impregnation of wood is expected to be highly automated in industrial settings. It is used to treat the butt-ends of fruit tree and vine posts or utility poles with creosote that will have ground contact.

It can be anticipated that exposure during hot/cold automated dipping of timber will be of the same magnitude or less than user exposure during automated dipping using a vacuum pressure process. As such scenario 1 forms a risk envelope for Hot and Cold impregnation of timber and an additional assessment has not been carried out. Please

refer to Scenario 1 for the predicted systemic exposure.

**Calculations for Scenario (2)**

The calculations for this scenario are the same as those used in scenario 1 and can be found in Appendix II: Human exposure calculations.

**Summary table – Scenario 2 - Systemic exposure from industrial uses**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
|---|---|---|---|---|
| Scenario 2 | 1 / Gloves | 0.00625 mg/kg bw/day | 2.09 mg/kg bw/day | 2.09625 mg/kg bw/day |
| Scenario 2 | 2a / Gloves (new),Coated coveralls (10%) | 0.00625 mg/kg bw/day | 0.729 mg/kg bw/day | 0.73525 mg/kg bw/day |
| Scenario 2 | 2b / New Gloves, Impermeable coveralls (5 %) and RPE with APF 20 (95% removal)<br><br>1 treatment cycle instead of default of 3. | 0.000104 mg/kg bw/day | 0.2298 mg/kg bw/day | 0.2299 mg/kg bw/day |

**Further information and consideration on Scenario (2)**

Due to the biocidal product classification a local effects assessment was also considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

*8.3.3. Scenario 3. Industrial use – Primary exposure during cleaning out dipping tank vessels after use*

**Description of Scenario (3)**

There is no generic model in the TNsG for cleaning of internal surfaces of treatment tanks. To predict exposure for this primary exposure scenario, the indicative exposure values from Handling Model 1 are used (TNsG User Guidance 2004, p. 26) have been used. These values reflect professional workers working in a wet environment with

intermittent handling of wet surfaces, i.e. treated wood and associated equipment. The exposure data in this model relate to industrial timber treatment using vacuum-pressure, with a full cycle duration of 180 minutes (User Guidance, 2004, p. 41). The inhalation duration of exposure is assumed as 180 min per cycle for this scenario.. Potential exposure is via the inhalation and dermal routes. Creosote at 100% w/w has been considered as in use concentration.

This is considered a worst case scenario and HEEG opinion 18 informs that cleaning of dip tanks is an infrequent task.

| **Tier** | **Parameters** | **Value** |
|---|---|---|
| Tier 1 | In use concentration of creosote | 100 % w/w |
| Tier 1 | Hand Exposure (inside gloves) | 260 mg/cycle |
| Tier 1 | Dermal absorption of creosote | 10 % |
| Tier 1 | Potential body exposure | 158 mg /cycle |
| Tier 1 | Inhalation exposure | 0.6 mg/m$^3$ |
| Tier 1 | Inhalation rate | 1.25 m$^3$ |
| Tier 1 | Inhalation duration | 180 min/cycle |
| Tier 1 | Number of treatment cycles/day | 1 |
| Tier 1 | Operator body weight | 60 kg |
| Tier 1 | Clothing penetration (impermeable coveralls) | 5 % |
| Tier 1 | RPE (APF20) | 95 % |

**Calculations for Scenario (3)**

The calculations for this scenario and can be found in Appendix II: Human exposure calculations and the findings summarised in the summary table Scenario 3 – Systemic exposure from industrial uses.

**Summary table – Scenario 3 - Systemic exposure from industrial uses**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
|---|---|---|---|---|
| Scenario 3 | New gloves, Impermeable coveralls and RPE with APF 20 (95% removal)<br><br>1 treatment cycle. | 0.001875 mg/kg bw/day | 0.2298 mg/kg bw/day | 0.23168 mg/kg bw/day |

**Further information and consideration on Scenario (3)**

Due to the biocidal product classification, a local effects assessment was also considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

*8.3.4. Scenario 4. Industrial use - Primary exposure during handling of wet treated wood*

**Description of Scenario (4)**

For fully automated dipping HEEG opinion 18 (For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping, 2015) states that “at the drying/storage site, transfer of wet wood from the forklift truck might be undertaken manually or more likely, the forklift truck might drop the wet treated wood at the drying point. At some point in the drying cycle piles of wooden articles in the storage area could fall, particularly if the tension straps fail, and the wooden articles will need to be manually restacked. It could be anticipated that this would not be a frequent occurrence; otherwise the wood yard would have devised a better means of drying/storing wooden articles. Therefore, it is assumed that in any day only one batch of timber from the dipping process will need to be manually re-stacked. In any particular day, these operations will normally be undertaken by a person other than the person who is undertaking the actual dipping of the wood.”

HEEG opinion 18 further states that “as the exposure of the person actually carrying out the dipping has already been assessed and this exposure being chiefly from handling

the wet treated wood (when fallen wooden articles need re-stacking/re-positioning) then, this same calculated exposure value can be used to define the exposure of the person re-stacking/re-positioning treated wood in the drying/storage area. It should be noted that, this exposure for is for a person re-stacking wet wood and in the drying/storage area, in many instances the wood will be dry thus, dermal exposure could be much less. Taking this into account might allow the exposure assessment to be refined if necessary".

Based on the above information, it can be concluded that secondary exposure during restacking of treated timber will be of the same magnitude or less than user exposure during automated dipping. As such scenario 1 (primary exposure during automatic dipping) forms a risk envelope for restacking treated timber and an additional estimate has not been carried out. Please refer to Scenario 1 for the predicted systemic exposure.

**Calculations for Scenario (4)**

The calculations for this scenario are the same as those used in scenario 1 and can be found in Appendix II: Human exposure calculations.

**Summary table – Scenario 4 - Systemic exposure from industrial uses**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
|---|---|---|---|---|
| Scenario 4 | 1 / New Gloves, Impermeable coveralls (5 %) and RPE with APF 20 (95% removal)<br><br>1 treatment cycle. | 0.000104 mg/kg bw/day | 0.2298 mg/kg bw/day | 0.2299 mg/kg bw/day |

**Further information and consideration on Scenario (4)**

Due to the biocidal product classification, a local effects assessment was also considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

*8.3.5. Combined scenarios*

It is anticipated that industrial users may treat wood and stack treated wood in the same working day, it is also possible to expect that industrial users may carry out the treatment of wood and clean the dipping equipment on the same working day. However as exposure from the individual scenarios exceeds the current DMEL no further calculations have been carried out in this assessment. Further information and risk

management measures will be considered in the risk characterisation section of this assessment.

## 8.4. Professional user exposure

### 8.4.1. Scenario 5. Professional use – Primary exposure – Brush application (outdoors)

**Description of Scenario (5)**

To assess the exposure of professional workers when applying the product with brush, the scenario "Professional brush treatment" described in the HEAdhoc Recommendation 6 has been followed. The calculated exposure values are in mg/m$^2$. The average application duration per m$^2$ is 7.6 min/m$^2$. Considering that the application task lasts 240 minutes/day, the surface of the applied area is 240 min / 7.6 min/m$^2$ = 31.6 m$^2$. The indicative values are normalised to 1% active substance. Due to the normalisation, at a product level the exposure values can be derived and for 100% creosote are as follows: 54.17 mg/m$^2$ to calculate exposure to hands and 23.82 mg/m$^2$ body. To calculate inhalation, a value of 0.16 mg/m$^2$ can be used at product level.

The BHHEM guidance (2015, p120) provided indicative values for a professional user applying a wood preservative through brush application along with an exposure duration and application area. These values are assumed to be representative of both brush and roller application. For tier 1 it is assumed that the professional users apply the product with no PPE. For tier 2a protective gloves and coated coveralls have been assumed and for tier 2b protective gloves(new), impermeable coveralls and suitable RPE have been applied.

As all wood to be treated with creosote should be machined/cut/sanded before treatment refinement of this scenario where brushing should only occur if treated wood has to be machined/cut on placement, a further refinement of reducing treatment time spent on this practice to 1 hour has been considered in tier 2c.

As the average application duration per m$^2$ is 7.6 min/m$^2$. The reduced application task in tier 2c lasts 60 minutes/day, the surface of the applied area is 60 min / 7.6 min/m$^2$ = 7.89 m$^2$.

| Tier | Parameters | Value |
|---|---|---|
| Tier 1 | In use concentration of creosote | 100 % w/w |
| Tier 1 | Operator body weight | 60 kg |
| Tier 1 | Dermal absorption of creosote | 10 % |

| Tier | Parameters | Value |
|---|---|---|
| Tier 1 | Potential body exposure | 23.82 mg/m$^2$ |
| Tier 1 | Hand Exposure | 54.17 mg/m$^2$ |
| Tier 1 | Adult Inhalation rate | 1.25 m$^3$/h |
| Tier 1 | Inhalation | 0.16 mg/m$^2$ |
| Tier 1 | Application area/day | 31.6 m$^2$ |
| Tier 1 | Exposure Duration | 240 mins |
| Tier 2a | Glove penetration (inside gloves) | 10 % |
| Tier 2a | Clothing penetration (coated coveralls) | 10 % |
| Tier 2b | Glove penetration (inside new gloves) | 5 % |
| Tier 2b | Clothing penetration (impermeable coveralls) | 5 % |
| Tier 2b | RPE (APF20) | 95 % |
| Tier 2c | Exposure Duration | 60 mins |
| Tier 2c | Application area/day | 7.89 m$^2$ |

**Calculations for Scenario (5)**

All calculations can be found in Appendix II: Human exposure calculations and the findings summarised in the table – Scenario 5 - Systemic exposure from professional uses.

**Summary table – Scenario 5 - Systemic exposure from professional uses**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
|---|---|---|---|---|
| Scenario 5 | 1 / No PPE | 0.0843 mg/day bw/day | 4.107 mg/day bw/day | 4.1917 mg/day bw/day |
| Scenario 5 | 2a Gloves, Coated coveralls | 0.0843 mg/day bw/day | 0.4107 mg/day bw/day | 0.49501 mg/day bw/day |
| Scenario 5 | 2b / New gloves, Impermeable coveralls and RPE with APF 20 (95% removal) | 0.00421 mg/day bw/day | 0.20537 mg/day bw/day | 0.20958 mg/day bw/day |
| Scenario 5 | 2c / New gloves, Impermeable coveralls and RPE with APF 20 (95% removal), exposure time reduced to 1 hour | 0.001052 mg/day bw/day | 0.051295 mg/day bw/day | 0.052347 mg/day bw/day |

**Further information and consideration on Scenario (5)**

Due to the biocidal product classification a local effects assessment was also considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

### *8.4.2. Scenario 6. Professional use – Primary exposure – Cleaning brush after application*

**Description of Scenario (6)**

As creosote is solvent- based, an exposure estimate for cleaning the brush after application is presented below based on information and the calculator provided in HEEG opinion 11.

| Tier | Parameters | Value |
|---|---|---|
| Tier 1 | In use concentration of creosote | 100 % w/w |
| Tier 1 | Operator body weight | 60 kg |
| Tier 1 | Dermal absorption of creosote | 10 % |
| Tier 1 | Brush size (large) | 10 x 10 x 2 cm with a corresponding value volume of 200 ml |
| Tier 1 | Volume remaining in brush after painting (assumed to be 1/8th of brush volume) | 25 ml |
| Tier 1 | Density of creosote | 1.17 g/ml |
| Tier 1 | Weight of paint remaining in brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml) | 25 ml x 1.17 g/ml = 29.25 g |
| Tier 1 | Minimum volume of each washing solution | 400 ml |
| Tier 1 | Percentage of residues remaining in brush after each washing step | 10 % |
| Tier 1 | Following each washing step, percentage of residues remaining in brush after squeezing | 50 % |
| Tier 1 | Percentage of residues absorbed by the cloth | 90 % |
| Tier 2a | Glove penetration (gloves) | 10 % |
| Tier 2b | Glove penetration (new gloves) | 5 % |

**Calculations for Scenario (6)**

All calculations can be found in Appendix II: Human exposure calculations and the findings summarised in the table – Scenario 6 - Systemic exposure from professional uses.

**Summary table – Scenario 6 - Systemic exposure from professional uses**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
|---|---|---|---|---|
| Scenario 6 | 1 / no PPE | - | 0.2565 mg a.s./kg bw | 0.2565 mg a.s./kg bw |
| Scenario 6 | 2a / Gloves | - | 0.02565 mg a.s./kg bw | 0.02565 mg a.s./kg bw |
| Scenario 6 | 2b / New gloves | - | 0.0128 mg a.s./kg bw | 0.0128 mg a.s./kg bw |

**Further information and consideration on Scenario (6)**

Due to the biocidal product classification, a local effects assessment was also considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

*8.4.3. Scenario 7. Professional – Secondary exposure – Sanding / Cutting treated wood*

**Description of Scenario (7)**

Professional (secondary) exposure to creosote for an adult professional cutting/sanding treated timber using a hand-held power sander has been estimated based on the following assumptions/parameters.

The highest retention rate for creosote is 210 kg creosote/$m^3$ for ‘softwood used in a number of fields including telegraph poles fencing/ tree stakes’. This is equivalent to 210 mg/$cm^3$ creosote when assuming all of the product is absorbed to a depth of 1 cm and penetrates no further. These values relate to the concentration in the treated zone, therefore no correction is required to take account of untreated ‘core’ timber.

Exposure is via the inhalation and dermal routes.

No gloves are worn (reflecting normal commercial practice when woodworking). This

has been followed for tier 1 and tier 2a. Tier 2a, as all wood to be treated with creosote should be machined/cut/sanded before treatment refinement reducing time spent on this practice to 1 hour has been considered. Tier 2b includes the use of RPE with APF of 20.

As the levels of exposure calculated were greater than the current DMEL a further refinement of using gloves was considered and shown in tier 2c demonstrating how this would affect dermal exposure for this scenario. It should however be noted this goes against commercial practice in wood working and is considered a hazard itself due to gloves potentially getting trapped in cutting equipment. The added protection gained from the use of gloves would not reduce the exposure below the current DMEL and therefore will not be considered further or taken forward to risk characterisation in this assessment.

When in dermal contact with treated timber, the user is exposed to the active substance contained in the outer 1 cm layer of the timber (TNsG 2002, Part 3, p. 50).

The UK Workplace Exposure Limit (WEL) for wood dust is 5 mg/m$^3$ (8-hour time-weighted average) (HSE, 2005). Inhalation exposure can be estimated based on this air concentration and assuming a duration of exposure of 6 hours for professionals and an inhalation rate of 1.25 m$^3$/h.

5 mg/m$^3$ x 1.25 m$^3$/h x 6 h = 37.5 mg wood dust inhaled in 6 hours

Assuming a density of 0.4 g/cm$^3$ (MOTA 4.2.5), 37.5 mg (0.0375 g) of wood dust is equivalent to 0.0375 ÷ 0.4 = 0.0938 cm$^3$ of treated wood.

Considering a refinement to 1 hr cutting/sanding wood and an inhalation rate of 1.25 m$^3$/h.

5 mg/m$^3$ x 1.25 m$^3$/h x 1 h = 6.25 mg wood dust inhaled in 1 hour.

Assuming a density of 0.4 g/cm$^3$ (MOTA 4.2.5), 6.25 mg (0.00625 g) of wood dust is equivalent to 0.00625 ÷ 0.4 = 0.015625 cm$^3$ of treated wood.

The surface area of both palms of hands is 410 cm² and during prolonged and repeated contact 20 % of the hand is contaminated (TNsG, Part 3, p. 51 and User Guidance, p. 52). The transfer efficiency from rough-sawn wood to the hands is 2 % (TNsG, Part 2, p. 204).

| **Tier** | **Parameters** | **Value** |
|---|---|---|
| Tier 1 | In use concentration of creosote | 100 % w/w |
| Tier 1 | Highest retention rate of creosote in treated wood | 210 mg/cm³ |

| Tier | Parameters | Value |
|---|---|---|
| Tier 1 | Depth of treated timber containing active substance to which user is exposed | 1 cm |
| Tier 1 | Dermal absorption of creosote | 10 % |
| Tier 1 | Surface area of hands | 410 $cm^2$ |
| Tier 1 | Proportion of hand surface area contaminated | 20 % |
| Tier 1 | Transfer efficiency wood to hands | 2 % |
| Tier 1 | Workplace Exposure Limit (WEL) for wood dust (8 hour TWA) | 5 $mg/m^3$ |
| Tier 1 | Duration of inhalation exposure | 6 hours |
| Tier 1 | Inhalation rate | 1.25 $m^3$ |
| Tier 1 | Density of wood dust | 0.4 $g/cm^3$ |
| Tier 1 | Volume of wood inhaled (from above) | 0.0938 $cm^3$ |
| Tier 1 | Operator body weight | 60 kg |
| Tier 2a | Duration of Inhalation Exposure | 1 hour |
| Tier 2a | Volume of wood inhaled (from above) | 0.015625 $cm^3$ |
| Tier 2b | RPE (APF 20, 95 % removal ) | 5 % |

| Tier | Parameters | Value |
|---|---|---|
| Tier 2c | Gloves | 10 % |

**Calculations for Scenario (7)**

An example calculation is presented for clarity. All remaining calculations can be found in Appendix II: Human exposure calculations and the findings summarised in the table – Scenario 7 - Systemic exposure from professional uses.

Systemic dose via the inhalation route (mg/kg bw/day) = volume of wood inhaled ($cm^3$) x concentration of a.s. in wood ($mg/cm^3$) x 100% absorption ÷ bodyweight (kg).

Tier 1 - Systemic dose via the inhalation route (mg/kg bw/day) = 0.0938 ($cm^3$) x 210 ($mg/cm^3$) x 100% absorption ÷ 60 (kg).

Systemic dose via the dermal route (mg/kg bw/day) = active substance residue on surface ($mg/cm^3$) x area of hands ($cm^2$) x proportion of hands contaminated (%) x transfer efficiency of wood (%) x dermal absorption (%) ÷ bodyweight (kg).

Tier 1 - Systemic dose via the dermal route (mg/kg bw/day) = 210 ($mg/cm^3$) x 410 ($cm^2$) x 20 (%) x 2(%) x 10 (%) ÷ 60 (kg).

**Summary table – Scenario 7 - Systemic exposure from professional uses**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
|---|---|---|---|---|
| Scenario 7 | 1 | 0.3283 mg a.s./kg bw | 0.574 mg a.s./kg bw | 0.9023 mg a.s./kg bw |
| Scenario 7 | 2a / exposure time reduced to 1hour | 0.0546875 mg a.s./kg bw | 0.574 mg a.s./kg bw | 0.6287 mg a.s./kg bw |

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
|---|---|---|---|---|
| Scenario 7 | 2b / RPE with APF 20 (95% removal); exposure time reduced to 1 hour | 0.002734375 mg a.s./kg bw | 0.574 mg a.s./kg bw | 0.57673 mg a.s./kg bw |
| Scenario 7 | 2c / RPE with APF 20 (95% removal); exposure time reduced to one hour; gloves | 0.002734375 mg a.s./kg bw | 0.0574 mg a.s./kg bw | 0.06013 mg a.s./kg bw |

**Further information and consideration on Scenario (7)**

Due to the biocidal product classification, a local effects assessment was also considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

#### *8.4.4. Combined scenarios*

It is anticipated that professional users may treat wood using a brush as well as sand/saw/cut the treated wood in the same working day. It is also possible to expect that professional users may carry out the treatment of wood by brush and clean the equipment also on the same working day. However as exposure from the individual scenarios exceeds the current DMEL no further calculations have been carried out in this assessment. Further information and risk management measures will be considered in the risk characterisation section of this assessment.

### *8.5. General public user exposure*

#### *8.5.1. Scenario 8. General Public – Secondary exposure – Sanding / Cutting treated wood*

**Description of Scenario (8)**

Creosote is for professional use only and generally there is no anticipated exposure for general public user. However the applicant has requested that creosote treated wood can be used as fencing at equestrian facilities and as stakes in orchards for fruit trees.

It is anticipated that workers at these facilities cannot be assumed to be trained professionals, therefore an assessment has been included for completeness for this use.

Primary exposure for a non-professional is considered to be within the risk envelope of scenario 7, tier 2a for a professional user carrying out this activity. The task duration is considered to be 1 hour for a non-professional user (TNsG User Guidance Version 1, p51) compared to 240 minutes for a professional user (ECHA guidance, 2015, p120). No PPE or further refinements are considered appropriate.

The highest retention rate for creosote is 210 kg creosote/$m^3$ for 'softwood used in a number of fields including telegraph poles fencing/ tree stakes. This is equivalent to 210 mg/$cm^3$ creosote when assuming all of the product is absorbed to a depth of 1 cm and penetrates no further. These values relate to the concentration in the treated zone, therefore no correction is required to take account of untreated 'core' timber.

Exposure is via the inhalation and dermal routes.

No gloves are worn (reflecting normal commercial practice when woodworking).

When in dermal contact with treated timber, the user is exposed to the active substance contained in the outer 1 cm layer of the timber (TNsG 2002, Part 3, p. 50).

The UK Workplace Exposure Limit (WEL) for wood dust is 5 mg/$m^3$ (8-hour time-weighted average) (HSE, 2005). Inhalation exposure can be estimated based on this air concentration and assuming a duration of exposure of 1 hour for the general public and an inhalation rate of 1.25 $m^3$/h.

5 mg/$m^3$ x 1.25 $m^3$/h x 1 h = 6.25 mg wood dust inhaled in 1 hour.

Assuming a density of 0.4 g/$cm^3$ (MOTA 4.2.5), 6.25 mg (0.00625 g) of wood dust is equivalent to 0.00625 ÷ 0.4 = 0.015625 $cm^3$ of treated wood.

The surface area of both palms of hands is 410 $cm^2$ and during prolonged and repeated contact 20 % of the hand is contaminated (TNsG, Part 3, p. 51 and User Guidance, p. 52). The transfer efficiency from rough-sawn wood to the hands is 2 % (TNsG, Part 2, p. 204).

| **Tier** | **Parameters** | **Value** |
|---|---|---|
| Tier 1 | In use concentration of creosote | 100 % |
| Tier 1 | Highest retention rate of creosote in treated wood | 210 mg/$cm^3$ |

| Tier | Parameters | Value |
|---|---|---|
| Tier 1 | Depth of treated timber containing active substance to which user is exposed | 1 cm |
| Tier 1 | Dermal absorption of creosote | 10 % |
| Tier 1 | Surface area of hands | 410 $cm^2$ |
| Tier 1 | Proportion of hand surface area contaminated | 20 % |
| Tier 1 | Transfer efficiency wood to hands | 2 % |
| Tier 1 | Workplace Exposure Limit (WEL) for wood dust (8 hour TWA) | 5 $mg/m^3$ |
| Tier 1 | Duration of inhalation exposure | 1 hour |
| Tier 1 | Inhalation rate | 1.25 $m^3$ |
| Tier 1 | Density of wood dust | 0.4 $g/cm^3$ |
| Tier 1 | Volume of wood inhaled (from above) | 0.015625 $cm^3$ |
| Tier 1 | Operator body weight | 60 kg |

**Calculations for Scenario (8)**

All calculations can be found in Appendix II: Human exposure calculations and the findings summarised in the table – Scenario 8 - Systemic exposure from general public uses.

**Summary table – Scenario 8 - Systemic exposure from general public uses**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated total uptake |
|---|---|---|---|---|
| Scenario (8) | Tier 1 No PPE, 1 hour exposure | 0.0546875 mg a.s./kg bw | 0.574 mg a.s./kg bw | 0.6287 mg a.s./kg bw |

**Further information and consideration on Scenario (8)**

Due to the biocidal product classification, a local effects assessment was also considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

*8.5.2. Combined scenarios*

Creosote is for professional use only**.** There are no realistic combined exposures anticipated for general public, secondary exposures.

## *8.6. Secondary exposure of the general public (bystanders) excluding dietary exposure*

### *8.6.1. Scenario 9. Professional / Industrial use – Secondary chronic exposure Cleaning work clothes at home*

**Description of Scenario (9)**

At TM III08 it was decided that this scenario should be considered where there was a possibility of workers taking soiled workwear home to launder (e.g. for small-scale dipping processes), but that the exposure scenario was not required when wood preservatives were applied under industrial conditions. For industrial treatments, it was assumed the employer would employ professional means to launder contaminated workwear where contact with dirty clothes would be insignificant. This scenario has therefore only been considered for application methods that can be undertaken on a small scale by professionals and/or non-professionals (i.e. when application is through brush/roller application or manual dipping).

As creosote has previously been approved for remedial treatment by brushing when installing fencing etcetera this scenario has been included in this assessment. An adult may be exposed to creosote whilst laundering contaminated work clothing (i.e. coveralls) at home. It is assumed that the laundering is undertaken in a domestic, automatic washing machine. It is also assumed that exposure will be by the dermal route (via the hands) from handling the contaminated clothing prior to and during introduction of the clothing into the washing machine.

For this scenario it has been assumed that laundering coveralls after application of

creosote by brush for remedial treatment is considered. The model assumes the coverall is washed after 5 days of wear.

This is considered to be a professional user applying the product containing 100% creosote to wood using a brush. To assess the exposure of professional workers when applying the product with brush, the scenario “Professional brush treatment” described in the HEAdhoc Recommendation 6 has been followed. The calculated exposure values are in mg/m$^2$. The average application duration per m$^2$ is 7.6 min/m$^2$. Considering that the application task lasts 240 minutes/day, the surface of the applied area is 240 min / 7.6 min/m$^2$ = 31.6 m$^2$. The indicative values are normalised to 1% active substance. Due to the normalisation, at a product level the exposure values can be derived and for 100% creosote the indicative value for body 23.82 mg/m$^2$.

The total surface area of a medium-sized coverall is 22700 cm$^2$ (which in the calculation gives a greater exposure to the person undertaking the laundering than for a larger sized coverall).

For an adult, the total area of both hands (palms and backs of hands) is 820 cm$^2$ (HEEG opinion 17) however it can be assumed that only the palms will come into contact with the contaminated coveralls (equating to a surface area of 410 cm$^2$). It is proposed that 30 % of the dried fluid will be transferred from the coveralls to wet hands (TNsG 2002, Part 2, p. 204). Using the dermal absorption value 10 % for creosote the systemic dose for a 60 kg adult.

In previous assessments it has been agreed that contaminated clothes should not be worn, therefore a refinement for clothes contaminated by 1 days work has been considered at tier 2.

| **Tier** | **Parameters** | **Value** |
|---|---|---|
| Tier 1 | Adult body weight | 60 kg |
| Tier 1 | Adult hand surface area (palms) | 410 cm$^2$ |
| Tier 1 | Surface area of laundered coverall | 22700 cm$^2$ |
| Tier 1 | Creosote residue on contaminated coveralls after application. | 3763.56 mg |
| Tier 1 | Residue per cm$^2$ on contaminated coveralls after brush application of creosote | 0.16580 mg/cm$^2$ |

| Tier | Parameters | Value |
|---|---|---|
| Tier 1 | Dermal penetration of creosote | 10 % |
| Tier 1 | Transfer from cotton coveralls to wet hands | 30 % |
| Tier 2 | 1 day surface contamination of coveralls | 1 |
| Tier 2 | Creosote residue on contaminated coveralls after application. | 752.712 mg |
| Tier 2 | Residue per $cm^2$ on contaminated coveralls after brush application of creosote | 0.03316 $mg/cm^2$ |

**Calculations for Scenario (9)**

All calculations can be found in Appendix II: Human exposure calculations and the findings summarised in the table – Scenario 9 - Systemic exposure from general public uses.

**Summary table – Scenario 9 - Systemic secondary exposure of general public bystanders**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
|---|---|---|---|---|---|
| Scenario (1) | Tier 1/No PPE | N/A | 0.03399 mg/kg bw/day | N/A | 0.03399 mg/kg bw/day |
| Scenario (2) | Tier 2a/refine to 1 day | N/A | 0.0068mg/kg bw/day | N/A | 0.0068 mg/kg bw/day |

**Further information and consideration on Scenario (9)**

Due to the biocidal product classification, a local effects assessment was also

considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

### *8.6.2. Scenario 10. Secondary exposure – Dermal and ingestion exposure from contact with treated wood [adult and children – contact treated poles or equestrian fences]*

**Description of Scenario (10)**

Creosote is exclusively used by industrial/professional users. Any occasional exposure to the public for example by touching treated wood is not expected to exceed the exposure experienced by workers.

Wood treated with creosote is not allowed to be used indoors, to construct toys or playgrounds. However as creosote-treated wood is intended to be used in agriculture, (e.g. poles in vineyard, orchard or equestrian fences), it is possible that there could be secondary long-term exposure to adult, children and toddlers through e.g. contact with treated poles in vineyard or orchard or equestrian fences. Indirect exposure of the general public via dermal and oral routes is possible and is addressed here based on a model provided in the TNsG on Human Exposure (2002) for secondary long-term exposure of toddlers playing on treated structures.

Surface application by brush from the applicants label states a range of 204-234 g/m$^2$ which equates to 20.4-23.4 mg creosote / cm$^2$ treated wood. The highest concentration of 23.4 mg/cm$^2$ will be used in this scenario as worst case.

This assessment has considered exposure to adults and also toddlers as they would be considered as worst case exposure for children. For adults this assessment has considered only dermal exposure. For toddlers oral exposure from mouthing hands after dermal exposure has been considered as worst case.

| Tier | Parameters | Value |
|---|---|---|
| Tier 1 | Surface application rate of creosote on treated wood | 23.4 mg/cm$^2$ |
| Tier 1 | Hand Contamination (Proportion of palms of hand in contact with the b.p., percentage contaminated skin TNsG on Human Exposure, part 2 (2002)) | 20 % |

| Tier | Parameters | Value |
|---|---|---|
| Tier 1 | Transfer coefficient of biocidal product from dried b.p. to hand TNsG on Human Exposure, part 2 (2002) | 2 % |
| Tier 1 | Oral Absorption | 100 % |
| Tier 1 | Dermal absorption of creosote | 10 % |
| Tier 1 | Adult body weight | 60 kg |
| Tier 1 | Adult hand surface area | 410 $cm^2$ |
| Tier 1 | Toddler body weight | 10 kg |
| Tier 1 | Toddler hand surface area | 115.2 $cm^2$ |

**Calculations for Scenario (10)**

Calculations for systemic exposure for this scenario are based on the following equations.

Systemic exposure via the dermal route = concentration of a.s. on the wood surface ($mg/cm^2$) x surface area of hand ($cm^2$) x area of hand contaminated (%) x transfer coefficient (%) x dermal absorption (%) ÷ bodyweight (kg)

Systemic exposure via the oral route = concentration of a.s. on the wood surface ($mg/cm^2$) x surface area of hand ($cm^2$) x area of hand contaminated (%) x transfer coefficient (%) x oral absorption (%) ÷ bodyweight (kg)

All calculations can be found in Appendix II: Human exposure calculations and the findings summarised in the table – Scenario 10 - Systemic secondary exposure of general public bystanders.

**Summary table – Scenario 10 - Systemic secondary exposure of general public bystanders**

| Exposure scenario | Tier / PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
|---|---|---|---|---|---|
| Scenario (10) | 1 / No PPE Adults | N/A | 0.06396 mg a.s./kg bw | - | 0.06396 mg a.s./kg bw |
| Scenario (10) | 1 / No PPE Toddler | N/A | - | 1.078272 mg a.s./kg bw | 1.078272 mg a.s./kg bw |

**Further information and consideration on Scenario (10)**

Due to the biocidal product classification a local effects assessment was also considered, however the local effects are not the critical concern due to its non-threshold carcinogenic effects. Full details can be found in risk characterisation section of this assessment along with any suitable risk management measures deemed appropriate.

*8.6.3. Scenario 11. Secondary acute exposure – Secondary exposure –Inhalation of volatilised residues indoor*

**Description of Scenario (11)**

Creosote treated wood is not for use in domestic premises and is not for use indoor, therefore the standard calculation for inhalation of volatilised residues is not required as this exposure is not foreseen and won't be considered further in this assessment.

*8.6.4. Combined scenarios*

There are no realistic combined exposures anticipated for general public, secondary exposures.

## *8.7. Dietary exposure*

*8.7.1. List of scenarios*

**Summary table of main representative dietary exposure scenarios**

| Scenario number | Type of use (e.g. animal husbandry, food industry, professional use, residential use) | Description of scenario | Subject of exposure (e.g. chicken, milk, beer) |
|---|---|---|---|
| 12. | Agricultural Fencing/Equestrian Fencing | Agricultural fencing/equestrian fencing treated with creosote | Livestock |
| 13. | Agriculture/Food Industry | Agricultural tree stakes/supports treated with creosote | Soft fruits, fruit, vineyard, and hops |

Although the current approval for creosote contains marine use and there may be the possibility of dietary exposure via fish, no further consideration has been given to this scenario given marine application is not in use in GB and guidance is currently unavailable. Should future product applications be made to GB, this scenario would need to be considered further at product authorisation.

*8.7.2. Information on non-biocidal use of the active substance*

Non-biocidal use of this active is not anticipated.

*8.7.3. Estimating livestock exposure to active substances used in biocidal products*

8.7.3.1. Scenario (12) Exposure to livestock from agricultural fencing treated with creosote.

**Description of Scenario (12)**

The biocidal product is intended for pre-treatment of timber by industrial users. Regarding potential exposure to the product during mixing and application, as the product is applied to wood only in industrial premises there is no potential for direct exposure to animals.

The treated timber is intended primarily for professional uses such as railway sleepers, utility poles and fencing. Therefore potential indirect exposure to livestock can be envisaged from the use on fences.

There is no available guidance on animal risk assessment. However, this assessment is based primarily on the BPR guidance (vol III, part B+C, chapter 6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products). The guidance states that animals can take up residues of the biocidal product by chewing

on (e.g. horses, rabbits, goats), rubbing against (large slaughter animals) or licking (e.g. ruminants) the treated materials. In addition, volatile substances being released from the treated material may be inhaled, but this is not relevant for creosote since the active /product is for outdoor use only.

The exposure is calculated using the The Federal Institute for Risk Assessment (BfR) calculator. A summary is presented here in the main body of the document and the full calculations can be found in Appendix II of this assessment.

The following scenarios were included:

- Oral exposure of animals licking surfaces treated with the biocidal product

Exposure = application rate (mg/m$^2$) * tongue surface area * licks per day / bw

- Oral exposure of animals chewing on wood treated with the biocidal product

Exposure = application rate (mg/m$^2$) * wood consumption / bw

- Dermal exposure of animals rubbing on surface treated with the biocidal product

Exposure = application rate (mg/m$^2$) * body surface area in contact with surface / bw

The default values given in the guidance make assumptions based on wood consumption, the animals body surface area and number of licks per day. It is assumed that animals are exposed through a number of exposures to treated wood, particularly in sheds and enclosed spaces. It is not expected that creosote treated timber will be used in this context except for agricultural fencing so exposure based on this assessment can be considered worst case. The extent of exposure can also depend on animal husbandry practices. It is accepted that animals tend to chew or lick due to boredom or a dietary deficiency. Good animal practice can be assumed to reduce exposures.

***Summary of the default data***

| **Animal** | **Body weight (kg)** | **Body surface area in contact with treated wood (m$^2$)** | **Wood consumption (m$^3$/day)** | **Tongue surface area (m$^2$)** | **Licks per day** |
|---|---|---|---|---|---|
| Horse | 400 | 1.62 | 0.0000186 | - | - |
| Beef cattle | 500 | 1.44 | - | - | - |

| Animal | Body weight (kg) | Body surface area in contact with treated wood ($m^2$) | Wood consumption ($m^3$/day) | Tongue surface area ($m^2$) | Licks per day |
|---|---|---|---|---|---|
| Dairy cattle | 650 | 1.68 | - | - | - |
| Calf | 200 | 0.87 | - | 0.008 | 10 |
| Fattening pig | 100 | 0.45 | - | 0.08 | 10 |
| Breeding pig | 260 | 0.84 | - | 0.08 | 10 |
| Sheep | 75 | 0.45 | - | - | - |
| Lamb | 40 | 0.30 | - | - | - |
| Slaughter goat | 13 | 0.15 | - | - | - |
| Lactating goat | 70 | 0.45 | - | - | - |
| Rabbit | 2.5 | 0.06 | 0.0000031 | - | - |

The BPR guidance uses a default maximum product uptake of 50 L/$m^3$. Creosote has a maximum retention of 210 kg/$m^3$ (UC4) which has been used to represent the likely treatment level for fencing. It should be noted that this is an analytical zone retention and overall it is possible the value will be less. For this reason calculations for both 50L/$m^3$ and the 210kg/$m^3$ (UC4) retention values have been considered in this assessment.

When considering an uptake of 50 L/$m^3$ for 100% w/w creosote, this gives the following amounts of active substance in treated wood:

50 L of a substance of density 1.17 g/ml or 1.17 kg/L = 58.5 kg

50 L/$m^3$ = 58.5 kg/$m^3$

58.5 kg/m$^3$ x 100 % w/w x 1000

58,500 g/m$^3$

For dermal exposure and oral licking a surface concentration is required. This is calculated from:

g/m$^3$ x 0.05 mm (0.05 x 10$^{-3}$ m depth) x 1000

For creosote

58,500 g/m$^3$ x 0.05 mm (0.05 x 10$^{-3}$ m depth) x 1000

2,925 mg/m$^2$

When considering an uptake of 210 kg/m$^3$ (UC4) for 100% w/w creosote, this gives the following amounts of active substance in treated wood:

210 kg/m$^3$ x 100 % w/w x 1000

210,000 g/m$^3$

For dermal exposure and oral licking a surface concentration is required. This is calculated from:

g/m$^3$ x 0.05 mm (0.05 x 10-3 m depth) x 1000

For creosote

210000 x 0.05 mm (0.05 x 10$^{-3}$ m depth) x 1000

10,500 mg/m$^2$

In accordance with the BPR guidance, a Tier 1 screening assessment was made, using The Federal Institute for Risk Assessment (BfR) calculator for estimating external exposure of livestock animals, to determine the oral and dermal exposure estimations.

***BfR input data***

BfR input data – Application rates

| **Active substance** | **Active Retention Rate (kg/m$^3$)** | **Dermal (mg/m$^2$)** | **Oral (chewing) (g/m$^3$)** | **Oral (licking) (mg/m$^2$)** |
|---|---|---|---|---|
| Creosote | 58.5 | 2,925 | 58,500 | 2,925 |

| Active substance | Active Retention Rate (kg/m$^3$) | Dermal (mg/m$^2$) | Oral (chewing) (g/m$^3$) | Oral (licking) (mg/m$^2$) |
|---|---|---|---|---|
| Creosote | 210 | 10,500 | 210,000 | 10,500 |

Output tables from the BfR calculator can be found in Appendix II.

The BPR Guidance gives a trigger value of 0.004 mg/kg bw as a level below which residues can be considered insignificant unless the substance is extremely toxic. All values in the tables for screening in Appendix II exceed this trigger value and further refinement was required.

The BfR calculator has been used with the following refinements:

- dislodgeable residues (2%) for oral exposure via licking, (BHHEM (p 171; ECHA 2015), the default value for dislodgeable residues from rough sand wood).

- dermal absorption (10%), (tox assessment), and

- and an additional factor for the barrier provided by fur/feathers (50%) (Fresenius course on Biocidal products and Dietary Risk Assessment (DRA) – 12th October 2023 (online course)

The refinement values have been used for oral exposure (via licking) and dermal exposure (through rubbing); and indicate that the total external exposure (dermal and oral) for creosote still exceeds the trigger value of 0.004 mg/kg bw., and would also exceed the consumer DMEL.

**Conclusion**

Consideration has been made as 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. Any use of creosote that leads to food residues should be considered unacceptable as creosote is classified as a genotoxic carcinogen. There is no harmonised guidance for assessing the risk for animals, however, considering these assumptions it can be concluded that the risk to livestock from contact with creosote treated wood cannot be ruled out.

The assessment of animal (livestock) exposure concludes that dietary intakes could be significant. In order to fully assess risks to livestock, an animal feeding study would be required (please consult HSE before setting up a study) and concurrently, data on a validated method of analysis must be generated. The data submission to meet this requirement should provide full details of the analytical method with suitable acceptable validation data (including recovery rates and the limit of quantification and detection for the active substance and residues), in relevant livestock matrices.

*8.7.4. Estimating transfer of biocidal active substances into foods as a result of professional and / or industrial application(s)*

8.7.4.1. Scenario (13) Evaluation of residues in fruit trees and consumer risk assessment

Use for treatment of agricultural fruit stakes has been assessed for use of creosote products (containing 100% creosote, as a ready to use liquid treatment). It can be used as (use class 4, UC4) where treated posts are used outdoors and embedded in the ground and are in direct contact with the soil.

Treatment of agricultural tree stakes/supports (fruit, vineyard, and hops) is requested for when a long service life is needed. Treatment is via pressure impregnation (pressure process/vacuum impregnation) at the following treatment rates:

One application cycle per batch

Softwood: 100 to 195 kg per $m^3$

Hardwood: 160 to 210 kg per m3

For wood treatments generally, there is the potential for transfer of residues into food crops, either by way of uptake of residues from the soil, especially if the residues are highly persistent in the soil, or via contact of the wooden posts with the growing crop directly.

An assessment has been carried out on information submitted by the applicant and can be found in Appendix VII of this document.

**Conclusion**

Three fruit tree residues studies have been evaluated to consider residues arising from uses of creosotes wooden stakes as supports in food production. The studies covered pome fruits (apples and pears) and stone fruits (cherries and plums).

The residues determined in the fruits have enabled an indicative risk assessment to be performed. It is indicative, since a residues definition for dietary risk assessment is not being proposed as the residue findings are of concern (since it is concluded that creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded (see section 12.2 on Reference values (HSE toxicological assessment)). In the indicative dietary risk assessment, the chronic and acute dietary intakes far exceed the consumer DMEL (see section A.6 of the residues assessment) indicating that an expectation of both long term and short term effects on health cannot be excluded arising from the assessment of the fruit tree uses of creosote.

It is not possible to propose risk mitigation measures that could reduce the indicative assessment dietary intakes to levels below the consumer DMEL. Mitigation measures and uncertainties in the assessment are discussed in section A.5.4 of Appendix VII. As noted above creosote is considered to be a genotoxic carcinogen. As such, for the proposed use of creosote on wooden posts used as supports for fruit trees (or other supports for food crops such as hops or grapevines) harmful effects on human health

cannot be excluded. (Full assessment and conclusion can be found in Appendix VII of this assessment).

### 8.8. Exposure associated with the production, formulation and disposal of the biocidal product

This is addressed by other regulation and is not considered in this assessment.

### 8.9. Combined residential scenarios

General public use is not anticipated as creosote is a professional use product. It is anticipated that a combined exposure is possible from dermal contact of treated wood in agricultural/equestrian setting and from dietary exposure. However as creosote is a non-threshold carcinogen any use of creosote that leads to food residues should be considered unacceptable and minimised.

## 9. Environmental exposure assessment

The 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 acts both as active substance and wood preservative so there is no formulated product. It is applied to timber only in industrial plants for preventative treatment of wood by vacuum pressure impregnation. Creosote treated wood is used in the use classes detailed in Section 2.1.

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, it can be assumed that storage places are sealed to prevent any direct release to the environment (local waterways, STP and ground). Labelling and associated literature 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). Any losses of the product must be collected for reuse or disposal as hazardous waste in accordance with local requirements.*

*Freshly treated timber must 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 must be collected for reuse or disposal as hazardous waste in accordance with local requirements.*

Emissions estimation has been undertaken to evaluate the following use patterns :

- UC 3: pressure impregnation: Preventive treatment of wood to be used as railway sleepers, agricultural fencing, equestrian fencing, industrial and highways fencing, cladding for non-residential buildings – all timber not in contact with the ground - 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 or agricultural fencing or equestrian fencing, hop poles, environmental barriers, industrial landscape retaining timbers, tree support posts (fruit, vineyards), jetty timbers and sheet piling – all timber in contact with the ground (UC4a) or in contact with fresh water (UC4b) -. 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: 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)

**Leaching rates**

No new leaching data have been provided. Previously agreed decisions reached within Document II-A of the original approval of creosote (2010) in terms of flux rates in UC 3, 4a, 4b and 5 have been presented below. Furthermore, decisions reached within Appendix 7 of the revised ESD (2013) now impact upon determination of Q*leachTime 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 approval of creosote (2010) were based upon leaching rates derived from pine. It is noted that there was a recommendation made within the original approval of creosote (2010) to use pine based data as a standard approach and this has also been accepted for the purposes of creosote renewal.

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 (mg/m$^2$/d) (Original approval of creosote (2010))** | **Flux corrected for retention rate (mg/m$^2$/d)** |
|---|---|---|
| UC 3 Time 1*<br><br>[A2.10.2/02, [redacted]] | Phe: 0.0095<br>Ant: 0.00057<br>Flu: 0.0089<br>B(a)A: 0.0051<br>Cre: 0.35 | Phe: 0.00994<br>Ant: 0.000597<br>Flu: 0.0093<br>B(a)A: 0.00534<br>Cre: 0.366 |
| UC 3 Time 2**<br>[A2.10.2/03, [redacted] | Phe: 0.0017<br>Ant: 0.00003 | Phe: 0.00178<br>Ant: 0.0000314 |

| | | |
|---|---|---|
| [redacted]] | Flu: 0.0013<br><br>B(a)A: 0.00013<br><br>Cre: 0.046 | Flu: 0.00136<br><br>B(a)A: 0.000136<br><br>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

UC 4a and 4b leaching rates have been derived from experimental data from pine treated at a retention of 91.5 kg/m3 and subjected to continual immersion in (fresh) water. The original approval of creosote (2010) 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). This approach has also been accepted for creosote renewal.

Flux rates have again been corrected to 90 kg/m3 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 (Original approval of creosote (2010)) (mg/m$^2$/d)** | **Flux corrected for retention rate (mg/m$^2$/d)** |
|---|---|---|
| UC 4a + 4b<br><br>Time 1*<br><br>[A2.10.2/07, [redacted]] | Phe: 12.6<br><br>Ant: 0.85<br><br>Flu: 4.0<br><br>Pyr: 2.6<br><br>Cre: 100 | Phe: 12.4<br><br>Ant: 0.84<br><br>Flu: 3.93<br><br>Pyr: 2.56<br><br>Cre: 98.4 |
| UC 4a + 4b<br><br>Time 2**<br><br>[A2.10.2/07, [redacted]] | Phe: 1.7<br><br>Ant: 0.33<br><br>Flu: 0.9<br><br>Pyr: 0.68 | Phe: 1.67<br><br>Ant: 0.32<br><br>Flu: 0.89<br><br>Pyr: 0.67 |

| | | |
|---|---|---|
| | Cre: 18 | Cre: 17.7 |

* Flux rate based on results at 0 – 31 d

** Flux rate based on results obtained between 31 – 180 d

The fence post and transmission pole assessment in the original approval of creosote (2010) 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 approval of creosote (2010) 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 4 b (fresh water) as only limited data were available specifically for UC 5. The original approval of creosote (2010) 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/m3 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*<br><br>[using A2.10.2/07, [redacted]] | Phe: 5.1<br><br>Ant: 0.35<br><br>Flu: 1.6<br><br>Pyr: 1.1<br><br>Cre: 40.8 | Derived from UC 4b Time 1 data, which is then corrected for freshwater v saltwater flux and notional retention of 150 $kg/m^3$ |
| UC 5 Time 2**<br><br>[using A2.10.2/07, [redacted]] | Phe: 0.69<br><br>Ant: 0.13<br><br>Flu: 0.40<br><br>Pyr: 0.28 | Derived from UC 4b Time 2 data, which is then corrected for freshwater v saltwater flux and notional retention of 150 $kg/m^3$ |

| | | |
|---|---|---|
| | Cre: 7.33 | |

* Flux rate based on results at 0 – 31 d

** Flux rate based on results obtained between 31 – 180 d

Creosote retention rates in timber were taken to be 90 kg/m$^3$ (UC 3 - 4) and 150 kg/m$^3$ (UC 5) and interpretation of relevant leaching data summarised above gave rise to the following cumulative Q*leach emissions from treated wood in-service at Time 1 (30 d) and Time 2 (20 year service life) :

| Cumulative loss at Time t | UC 3 | UC 4a + 4b | UC 5 |
|---|---|---|---|
| TIME 1 Q*leach (in mg/m$^2$) | 10.98 | 2952 | 1224 |
| TIME 2 Q*leach (in mg/m$^2$) | 383.93 | 131631 | 54513.1 |

Although a service life of 25 – 30 yr is stated for creosote treated wood, current guidance on environmental exposure assessments for PT8 recommends the use of a maximum of only 20 yr in emissions assessment. This has been used to determine $Q_{leach,time\ 2}$ in mg/m$^2$ (in line with the approach taken in the original approval of creosote (2010)). A service life of 20 years would be realistic for a generalised scenario for the vineyard / orchard emission model. However, in the case of creosote, it may be considered that 25 - 30 years can be achieved with partly treated posts and these higher service lives might be realistic. For a “persistent” active substance such as creosote (or more specifically as a “*substance with PBT constituents*”), it is possible that, in some cases, longer service lives and thus higher exposure to soil may occur. This should be noted when considering the results of the relevant environmental exposure and risk characterisations presented further below.

The focus of the environmental assessment will be on total creosote levels and not individual components of concern (such as phenanthrene, anthracene, fluoranthene, pyrene). Although ECHA guidance indicates that notional risks at “New TIME 2” (365 d)” should be included for PT8 products, these values have been omitted as they would add significant complexity to the assessment and are not yet currently used in regulatory decision making. Therefore, in subsequent calculations, TIME 1 refers to 30 d and TIME 2 refers to service life (set arbitrarily at 20 years or 7300 d).

Exposure modelling makes use of publicly available ECHA PT 8 calculator documents (MS Excel) and specific models published in TAB relevant to this application, including vineyard stake modelling (ENV 216) and PECsw - PECsed partitioning (ENV 209).

**General information**

| | |
|---|---|
| **Assessed PT** | PT8 |

| | |
|---|---|
| **Assessed scenarios** | Scenario 1: in-service losses from UC 3 scenarios (house, bridge-over-pond, noise barrier, railway sleeper). In addition, fence scenario is included to take account of proposed use on "non-residential cladding" ;<br><br>Scenario 2: in-service losses from UC 4a scenarios (transmission pole, fruit / vineyard stakes). In addition, fence post scenario is included to take account of potential use on a range of support posts ;<br><br>Scenario 3: in-service losses from UC 4b scenarios (sheet piling, jetty-on-a-lake) ;<br><br>Scenario 4: in-service losses from UC 5 scenarios (harbour wharf – marine). |
| **ESD(s) used** | Emission Scenario Document for Product Type 8: Revised Emission Scenario Document for Wood Preservatives ENV/JM/MONO(2013)21 : 2013. |
| **Approach** | Scenarios 1 - 4: Average consumption |
| **Distribution in the environment** | Guidance on the Biocidal Products Regulation. Volume IV: Environment – Parts B + C: Assessment and Evaluation (ECHA, 2017) plus relevant TAB entries |
| **Groundwater simulation** | Tier 1 screening calculations ($PEC_{porewater}$) model in Vol IV, Parts B+C (2017)<br><br>Where simplistic porewater levels are predicted to exceed drinking water trigger concentrations, then higher tier (TIER 2) FOCUS PEARL 4.4.4 modelling will be applied. |
| **Confidential annexes** | NO |

| | |
|---|---|
| **Life-cycle steps assessed** | All Scenarios:<br><br>Production: NO<br><br>Formulation: NO<br><br>Use: NO (in this specific instance, application / storage losses have been disregarded as creosote is assumed to have been applied only at pre-treatment sites where all losses to surface water, ground and STP are prevented due to bunding)<br><br>Service life: YES |
| **Remarks** | None |

**Biocidal product specific data**

No product specific data are relevant to this product as active substance is considered to make up 100% of the formulation. All in-service leaching data is based upon data supplied at first approval as reported in the original approval of creosote (2010).

## *9.1. Emission estimation*

### *9.1.1. Scenario (1) : emissions from UC 3 in-service*

Note that in general the HOUSE scenario is more protective for PT 8 assessment. However an assessment based on the FENCE scenario has been undertaken using latest ECHA modelling sheets. This is due to the concern that reliance on a "residential" HOUSE scenario may be too conservative for "non-residential" use and thus both HOUSE and FENCE applications are included.

It has been assumed that use on railway sleepers does not lead to exposure of surface water or soil. As such, only the PEARL 4.4.4 groundwater assessment is considered valid and no further consideration of other environmental compartments for the railway sleeper use is made.

**Calculations for Scenario (1)**

Calculations are performed on several publicly available PT 8 modelling sheets that take account of ESD scenarios, revisions / refinements published within TAB and equations specified in Vol IV, Parts B+C (2017).

In terms of the BRIDGE-OVER-POND scenario, modelling utilises latest principles of PECsw – PECsed partitioning outlined in ENV 209 of TAB. Whilst those partitioning calculator sheets appear in TAB_Feb_2021, they were in development for several years before being finalised – discussion of the revised approach to suspended matter / sediment in pond and jetty scenarios is discussed under ENV 113 of TAB v2.1 (Dec 2019).

**Resulting local emission to relevant environmental compartments**

| Compartment | Local emission ($Elocal_{compartment}$) (kg/d) | Remarks |
|---|---|---|
| Wastewater | 7.69E-4 (Time 1)<br>1.10E-4 (Time 2) | Only relevant for noise barrier scenario |

Elocal values are only relevant for losses from noise barriers, where a fraction of losses are directed to local STP : emissions modelling for other scenario predicts actual concentrations (PECs) in soil or water.

*9.1.2. Scenario (2) : emissions from UC 4a in-service*

The FENCE POST scenario has been undertaken using latest modelling sheets. Although the TRANSMISSION POLE scenario is more protective in general for PT 8 assessment, there is concern that this may be too conservative and thus both TRANSMISSION POLE and FENCE POST applications are included.

When performing exposure calculations in the latest ECHA calculator sheets, it is clear that, in several UC 4 scenarios, only one entry is feasible for Q*leach value. However, part of the treated wood will be in contact with ground or water and the remainder will be above that medium. This requires consideration of differential leach rates for above and below ground timbers. In order to make use of latest Excel modelling sheets, composite Q*leach rates for creosote have been generated based on simple proportioning, using :

| Cumulative leaching loss at Time t | UC 3 | UC 4 |
|---|---|---|
| TIME 1 Q*leach (in $mg/m^2$) | 10.98 | 2952 |
| TIME 2 Q*leach (in $mg/m^2$) | 383.93 | 131631 |

<u>Transmission pole model</u> assumes 5.5 m of wood above soil and 1.6 m below soil, so composite Q*leach values would be :

Time 1 : (5.5 / 7.1 x 10.98) + (1.6 / 7.1 x 2952) = 673.75 $mg/m^2$

Time 2 : (5.5 / 7.1 x 383.93) + (1.6 / 7.1 x 131631) = 29960.73 $mg/m^2$

<u>Fence post model</u> assumes 0.8 m of wood above soil and 0.2 m below soil, so composite Q*leach values would be :

Time 1 : (0.8 / 1.0 x 10.98) + (0.2 / 1.0 x 2952) = 599.18 mg/m$^2$

Time 2 : (0.8 / 1.0 x 383.93) + (0.2 / 1.0 x 131631) = 26633.34 mg/m$^2$

In terms of the vineyard stake scenario (in accordance with ENV 216 of TAB) again, the current model requires a composite Q*leach value for UC 3 + UC 4a losses using information about the quantity of treated wood above and below soil as follows :

Time 1 : (0.25 / 0.8 x 10.98) + (0.55 / 0.8 x 2952) = 1302.31 mg/m$^2$

Time 2 : (0.25 / 0.8 x 383.93) + (0.55 / 0.8 x 131631) = 90616.29 mg/m$^2$

One point to note is that the model is generic and assumes application methods are available to partially treated each post / stake : only 0.8 m of the wooden article is treated and 1.45 m remains untreated. However, wood will typically be treated by variations of vacuum-pressure impregnation in sealed vessels so it is not clear how such precise application (each 2.25 m stake is only treated for 0.8 m) can be achieved. Furthermore, soil monitoring data submitted as part of the renewal to support fruit consumption assessment ([redacted] 2020) indicates that whole stakes were treated with creosote.

In addition, controllable superficial methods of application will only be used for creosote to re-apply product where it will have been removed due to modifications such as sawing, cutting, shaping and machining – that does not necessarily appear relevant and thus risks posed by fruit stakes may be under-estimated. Mention is made of treatment of stakes by hot and cold impregnation – this appears to be an uncontrolled application method where wood is added to a giant cauldron of hot creosote and then transferred to a vessel containing cold creosote (ambient temperature) – this also does not suggest that stakes can be part-treated.

Therefore, as the application method for treating fruit stakes / hop stakes / vine poles with creosote might not be sufficiently reliable to only treat sections of wood (namely the bottom 0.8 m of a 2.25 m pole), then the quantity of wood above ground likely to leach must be increased. Simplistically, there is an additional 1.45 m of pole above ground that would be subject to UC 3 leaching. Surface area of the additional treated wood above ground would be :

$\Pi$ x 9.36 x 145 = 4263.77 cm$^2$ (0.4264 m$^2$).

Minor revision to existing modelling sheets can be made so that emissions from this supplemental area can be predicted at Time 1 and Time 2, with degraded outputs then added to the “partial stake” emissions

**Calculations for Scenario (2)**

Calculations are performed on several publicly available modelling sheets that take account of ESD scenarios, revisions / refinements published within TAB and equations specified in Vol IV, Parts B+C (2017).

*9.1.3. Scenario (3) : emissions from UC 4b in-service*

When performing exposure calculations using ECHA calculator sheets, it is clear that, in several UC 4 scenarios, only one entry is feasible for Q*leach value. However, part of the treated wood will be in contact with ground or water and the remainder will be above that medium. In order to make use of Excel modelling sheets, composite Q*leach rates for creosote have been generated based on simple proportioning, using :

| Cumulative leaching loss at Time t | UC 3 | UC 4 |
|---|---|---|
| TIME 1 Q*leach (in mg/m$^2$) | 10.98 | 2952 |
| TIME 2 Q*leach (in mg/m$^2$) | 383.93 | 131631 |

Jetty-in-a-lake model assumes 16.2 m$^2$ of planking (crudely assumed to be above water level) plus 10 m$^2$ of poles (assumed to be submerged) in section 4.3.5.1 of the PT 8 ESD, so composite Q*leach values would be :

Time 1 : (16.2 / 26.2 x 10.98) + (10.0 / 26.2 x 2952) = 1142.17 mg/m$^2$

Time 2 : (16.2 / 26.2 x 383.93) + (10.0 / 26.2 x 131631) = 50478.23 mg/m$^2$

With regard to the sheet piling scenario, existing model sheets only predict PECwater values of 615 µg/l (Time 1) and 113 µg/l (Time 2) : no scenario is modelled on the PECsw - PECsed partitioning calculator sheets for treatment of these structures. Therefore, simplistic conversion to PEC sediment values using agreed calculations (including equation 89) taken from Vol IV, Parts B+C as follows :

$PEC_{sed}$ = ($K_{susp\text{-}water}$ / $RHO_{susp}$) x $PEC_{water}$ x 1000

where $K_{susp\text{-}water}$ is 2.34E+2 m$^3$/m$^3$ and $RHO_{susp}$ is 1150 kg/m$^3$

Time 1 PECsed = 2.34E+2 / 1150 x 6.15E-1 mg/l x 1000 = 125.26 mg/kg wwt

Time 2 PECsed = 2.34E+2 / 1150 x 1.13E-1 mg/l x 1000 = 23.016 mg/kg wwt

**Calculations for Scenario (3)**

In terms of the JETTY-ON-A-LAKE scenario, modelling utilises principles of PECsw – PECsed partitioning outlined in ENV 209 of TAB.

*9.1.4. Scenario (4) : emissions from UC 5 in-service*

With regard to the harbour wharf scenario, existing model sheets only predict PECwater values of 12.3 µg/l (Time 1) and 2.25 µg/l (Time 2) : no scenario is modelled on the

PECsw - PECsed partitioning calculator sheets. Therefore, simplistic conversion to PEC sediment values using agreed calculations (including equation 89) taken from Vol IV, Parts B+C as follows :

$PEC_{sed}$ = ($K_{susp\text{-}water}$ / $RHO_{susp}$) x $PEC_{water}$ x 1000

where $K_{susp\text{-}water}$ is 2.34E+2 $m^3/m^3$ and $RHO_{susp}$ is 1150 $kg/m^3$

Time 1 PECsed = 2.34E+2 / 1150 x 12.3E-3 mg/l x 1000 = 2.51 mg/kg wwt

Time 2 PECsed = 2.34E+2 / 1150 x 2.25E-3 mg/l x 1000 = 4.59E-1 mg/kg wwt

**Calculations for Scenario (4)**

Calculations are undertaken on several publicly available modelling sheets that take account of ESD scenarios, revisions / refinements published within TAB and equations specified in Vol IV, Parts B+C (2017).

## 9.2. Fate and distribution in exposed environmental compartments

**Identification of relevant receiving compartments based on the exposure pathway**

| Scenario | Freshwater | Sediment | Seawater | Marine sediment | STP | Soil | Groundwater |
|---|---|---|---|---|---|---|---|
| Scenario 1 (UC 3 in-service) | Y | Y | N | N | Y | Y | Y |
| Scenario 2 (UC 4a in-service) | N | N | N | N | N | Y | Y |
| Scenario 3 (UC 4b in-service) | Y | Y | N | N | N | N | N |
| Scenario 4 (UC 5 in-service) | N | N | Y | Y | N | N | N |

Exposure calculations only consider in-service losses, as all pre-treatment sites and storage areas are presumed to be bunded to comply with other legislation. As a consequence, measures will be in place to prevent all losses to ground, local surface waters and drains.

Furthermore, due to restrictions placed upon creosote whereby treated timbers may not be placed within residential (or occupied) buildings, UC 1 and UC 2 have been disregarded from assessment.

**Input parameters (only set values) for calculating the fate and distribution in the environment - creosote**

| Input | Value | Unit | Remarks |
|---|---|---|---|
| Molecular weight | 200 | g/mol | Notional average of all grades (B + C) |
| Organic carbon/water partition coefficient (Koc) | 9333 | l/kg | Data from original approval of creosote (2010) |
| Water solubility | 8.11 | mg/l | Data from original approval of creosote (2010) (20 ºC) |
| Vapour pressure | 4.00E-1 | Pa | Data from original approval of creosote (2010) (20 ºC) |
| $DT_{50}$ for biodegradation in surface water | 1000 | d (at 12 ºC) | Decision from original approval of creosote (2010) |
| “k” rate for aquatic degradation | 6.93E-4 | $d^{-1}$ | Calculated rate |

| Input | Value | Unit | Remarks |
|---|---|---|---|
| $DT_{50}$ for degradation in soil | 734 | d (at 12 ºC) | Based on data from original approval of creosote (2010) with $DT_{50}$ of 387 d (20 ºC). This was the longest value from 2 soils based on analysis of the PAH chrysene, taken as a worst case of the substances analysed. Note that normalisation was based on equation 28 from Vol IV part B+C and a longer value would be estimated if the latest activation energy was to be used in line with TAB ENV182. |
| "k" rate for soil degradation | 9.44E-4 | $d^{-1}$ | Calculated rate |
| Soil-water partitioning co-efficient ($K_{soil-water}$) | 2.80E+2 | $m^3/m^3$ | Calculated value |
| Suspended matter-water partitioning co-efficient ($K_{susp-water}$) | 2.34E+2 | $m^3/m^3$ | Calculated value |

**Calculated fate and distribution in the STP (if STP is a relevant compartment) – creosote**

| Compartment | Percentage (%) | Remarks |
|---|---|---|
| Air | - | Not required for emissions modelling |
| Water | 53.6 | SimpleTreat value used to derive $Clocal_{effluent}$ (which represents $PEC_{STP}$) |
| Sludge | - | Not required for emissions modelling |

### 9.3. Calculated PEC values

**Summary table on calculated PEC values**

| Scenario | $PEC_{STP}$ (mg/l) | $PEC_{water}$ (µg/l) | $PEC_{sed}$ (mg/kg $_{wwt}$) | $PEC_{seawater}$ (µg/l) | $PEC_{seased}$ (mg/kg$_{wwt}$) | $PEC_{soil}$ (mg/kg$_{wwt}$) | $PEC_{GW}$ (µg/l) |
|---|---|---|---|---|---|---|---|
| 1 (UC 3 – House) : Time 1<br>1 (UC 3 – House) : Time 2 | - | - | - | - | - | 6.12E-2<br>3.15E-1 | **3.72E-1**<br>**1.91** |
| 1 (UC 3 – Fence) : Time 1<br>1 (UC 3 – Fence) : Time 2 | - | - | - | - | - | 5.09E-2<br>2.62E-1 | **3.09E-1**<br>**1.59** |
| 1 (UC 3 – Noise barrier) : Time 1<br>1 (UC 3 – Noise barrier : Time 2 | 2.06E-4<br>2.95E-5 | - | - | - | - | - | - |

| Scenario | $PEC_{STP}$ (mg/l) | $PEC_{water}$ (µg/l) | $PEC_{sed}$ (mg/kg $_{wwt}$) | $PEC_{seawater}$ (µg/l) | $PEC_{seased}$ (mg/kg$_{wwt}$) | $PEC_{soil}$ (mg/kg$_{wwt}$) | $PEC_{GW}$ (µg/l) |
|---|---|---|---|---|---|---|---|
| 1 (UC 3 Bridge-over-pond) : Time 1 [C at t]<br>1 (UC 3 Bridge-over-pond) : Time 2 [C at t] | - | 6.33E-2<br>4.39E-1 | 1.29E-2<br>8.95E-2 | - | - | - | - |
| 1 (UC 3 Bridge-over-pond) : Time 1 [TWA]<br>1 (UC 3 Bridge-over-pond) : Time 2 [TWA] | - | 3.18E-2<br>3.55E-1 | 6.47E-3<br>7.23E-2 | - | - | - | - |
| 2 (UC 4a – Transmission pole) : Time 1<br>2 (UC 4a – Transmission pole) : Time 2 | - | - | - | - | - | 9.34E-1<br>6.11 | **5.67**<br>**37.10** |

| Scenario | $PEC_{STP}$ (mg/l) | $PEC_{water}$ (µg/l) | $PEC_{sed}$ (mg/kg $_{wwt}$) | $PEC_{seawater}$ (µg/l) | $PEC_{seased}$ (mg/kg$_{wwt}$) | $PEC_{soil}$ (mg/kg$_{wwt}$) | $PEC_{GW}$ (µg/l) |
|---|---|---|---|---|---|---|---|
| 2 (UC 4a – Fence post) : Time 1<br><br>2 (UC 4a – Fence post) : Time 2 | - | - | - | - | - | 2.87E-1<br>1.88 | **1.74**<br>**11.40** |
| 2 (UC 4a – Vineyard stake) : Time 1 [partial]<br><br>2 (UC 4a – Vineyard stake) : Time 2 [partial] | - | - | - | - | - | 1.86E-1<br>1.90 | **1.13**<br>**11.60** |
| 2 (UC 4a – Vineyard stake) : Time 1 [whole]<br><br>2 (UC 4a – Vineyard stake) : Time 2 [whole] | - | - | - | - | - | 1.87E-1<br>1.91 | **1.14**<br>**11.64** |

| Scenario | $PEC_{STP}$ (mg/l) | $PEC_{water}$ (µg/l) | $PEC_{sed}$ (mg/kg $_{wwt}$) | $PEC_{seawater}$ (µg/l) | $PEC_{seased}$ (mg/kg$_{wwt}$) | $PEC_{soil}$ (mg/kg$_{wwt}$) | $PEC_{GW}$ (µg/l) |
|---|---|---|---|---|---|---|---|
| 3 (UC 4b – Jetty-on-a-lake) : Time 1 [C at t]<br><br>3 (UC 4b – Jetty-on-a-lake) : Time 2 [C at t] | - | 1.38<br><br>12.1 | 2.81E-1<br><br>2.47 | - | - | - | - |
| 3 (UC 4b – Jetty-on-a-lake) : Time 1 [TWA]<br><br>3 (UC 4b – Jetty-on-a-lake) : Time 2 [TWA] | - | 6.93E-1<br><br>9.79 | 1.41E-1<br><br>1.99 | - | - | - | - |
| 3 (UC 4b – Sheet piling) : Time 1<br><br>3 (UC 4b – Sheet piling) : Time 2 | - | 615.0<br><br>113.0 | 125.26<br><br>23.02 | - | - | - | - |

| Scenario | $PEC_{STP}$ (mg/l) | $PEC_{water}$ (µg/l) | $PEC_{sed}$ (mg/kg $_{wwt}$) | $PEC_{seawater}$ (µg/l) | $PEC_{seased}$ (mg/kg$_{wwt}$) | $PEC_{soil}$ (mg/kg$_{wwt}$) | $PEC_{GW}$ (µg/l) |
|---|---|---|---|---|---|---|---|
| 4 (UC 5 – Harbour wharf) : Time 1<br><br>4 (UC 5 – Harbour wharf) : Time 2 | - | - | - | 12.3<br><br>2.25 | 2.51<br><br>4.59E-1 | - | - |

### *9.4. Primary and secondary poisoning*

The conclusions drawn from the original approval of creosote (2010) remain valid as no new data are available regarding primary and secondary poisoning.

However, it should be noted that creosote is a UVCB substance containing PBT and vPvB constituents. As such, the standard quantitative approach to environmental risk assessment may not provide sufficient confidence that the environmental compartments are adequately protected and the presence of PBT and vPvB constituents leads to additional uncertainty in the estimation of risks to the environment. Therefore, based on the currently available risk assessment methodologies it cannot be demonstrated that there are no unacceptable effects to the environment, including via primary and secondary poisoning.

## 10. Assessment of effects on human health for the product

The representative product is identical to the active substance. Therefore the hazard profile, classification and dermal absorption value determined for the active substance apply to the representative product.

## 11. Environmental effects assessment for the product

No product specific data are relevant to this product as active substance is considered to make up 100% of the formulation.

# Part C – Risk characterisation of the biocidal product(s)

## 12. Risk characterisation for human health

### *12.1. Critical endpoints*

#### *12.1.1. Systemic effects*

The critical systemic effect of creosote is its carcinogenic potential, for which a non-threshold mechanism cannot be excluded. This critical effect may occur following acute, medium-term or long-term exposure. The critical study is the dermal mouse carcinogenicity study from which a T25 (the dose causing a 25% increase in the tumour incidence) was calculated to be 260 mg/kg bw/d. This value was already determined and used in the risk assessment of creosote performed by an EU body (CSTEE, 1999). A NOAEL is not an appropriate point of departure (PoD) for a non-threshold carcinogen. This is in line with the biocide guidance (Guidance on the BPR: Volume III Assessment & Evaluation (Parts B+C) Version 2.1 February 2017, section 2.4.1.1).

| Duration | Study | Route | Relevant effects | NOAEL / LOAEL | References |
|---|---|---|---|---|---|
| Acute | Mouse cancer bioassay | Dermal | Tumours | T25 = 260 mg/kg bw/d | Fraunhofer Institute, 1997 |
| Medium-term | Mouse cancer bioassay | Dermal | Tumours | T25 = 260 mg/kg bw/d | Fraunhofer Institute, 1997 |
| Long-term | Mouse cancer bioassay | Dermal | Tumours | T25 = 260 mg/kg bw/d | Fraunhofer Institute, 1997 |

#### *12.1.2. Local effects*

The local effects (skin and eye irritation and skin sensitisation) of creosote are not critical due to its non-threshold carcinogenic effects.

| Route | Effect | Study | Classification | Hazard category |
|---|---|---|---|---|
| Dermal | NA | NA | NA | NA |
| Respiratory | NA | NA | NA | NA |

*12.1.3. Absorption*

| Route | Study | Test substance | Concentration of test substance | Applicability (concentration ranges) | Value |
|---|---|---|---|---|---|
| Oral | Worst-case assumption | Creosote | NA | Any concentrations | 100% |
| Dermal | Weight-of-evidence-approach | Creosote | 100% creosote | 100% creosote | 10% |
| Inhalation | Worst-case assumption | Creosote | NA | Any concentrations | 100% |

## 12.2. Reference values

Since creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded, AELs cannot be derived. A systemic DMEL (Derived Minimal Effect Level) for workers and an oral DMEL for consumers based on its carcinogenic effects have been established in line with the ECHA (2008) REACH Guidance on information requirements and chemical safety assessment, Chapter R.8. For the consumer dietary risk assessment, the applicant has proposed to use the TDI (Tolerable Daily Intake) of 30-40 µg/kg bw/d set for the non-carcinogenic effects of 5 non-carcinogenic PAHs, established in an RIVM report ([redacted] 2001) as the creosote for which renewal is sought tends to contain a significant amount of non-carcinogenic PAHs. HSE notes that this is correct; however, some carcinogenic PAHs are still present in the proposed specification. In addition, the batch analysis is limited and there could be other carcinogenic PAHs not analysed for. Furthermore, the RIVM evaluation supporting these TDIs and stating that some PAHs are not carcinogenic is from 2001. Therefore, the report does not take into account any new studies that may have become available since then. Also, the interpretation of the available studies has not been performed to current standards, and more importantly, none of the toxicity data to address the toxicology profiles of the individual creosote constituents have been submitted to HSE

for an independent evaluation. It is HSE's view that the proposed TDIs for 5 non-carcinogenic PAHs underestimate the carcinogenic risks of creosote, as a whole mixture. A carcinogenicity study in which creosote as a whole was tested is available. Although the tested creosote may not be representative of what is marketed today, the derivation of a carcinogenic DMEL from such study provides a more accurate reference value for the risk assessment.

### *12.2.1. Uncertainties and assessment factors*

#### 12.2.1.1. DMEL derivation

**Systemic DMEL for workers**

The CSTEE (1999) determined a T25 for BaP (benzo(a)pyrene) of 13 µg/kg bw/d, from the dermal cancer study in mice. BaP, a marker of carcinogenic potency of creosote, was tested alongside creosote in the study. This value was converted to a dose of 1300 mg/kg bw/d creosote (assuming a BaP content of 10 ppm). The creosote value was further divided by a factor of 5, as creosote was 5 times more potent than the control based on BaP content, resulting in a T25 for creosote of 260 mg/kg bw/d.

This value needs to be further corrected to adjust for differences in exposure conditions between the animals tested in the study (exposed for 24 hours/day, 2 days per week, 52 weeks per year, for a lifetime) and the workers exposed to creosote during its biocidal use (3 hr maximum per day, 5 days per week, 48 weeks per year, for a working life of 40 years rather than a lifetime of 75 years).

The following adjustments were performed:

2/5 x 52/48 x 75/40 = 0.8125

This leads to a corrected T25 of 210 mg/kg bw/d.

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

A correction for the daily duration of exposure (24 hr in mice and 3 hr max for the workers) was not considered appropriate as according to the ECHA (2008) guidance, such a correction should be performed only if the dose metric is a concentration, which is not the case here, given that the dose metric is a daily dose per kg bodyweight in the mouse.

The corrected T25 is an external dermal dose; this needs to be converted to a systemic dose by taking into account the dermal absorption of creosote in the mouse. There is no direct information about the dermal absorption of creosote in the mouse. However, it is most likely that absorption was 100% as creosote was applied to the mouse skin in a solvent (toluene) to maximise absorption. There is also evidence that human skin is 8 times less permeable than rat skin ([redacted] 2002b). Considering that dermal absorption of creosote in humans has been set at 10%, dermal absorption of creosote in rodents would be 80% and possibly even higher, when taking into account that the test material was applied in a solvent. Overall, a dermal absorption value of 100% for creosote in the dermal cancer study is considered appropriate. As a consequence, the

corrected systemic T25 is still 210 mg/kg bw/d.

Corr_systemicT25 = 210 mg/kg bw/d

An overall assessment factor (AF) of 25,000 is recommended in the ECHA (2008) guidance when the PoD is the T25 and the DMEL is being derived for workers. Therefore, by dividing the corrected systemic T25 by 25,000 a DMEL for workers of 8.4 µg/kg bw/d is established.

**Systemic DMEL for the general public**

The starting point for the derivation of the systemic DMEL for the general public is also the T25 of 260 mg/kg bw/d.

This value needs to be further corrected to adjust for differences in exposure conditions between the animals tested in the study (exposed for 24 hours/day, 2 days per week, 52 weeks per year, for a lifetime) and the general public potentially exposed to creosote via the dermal or inhalation route (worst case of 7 days per week, 52 weeks per year, for a lifetime of 75 years).

The following adjustment for day per week exposure was performed:

2/7 = 0.29

This leads to a corrected T25 of 75 mg/kg bw/d.

CorrT25 = 0.29 x 260 = 75 mg/kg bw/d

The corrected T25 is an external dermal dose; this needs to be converted to a systemic dose by taking into account the dermal absorption of creosote in the mouse. There is no direct information about the dermal absorption of creosote in the mouse. However, it is most likely that absorption was 100% as creosote was applied to the mouse skin in a solvent (toluene) to maximise absorption. There is also evidence that human skin is 8 times less permeable than rat skin ([redacted] 2002b). Considering that dermal absorption of creosote in humans has been set at 10%, dermal absorption of creosote in rodents would be 80% and possibly even higher, when taking into account that the test material was applied in a solvent. Overall, a dermal absorption value of 100% for creosote in the dermal cancer study is considered appropriate. As a consequence, the corrected systemic T25 is still 75 mg/kg bw/d.

Corr_systemicT25 = 75 mg/kg bw/d

An overall assessment factor (AF) of 250,000 is recommended in the ECHA (2008) guidance when the PoD is the T25 and the DMEL is being derived for consumers. Therefore, by dividing the corrected oral T25 by 250,000 an oral DMEL for consumers of 0.3 µg/kg bw/d is established.

This is a chronic value. There are no appropriate data to derive an acute DMEL. However, as in theory, it is possible that even one single exposure could lead to genetic damage and eventually to carcinogenicity, this chronic value should also be used when

assessing acute exposure scenarios. It should be noted, however, that for acute exposures, the chronic DMEL is an extremely conservative value.

**Oral DMEL for consumers**

The starting point for the derivation of the oral DMEL for consumers is also the T25 of 260 mg/kg bw/d.

This value needs to be further corrected to adjust for differences in exposure conditions between the animals tested in the study (exposed for 24 hours/day, 2 days per week, 52 weeks per year, for a lifetime) and the consumers potentially exposed to creosote via the diet (7 days per week, 52 weeks per year, for a lifetime of 75 years).

The following adjustment for day per week exposure was performed:

2/7 = 0.29

This leads to a corrected T25 of 75 mg/kg bw/d.

CorrT25 = 0.29 x 260 = 75 mg/kg bw/d

The corrected T25 is an external dermal dose. This needs to be converted in an external oral dose. A dermal absorption value of 100% for creosote in the dermal cancer study is considered appropriate. An oral absorption value of 100% is also considered appropriate. As a consequence, the corrected oral T25 is still 75 mg/kg bw/d.

Corr_oralT25 = 75 mg/kg bw/d

An overall assessment factor (AF) of 250,000 is recommended in the ECHA (2008) guidance when the PoD is the T25 and the DMEL is being derived for consumers. Therefore, by dividing the corrected oral T25 by 250,000 an oral DMEL for consumers of 0.3 µg/kg bw/d is established.

This is a chronic value. There are no appropriate data to derive an acute DMEL. However, as in theory, it is possible that even one single exposure could lead to genetic damage and eventually to carcinogenicity, this chronic value should also be used when assessing acute exposure scenarios. It should be noted, however, that for acute exposures, the chronic DMEL is an extremely conservative value.

*12.2.2. Reference values to be used in risk characterisation*

| Reference | Study | NOAEL (LOAEL) | AF | Correction for oral absorption | Value |
|---|---|---|---|---|---|
| $AEL_{short\text{-}term}$ | NA | NA | NA | NA | NA |

| Reference | Study | NOAEL (LOAEL) | AF | Correction for oral absorption | Value |
|---|---|---|---|---|---|
| $AEL_{medium\text{-}term}$ | NA | NA | NA | NA | NA |
| $AEL_{long\text{-}term}$ | NA | NA | NA | NA | NA |
| ARfD | NA | NA | NA | NA | NA |
| ADI | NA | NA | NA | NA | NA |
| $DMEL_{systemic_workers}$ | Dermal mouse cancer study | CorrT25 = 210 mg/kg bw/d | 25,000 | NA | 8.4 µg/kg bw/d |
| $DMEL_{systemic_general\ public}$ | Dermal mouse cancer study | CorrT25 = 75 mg/kg bw/d | 250,000 | NA | 0.3 µg/kg bw/d |
| $DMEL_{oral_consumers}$ | Dermal mouse cancer study | CorrT25 = 75 mg/kg bw/d | 250,000 | 100% | 0.3 µg/kg bw/d |

*12.2.3. Maximum residue limits or equivalent*

| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
|---|---|---|---|
| POAO:<br>No MRLs are being proposed in products of animal origin (POAO) as a result of this assessment (use scenario - Agricultural fencing/equestrian fencing treated with creosote (livestock)) | | | |
| POPO:<br>No MRLs are being proposed in products of plant origin (POPO) as a result of this assessment (use scenario - Agricultural tree stakes/supports treated with creosote (fruits, grapes ( vineyard), and hops)) | | | |
| Existing MRLs:<br><br>For sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene (noting that the components benzo[a]anthracene and chrysene are present in low amounts in creosote). | Assimilated Regulation 835/2011 | Oils and fats (excluding cocoa butter and coconut oil) | 10 µg/kg |

| MRLs or other relevant reference values | Reference | Relevant commodities | Value |
|---|---|---|---|
| As above | As above | Cocoa beans and derived products | 30 µg/kg |
| As above | As above | Coconut oil | 20 µg/kg |
| As above | As above | Smoked meat and smoked meat products | 12 µg/kg |
| As above | As above | Muscle meat of smoked fish and smoked fishery products), excluding fishery products listed below. | 12 µg/kg |
| As above | As above | Smoked sprats; bivalve molluscs (fresh, chilled or frozen) ; heat treated meat and heat treated meat products | 30 µg/kg |
| As above | As above | Smoked bivalve molluscs | 35 µg/kg |
| As above | As above | Processed cereal based foods and baby foods for infants and young children | 1 µg/kg |

| MRLs or other relevant reference values | Reference | Relevant commodities | Value |
|---|---|---|---|
| As above | As above | Infant formulae and follow-on formulae, including infant milk and follow-on milk | 1 µg/kg |
| As above | As above | Dietary foods for special medical purposes intended specifically for infants | 1 µg/kg |

## 12.3. Industrial uses

The table below presents estimated uptake of creosote for an industrial user for each relevant scenario from the use of creosote. Exposure is then compared to the appropriate DMEL. For consideration of the appropriate DMEL, please refer to Part C Section 12.2 of this CAR. All scenarios for an industrial user from the use of creosote are concluded to result in unacceptable risk even when appropriate PPE is worn.

### *12.3.1. Systemic effects*

| Task / Scenario | Tier | Systemic NOAEL (mg/kg bw/d) | DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / DMEL (%) | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| 1 | 1 | N/A | 0.0084 | 2.09625 | 24955% | No |
| 1 | 2a | N/A | 0.0084 | 0.73525 | 8753% | No |
| 1 | 2b | N/A | 0.0084 | 0.2299 | 2737% | No |
| 2 | 1 | N/A | 0.0084 | 2.09625 | 24955% | No |
| 2 | 2a | N/A | 0.0084 | 0.73525 | 8753% | No |

| Task / Scenario | Tier | Systemic NOAEL (mg/kg bw/d) | DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / DMEL (%) | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| 2 | 2b | N/A | 0.0084 | 0.2299 | 2737% | No |
| 3 | 1 | N/A | 0.0084 | 0.23168 | 2758% | No |
| 4 | 1 | N/A | 0.0084 | 0.2299 | 2737% | No |

**Combined scenarios**

It is anticipated that industrial users may treat wood and stack treated wood in the same working day. It is also possible that industrial users may carry out the treatment of wood and clean the dipping equipment on the same working day. However as exposure from the individual scenarios significantly exceeds the current DME, even when appropriate risk management measures (RMM'S) have been included, no further calculations have been carried out in this assessment.

*12.3.2. Local effects*

Creosote is classified skin irritation (Cat. 2), skin sensitisation (Cat. 1) and eye irritation (Cat. 2). The local effects (skin and eye irritation and skin sensitisation) of creosote are not considered critical for local effects due to its non-threshold carcinogenic effects.

Risk management measures have been determined to reduce exposure as far as possible and are listed in this document. Measures such as protective impermeable coveralls, new gloves (each use), goggles and suitable RPE are proposed for industrial users and these precautionary measures are potentially useful against local effects.

*12.3.3. Conclusion*

The exposure/risk for industrial users is considered unacceptable for all scenarios.

As some of these industrial uses have been authorised previously under socioeconomic arguments, the following risk management measures are indicated to reduce exposure as far as possible, however it should be noted that including these in the current assessment, exposure still exceeds the current DMEL. These RMM's have been proposed based on this and previous assessments of creosote.

These RMM's are not exhaustive and any additional measures available can be applied in addition:

- All protective measures in place for treatment applications must be strictly followed.

- New gloves must be worn for each shift/task and changed immediately if significant contamination occurs.
- Wear suitable protective gloves and impermeable coveralls when handling creosote, touching contaminated surfaces, during application and when handling treated wood.
- All PPE must be changed frequently, and immediately after contamination. When disposing of contaminated PPE this should be in accordance with local requirements for the disposal of hazardous waste.
- Where there is risk of skin contact, wash skin with suitable cleaning solutions as soon as possible after each work task.
- Risk of exposure means direct skin contact or where inhalation of vapour can occur. However, risks can 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. Increased risks are possible during hot and cold impregnation where there is an open system in place. In these cases, additional protection can be advised.
- Where there is risk of inhalation exposure, respiratory protection, such as a full face mask with particle filter P3 in combination with gas filter A (brown), must be worn.
- A thinner pair of (cotton) gloves must be worn under chemical resistant gloves.
- Chemical resistant (impermeable) coveralls, or equivalent, must be worn over regular work clothes (long-sleeved shirts and long trousers).
- Sky lifts (aerial access platforms) must be used for transmission pole maintenance wherever possible, to minimise contact with treated timber.
- Mechanical or automated processes must be used to avoid contact with creosote and treated timber wherever possible (including down-stream work, for example during work with poles in service).
- Creosote-resistant boots must be worn when entering treatment vessels (e.g. for cleaning or maintenance).
- Tight sealings (sleeve capes) must be used e.g. at the border of gloves and sleeves and at the border of trousers and boots.

In addition:

- Non-essential employees must be kept out of treatment areas, especially when opening treatment vessels.
- Working areas, such as treatment areas, must be monitored or inspected regularly to ensure a suitable cleaning frequency. Other areas such as changing

and washing rooms, break rooms and control rooms must be cleaned weekly.

- Relevant equipment and tools (with the exception of brushes) must be cleaned if contaminated.
- Where there is risk of skin contact with treated timber, suitable protective gloves and chemical resistant (impermeable) coveralls, or equivalent, must be worn over regular work clothes (long-sleeved shirts and long trousers).
- Do not clean brushes after surface treatment – dispose of as hazardous waste in accordance with local requirements.

Exposure from all the individual scenarios significantly exceeds the current DMEL and still exceeds when appropriate risk management measures (RMM'S) have been included. Combining any of the listed work practices would be advised against because of the risk of exposure from individual exposure assessments.

Further information was received from the applicant following a discussion regarding the product label. This information stated that the retention of product/active in the wood for treated marine installations (UC5) was nearly double that previously assessed for other end uses. No further calculations have been done specifically for this as exposure in all of the other industrial uses assessed already exceed the current DMEL significantly.

## 12.4. Professional uses

### 12.4.1. Systemic effects

| Task / Scenario | Tier | Systemic NOAEL (mg/kg bw/d) | DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / DMEL (%) | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| 5 | 1 | N/A | 0.0084 | 4.1917 | 49901% | No |
| 5 | 2a | N/A | 0.0084 | 0.4950 | 5893% | No |
| 5 | 2b | N/A | 0.0084 | 0.2096 | 2495% | No |
| 5 | 2c | N/A | 0.0084 | 0.052347 | 623% | No |
| 6 | 1 | N/A | 0.0084 | 0.2565 | 3054% | No |

| Task / Scenario | Tier | Systemic NOAEL (mg/kg bw/d) | DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / DMEL (%) | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| 6 | 2a | N/A | 0.0084 | 0.02565 | 305% | No |
| 6 | 2b | N/A | 0.0084 | 0.0128 | 152% | No |
| 7 | 1 | N/A | 0.0084 | 0.9023 | 10742% | No |
| 7 | 2a | N/A | 0.0084 | 0.6287 | 7485% | No |
| 7 | 2b | N/A | 0.0084 | 0.57673 | 6866% | No |
| 7 | 2c | N/A | 0.0084 | 0.06013 | 716% | No |

**Combined scenarios**

It is possible that a professional user may sand/saw/cut treated wood and then paint it with preservative using a paint brush and wash the paint brush on the same working day.

Exposure from all the individual scenarios exceeds the current DMEL and still exceeds when appropriate risk management measures (RMM'S) have been included. Combining any of the listed work practices would be advised against due to the individual exposure assessments.

*12.4.2. Local effects*

Creosote is classified skin irritation (Cat. 2), skin sensitisation (Cat. 1) and eye irritation (Cat. 2). The local effects (skin and eye irritation and skin sensitisation) of creosote are not considered critical for local effects due to its non-threshold carcinogenic effects.

Risk management measures have been determined to reduce exposure as far as possible and are listed in this document. Measures such as protective impermeable coveralls, new gloves (each use), goggles and suitable RPE are proposed for professional users and these precautionary measures are potentially useful against local effects.

*12.4.3. Conclusion*

The exposure/risk for professional users is considered unacceptable for all scenarios.

As some of these uses have been authorised previously under socioeconomic arguments the following risk management measures are indicated to reduce exposure as far as possible, however it should be noted that despite including these in the current assessment, exposure still exceeds the current DMEL. These RMM's have been proposed based on this and previous assessments of creosote.

These RMM's are not exhaustive and any additional measures available can be applied in addition:

- All protective measures in place for treatment applications must be strictly followed.
- New gloves must be worn for each shift/task and changed immediately if significant contamination occurs.
- Wear suitable protective gloves and impermeable coveralls when handling creosote, touching contaminated surfaces, during application and when handling treated wood.
- All PPE must be changed frequently, and immediately after contamination. When disposing of contaminated PPE this should be in accordance with local requirements for the disposal of hazardous waste.
- Where there is risk of skin contact, wash skin with suitable cleaning solutions as soon as possible after each work task.
- Risk of exposure means direct skin contact or where inhalation of vapour can occur. However, risks can 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. Increased risks are possible during hot and cold impregnation where there is an open system in place. In these cases, additional protection can be advised.
- Where there is risk of inhalation exposure, respiratory protection, such as a full face mask with particle filter P3 in combination with gas filter A (brown), must be worn.
- A thinner pair of (cotton) gloves must be worn under chemical resistant gloves.
- Chemical resistant (impermeable) coveralls, or equivalent, must be worn over regular work clothes (long-sleeved shirts and long trousers).
- Sky lifts (aerial access platforms) must be used for transmission pole maintenance wherever possible, to minimise contact with treated timber.
- Mechanical or automated processes must be used to avoid contact with creosote and treated timber wherever possible (including down-stream work, for example during work with poles in service).
- Creosote-resistant boots must be worn when entering treatment vessels (e.g. for

cleaning or maintenance).

- Tight sealings (sleeve capes) must be used e.g. at the border of gloves and sleeves and at the border of trousers and boots.

In addition:

- Non-essential employees must be kept out of treatment areas, especially when opening treatment vessels.
- Working areas, such as treatment areas, must be monitored or inspected regularly to ensure a suitable cleaning frequency. Other areas such as changing and washing rooms, break rooms and control rooms must be cleaned weekly.
- Relevant equipment and tools (with the exception of brushes) must be cleaned if contaminated.
- Where there is risk of skin contact with treated timber, suitable protective gloves and chemical resistant (impermeable) coveralls, or equivalent, must be worn over regular work clothes (long-sleeved shirts and long trousers).
- Do not clean brushes after surface treatment – dispose of as hazardous waste in accordance with local requirements.

Exposure from all the individual professional user scenarios assessed exceeds the current DMEL and still exceeds when appropriate risk management measures (RMM'S) have been included. Combining any of the listed work practices would be advised against because of the risk of exposure from individual exposure assessments.

Further information was received from the applicant following a discussion regarding the product label. This information stated that the retention of product/active in the wood for treated marine installations (UC5) was nearly double that previously assessed for other end uses. No further calculations have been done specifically for this as exposure in all of the other industrial uses assessed already exceed the current DMEL significantly.

### *12.5. General public uses*

Creosote is for professional use only and generally there is no anticipated exposure for general public user. However the applicant has requested that creosote treated wood can be used as fencing at equestrian facilities and as stakes in orchards for fruit trees. It is anticipated that workers at these facilities cannot be assumed to be trained professionals, therefore an assessment has been included for completeness for this use.

*12.5.1. Systemic effects*

| Task / Scenario | Tier | Systemic NOAEL (mg/kg bw/d) | DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / DMEL (%) | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| 8 | 1 | N/A | 0.0003 | 0.6287 | 209567% | No |

**Secondary (indirect) exposure as a result of use**

| Task / Scenario | Tier | Systemic NOAEL (mg/kg bw/d) | DMEL (mg/kg bw/d) | Estimated uptake (mg/kg bw/d) | Estimated uptake / DMEL (%) | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| 9 | 1 | N/A | 0.0003 | 0.03399 | 11330% | No |
| 9 | 2 | N/A | 0.0003 | 0.0068 | 2267% | No |
| 10 | 1 Adult | N/A | 0.0003 | 0.06396 | 21320% | No |
| 10 | 1 Toddler | N/A | 0.0003 | 1.078272 | 359424% | No |

**Combined scenarios**

No combined exposure for secondary exposure to the general public is foreseen.

*12.5.2. Local effects*

Creosote is classified skin irritation (Cat. 2), skin sensitisation (Cat. 1) and eye irritation (Cat. 2). The local effects (skin and eye irritation and skin sensitisation) of creosote are not considered critical for local effects due to its non-threshold carcinogenic effects.

PPE measures cannot be proposed to minimise exposure for general public users and as creosote is carcinogenic the possible secondary exposure of the general public should be minimised.

*12.5.3. Conclusion*

The risk for general public secondary exposure is demonstrated to be unacceptable for all scenarios.

With respect to laundering of clothes this is an extreme worst case however it could be stipulated that contaminated clothes should be laundered professionally or coveralls disposed of as hazardous waste.

With respect to dermal exposure from equestrian fencing or fruit stakes, again this is a worst case exposure based on a child playing on treated structures. Exposure via this route is likely to be less than that assessed, however concern remains due to the classification of the active and exposure is above the DMEL which is not tolerable for the general public for a non-threshold carcinogen.

As some of these uses where exposure occurs have been authorised previously under socioeconomic arguments the following risk management measures are indicated to reduce exposure as far as possible, however it should be noted that RMM's for the general public are limited.

- All protective measures in place for treatment applications must be strictly followed.
- Strict adherence to personal hygiene measures shall be encouraged where contact with equestrian fencing cannot be ruled out.
- Do not launder creosote contaminated clothing or coveralls at home. Professional laundering should occur, or disposal of contaminated clothing as hazardous waste in accordance with local requirements.

### *12.6. Indirect exposure via food*

**For dietary risk assessment from livestock exposed by agricultural fencing.**

Consideration has been made as 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. Any use of creosote that leads to food residues should be considered unacceptable as creosote is classified as a genotoxic carcinogen. There is no harmonised guidance for assessing the risk for animals, however, considering these assumptions it can be concluded that the risk to livestock from contact with creosote treated wood cannot be ruled out.

The assessment of animal (livestock) exposure concludes that dietary intakes could be significant. In order to fully assess risks to livestock, an animal feeding study would be required (please consult HSE before setting up a study) and concurrently, data on a validated method of analysis must be generated. The data submission to meet this requirement should provide full details of the analytical method with suitable acceptable validation data (including recovery rates and the limit of quantification and detection for the active substance and residues), in relevant livestock matrices.

**For dietary risk assessment of foodstuff exposed by agricultural stakes.**

The residues determined in the fruits have enabled an indicative risk assessment to be performed. It is indicative, since a residues definition for dietary risk assessment is not

being proposed as the residue findings are of concern (since it is concluded that creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded (see section 12.2 on Reference values (HSE toxicological assessment)). In the indicative dietary risk assessment, the chronic and acute dietary intakes far exceed the consumer DMEL (see section A.6 of the full residues assessment (Appendix VII)) indicating that an expectation of both long term and short term effects on health cannot be excluded arising from the assessment of the fruit tree uses of creosote.

It is not possible to propose risk mitigation measures that could reduce the indicative assessment dietary intakes to levels below the consumer DMEL. Mitigation measures and uncertainties in the assessment are discussed in section A.5.4 of Appendix VII. As noted above creosote is considered to be a genotoxic carcinogen.

As such, for the proposed use of creosote on wooden posts used as supports for fruit trees (or other supports for food crops such as hops or grapevines) harmful effects on human health cannot be excluded. (Full assessment and conclusion can be found in Appendix VII of this assessment).

### *12.7. Production / formulation of active substance*

Production/formulation of active substance is covered by other legislation and not addressed further in this assessment.

### *12.8. Aggregated exposure*

There is no available guidance at this time, so no assessment has been completed as part of this renewal.

## 13. Risk characterisation for the environment

### *13.1. Atmosphere*

**Conclusion**

Airborne concentrations are extremely unlikely to occur during service life. Losses during application / storage at pre-treatment sites are not considered relevant, as measures will be applied under other legislation to prevent losses to environmental compartments.

Risks to the air compartment are therefore considered to be negligible from proposed use patterns in UC 3 – UC 5.

### *13.2. Sewage treatment plant (STP)*

**Summary table on calculated PEC / PNEC values**

| Scenario | PEC / $PNEC_{STP}$ |
|---|---|
| Scenario 1 : UC 3<br>[Noise barrier] | 1.58E-3 (Time 1)<br>2.27E-4 (Time 2) |

**Conclusion**

UC 3: The risks to STP dwelling organisms posed by leaching losses of creosote from treated wood is considered acceptable.

UC 4 and UC 5: Emissions from these scenarios are not expected to reach local STP.

### *13.3. Aquatic compartment*

**Summary table on calculated PEC / PNEC values**

| Scenario | PEC / $PNEC_{water}$ |
|---|---|
| Scenario 1 : UC 3<br>[Bridge over pond] : C at Time t | 6.33E-1 (Time 1)<br>**4.39** (Time 2) |
| Scenario 1 : UC 3<br>[Bridge over pond] : TWA | 3.18E-1 (Time 1)<br>**3.55** (Time 2) |

| Scenario | PEC / $PNEC_{water}$ |
|---|---|
| Scenario 3 : UC 4b<br>[Jetty on a lake] : C at Time t | **13.8** (Time 1)<br>**121.0** (Time 2) |
| Scenario 3 : UC 4b<br>[Jetty on a lake] : TWA | **6.93** (Time 1)<br>**97.9** (Time 2) |
| Scenario 3 : UC 4b<br>[Sheet piling] | **6150** (Time 1)<br>**1130** (Time 2) |

| Scenario | PEC / $PNEC_{sed}$ |
|---|---|
| Scenario 1 : UC 3<br>[Bridge over pond] : C at Time t | 6.45E-3 (Time 1)<br>4.48E-2 (Time 2) |
| Scenario 1 : UC 3<br>[Bridge over pond] : TWA | 3.24E-3 (Time 1)<br>3.62E-2 (Time 2) |
| Scenario 3 : UC 4b<br>[Jetty on a lake] : C at Time t | 1.41E-1 (Time 1)<br>**1.24** (Time 2) |
| Scenario 3 : UC 4b<br>[Jetty on a lake] : TWA | 7.05E-2 (Time 1)<br>1.00 (Time 2) |
| Scenario 3 : UC 4b<br>[Sheet piling] | **62.63** (Time 1)<br>**11.51** (Time 2) |

| Scenario | PEC / $PNEC_{seawater}$ |
|---|---|
| Scenario 4 : UC 5<br>[Harbour wharf] | **615** (Time 1)<br>**112.5** (Time 2) |

| Scenario | PEC / $PNEC_{sea_sed}$ |
|---|---|
| Scenario 4 : UC 5<br>[Harbour wharf] | **12.6** (Time 1)<br>**2.3** (Time 2) |

**Conclusion**

UC 3 : Modelling using PECsw – PECsed partitioning in line with ENV 209 demonstrates unacceptable risks in the aquatic phase (even when applying TWA refinement). This would indicate that if UC 3 application could be supported due to acceptable terrestrial risks, then creosote products would require additional labelling / literature to include the Risk Mitigation Measure (RMM) for general timber (excluding railway sleepers) that :

- [N-191] With the exception of railway sleepers, treatment must only be applied to timber which will not be used above or adjacent to surface waters.

UC 4 and UC 5: Modelling shows that jetty and sheet piling uses (UC 4b) plus harbour wharf uses (UC 5) would give rise to unacceptable risks. Whilst there appear to be some significant differences in scale of risk at different time points in the water and sediment compartments, the calculations all show significant risks at least in the aquatic phase. With clear failures in every scenario at Time 2 for aquatic phase

As an overall summary, all placement of treated wood near / over surface water (UC 3), placement of treated wood in surface water contact (UC 4b) and placement of treated wood in seawater contact (UC 5) cannot be supported. The only exemption would be use of treated railway sleepers, as loss of leachate is considered to be prevented by engineering controls placed under track on rail bridges (section 4.4.6.2 of PT 8 ESD).

### *13.4. Terrestrial compartment*

**Summary table on calculated PEC / PNEC values**

| **Scenario** | **PEC / PNEC$_{soil}$** |
|---|---|
| Scenario 1 : UC 3<br>[House] | 2.04E-1 (Time 1)<br>**1.05** (Time 2) |
| Scenario 1 : UC 3<br>[Fence] | 1.70E-1 (Time 1)<br>8.73E-1 (Time 2) |
| Scenario 2 : UC 4a<br>[Transmission pole] | **3.11** (Time 1)<br>**20.37** (Time 2) |
| Scenario 2 : UC 4a<br>[Fence post] | 9.57E-1 (Time 1)<br>**6.27** (Time 2) |
| Scenario 2 : UC 4a<br>[Vine stake - partial] | 6.20E-1 (Time 1)<br>**6.33** (Time 2) |
| Scenario 2 : UC 4a<br>[Vine stake - whole] | 6.23E-1 (Time 1)<br>**6.37** (Time 2) |

**Conclusion**

UC 3: use on fencing gives rise to acceptable risks at both Time 1 and Time 2 in relation to soil dwelling organisms. However, if non-residential cladding use is considered to be similar in scale to that used to assess cladding on domestic dwellings in the HOUSE scenario, then this use gives rise to marginally unacceptable risks at Time 2 (ie based on a PEC/PNEC ratio of 1.05). Although creosote is also applied to railway sleepers (UC 3), no exposure to soil is expected in the ESD, as the ground under rail track is assumed to be a technosphere (man-made compartment).

UC 4: all UC 4a scenarios used to predict terrestrial concentrations from placement of treated timber (fruit / vine stakes, transmission poles, fence posts) indicate that risks to soil dwelling organisms are likely to be unacceptable in every case at service life (and at Time 1 – 30 d in most cases).

### *13.5. Groundwater*

**Summary table on calculated PEC / PNEC values (Tier 1 pore water screening)**

| Scenario | PEC / $PNEC_{GW}$ |
|---|---|
| Scenario 1 : UC 3<br>[House] | **3.72** (Time 1)<br>**19.1** (Time 2) |
| Scenario 1 : UC 3<br>[Fence] | **3.09** (Time 1)<br>**15.9** (Time 2) |
| Scenario 2 : UC 4a<br>[Transmission pole] | **56.7** (Time 1)<br>**371.0** (Time 2) |
| Scenario 2 : UC 4a<br>[Fence post] | **17.4** (Time 1)<br>**114.0** (Time 2) |
| Scenario 2 : UC 4a<br>[Vine stake - partial] | **11.3** (Time 1)<br>**116.0** (Time 2) |
| Scenario 2 : UC 4a<br>[Vine stake - whole] | **11.4** (Time 1)<br>**116.4** (Time 2) |

All values in this table represent Tier 1 screening using partitioning calculations to derive porewater PECs based on soil concentration. Values are then compared against the drinking water standard of 0.1 µg/l (default for “pesticidal actives”) in order to generate a notional risk quotient. Although creosote is a complex mixture, this simple tier 1 approach is likely to be approach as a screening step.

Any values falling below this 0.1 µg/l limit are considered to be acceptable, but anything exceeding the limit must be supported by higher tier FOCUS PEARL 4.4.4 modelling (showing acceptable levels in all four GB relevant soil scenarios – Chateaudun, Hamburg, Kremsmunster and Okehampton) in accordance with standard guidance.

All groundwater risks at tier 1 screening are considered to be unacceptable.

Note that creosote may be referred to as a dense non-aqueous phase liquid (DNAPL). These chemicals are immiscible in water, but also more dense than water. This means that these chemicals may be prone to vertical transport through subsurface soil layers and into groundwater, depending on the quantity released and the residual capacity of the soil. The standard higher tier groundwater model recommended for biocide assessments (FOCUS PEARL 4.4.4) is based on the assumption of equilibrium partitioning between the substance and the soil organic carbon content, and simulates more classical leaching via chromatographic flow. The assumptions in the FOCUS models are not necessarily appropriate for complex mixtures of DNAPL chemicals such as creosote. But in the absence of alternative models that may be better able to simulate the leaching risk of creosote, the standard FOCUS modelling approach has been applied. However HSE notes the validity of the modelling in this case is subject to a degree of uncertainty.

In the case of use on railway sleepers (UC 3), it was not possible to undertake porewater screening because there is no associated soil exposure assessment from which to calculate pore water concentrations. Therefore, in line with guidance in the PT 8 ESD, FOCUS PEARL 4.4.4 modelling has been performed directly as the Tier 1 approach for this scenario. Creosote leached from the treated sleepers into the ballast and underlying artificial or natural subgrade layers may reach groundwater (and this, according to the ESD for PT 8, is considered to be the main receiving environmental compartment). Emissions to soil are not considered to be relevant to the risk assessment since the soil beneath the ballast is stated to be an artificial environment belonging to the technosphere. The ballast prevents lateral run-off therefore emission to adjacent soil and surface waters is also not considered to be relevant.

It is noted that the original approval of creosote (2010) did not undertake specific groundwater modelling for railway sleepers but concluded that they would be covered by the assessment performed in relation to the HOUSE scenario. However, changes in modelling approach in TAB v1.3 (Technical Agreements for Biocides, version 1.3, August 2017) suggest that a more conservative Freundlich adsorption isotherm (1/n) value of 1.0 should be used in PEARL 4.4.4 modelling, as detailed kinetic analysis was not included in the adsorption/desorption study used to derive Koc for the active substance.

Groundwater modelling of railway sleepers has been considered and in line with models presented within the ESD (2013) for niche applications, Qleach,time 1 and Qleach,time 2 values of 0.045 kg/ha and 1.577 kg/ha respectively were obtained at 30 d and 20 yr respectively.

These values are based on sleeper area of 1.59 m2, 2583 sleepers per ha and Q*leach value of 10.98 mg/m2 (Time 1) and 383.931 mg/m2 (Time 2).

However, it must be noted that extrapolation of cumulative loss in the first 30 d to represent annual leaching to ground that could reach aquifers does not reflect the leaching behaviour of creosote in supporting studies (presented in original approval of creosote (2010) and summarised in this document). It is clear that leaching slows significantly beyond 30 d and, as such, the potential for groundwater contamination should be based upon the long-term Qleach value. Furthermore, the revised approach

taken in this document to Time 2 leaching loss takes account of losses from 0 – 30 d + 31 – 7300 d in line with Appendix 7 of the latest ESD so offers a more realistic annual loss when extrapolated. Taking account of the Supplement to Appendix 4 of the 2013 ESD (para 588 in particular), losses in a single year have been predicted as:1.577 kg/ha (Time 2 Qleach) x 365/7300 = 0.079 kg/ha/yr.

In addition, Section 4.4.6.4 of the ESD indicates that a 10 % dilution factor may be made to account for sleepers only covering 10 % of available ground in any hectare, such that the worst case (Time 1) value would decrease to 0.079 x 0.1 = 0.0079 kg/ha/yr.

If it is assumed that the quantity of creosote is released as 10 equal applications per year, then FOCUS PEARL 4.4.4 modelling can be performed with the following input values:

| **Input parameters for FOCUS PEARL 4.4.4 modelling of creosote following use on railway sleeper** | **Value** |
|---|---|
| Application rate (kg/ha) per application | 7.9E-04 |
| Number of applications in year | 10 |
| Koc | 9332 |
| DT50 (d, 20 °C) | 387 |
| Molecular weight (g/mol) | 200* |
| Water solubility (mg/l, 25 °C) | 8.11 |
| Vapour pressure (Pa, 25 °C) | 0.5 |
| Freundlich adsorption isotherm (1/n) | 1.0 (in line with TAB v1.3 – ENV 19) |
| Q10 value | 2.2 (molar activation energy of 54 kJ/mol) |

**Summary table on calculated PEC / PNEC values (PEARL 4.4.4 modelling)**

| Scenario | PEC / $PNEC_{GW}$ |
|---|---|
| Scenario 1 : UC 3<br><br>[Railway sleeper] | PASS in all GB relevant soil scenarios |

Results demonstrate that groundwater concentrations of creosote are predicted to be <0.0000001 µg/l in all 4 GB relevant scenarios and thus risks posed by creosote treated railway sleepers are considered to be acceptable based on the standard FOCUS modelling. It should be noted that these calculations assume a 20 yr service life, yet the footnote to Table 4.41 of the ESD indicates that a 26 yr service life could be assumed for railway sleepers. However, this would have no practical impact on predicted groundwater concentrations as they are already predicted to be <0.0000001 µg/l in FOCUS modelling.

As a general point, it is acknowledged that a standard FOCUS PEARL 4.4.4 simulation may not necessarily be entirely appropriate for railway sleeper uses, as FOCUS assumes application of a.s. to microbially active and sorbing top soils (but in reality, the sorption and degrading potential of ballasts may be substantially reduced). Although this could be simulated to some extent by applying the dose directly to a deeper soil layer to avoid degradation/sorption in topmost layers, that would not occur under railway ballast. A railway/groundwater scenario has been developed within the HardSPEC modelling program, due to specific concerns over leaching from amenity herbicides applied to railway track beds that could not necessarily be reliably simulated with FOCUS. However, the plant protection model relates only to spray application of herbicide onto sleepers and no progress has been made at national level specifically for biocides to develop models to assess leaching loss from impregnated timber, so FOCUS PEARL represents the only option at present. In addition as noted above, the applicability of the FOCUS models to simulate the behaviour of complex DNAPL mixtures such as creosote is associated with a degree of uncertainty.

For the other scenarios, unacceptable risks to groundwater were identified on the basis of the Tier 1 porewater screening calculations.

Groundwater modelling has been undertaken as a result of inclusion of non-residential cladding as a use scenario. As a worst case starting point, the standard approach used for rural housing will be applied and refinement using $F_{weatherside}$ will not be included.

Concentrations predicted to reach local aquifers have been recalculated using higher tier FOCUS PEARL v.4.4.4 Groundwater modelling on predicted cumulative losses at Time 2 (service life). The following assumptions were made for all those FOCUS scenarios considered relevant to GB (Chateaudun, Hamburg, Kremsmunster and Okehampton):

- The housing density is 16 wooden houses per hectare in rural locations, with

each HOUSE having treated area of 125 m² - this results in the total area of 2000 m² treated wood per hectare (ENV 98 of TAB v2.0 : Aug 2018) ;

- Emission of active substances has been modelled using annual average leaching loss for UC 3 treated timber (383.93 mg/$m^2$ over 20 years) ;

- The GB approach models all of the compound entering the soil compartment in 10 equally spaced events per year to simulate the leaching, with application dates spread evenly from January - December, no crop interception and simulation for the grassland scenario (to best represent garden areas) ;

- As a result of ENV 27 in TAB v2.0 (Aug 2018), an additional refinement – $F_{weatherside}$ – can now be applied to PT 8 products when groundwater contamination is being assessed **IF** leaching data have been derived from semi-field data. Test panels will be orientated towards prevailing weather conditions, and it has been now accepted that houses can only be exposed to direct rainfall on 1 – 2 sides (and not all 4). Whilst a proposal to reduce groundwater risk was included in the Appendix 4 supplement to 2013 ESD, refinement is now acceptable (using an $F_{weatherside}$ value of 0.5). This has no bearing on soil concentration ($PEC_{soil}$) as assessment considers risks in the soil compartment which has been exposed. In the first instance, $F_{weatherside}$ will not be applied, as it is not clear whether refinement is appropriate for application to non-residential cladding, fencing etc.

Even so, several assumptions are made in the groundwater assessment calculation that will still likely lead to an overestimate of exposure (and thus offer a degree of protection):

- The groundwater assessment assumes that all of the inputs to the aquifer come from land containing buildings with a high density of treated wood. In reality, it would be expected that the aquifer would also receive inputs from areas where the density of treated wood was much lower, thus lowering the groundwater concentration via dilution ;

- For the groundwater exposure assessment, all leachate losses from treated timbers are assumed to be available for leaching to groundwater with no interception by surface drainage systems. Similarly for the surface water assessment, all leachate losses are assumed to enter surface water, with no loss via vertical leaching. This represents a conservative assessment for each of compartment, as losses are likely to be distributed between both surface water and groundwater ;

- The output from the FOCUS groundwater models represents predicted concentrations at a depth of 1 m. In reality, most UK / GB groundwater aquifers used for water abstraction purposes will be much deeper – consequently, the potential for further degradation, adsorption or dilution to occur before residues reach such an aquifer could be significant and further reduce concentrations expected under realistic use conditions.

Application rates are based on ten equal applications throughout the year and are

calculated as follows:

Creosote : cumulative leaching is predicted to be 383.93 mg/m$^2$ over 20 years and this gives an annual leaching rate of 19.1965 mg/m$^2$/yr (equivalent to 1.92E-05 kg/m$^2$/yr).

Modelling of soil contamination would be predicted using worst case annual leaching loss of each compound in the following equation:

$$\boldsymbol{Application\ rate\ (kg.ha^{-1}) = \frac{((16\ houses\ \times 125m^2) \times Annual\ leaching)}{10\ monthly\ applications}}$$

Application rate of creosote = (2000 x 1.92E-5) / 10 = 3.84E-3 kg/ha

Groundwater modelling with PEARL 4.4.4 will be undertaken by use of the following input parameters :

| **Parameter : CREOSOTE** | Input values for PEARL 4.4.4 |
|---|---|
| **Application Run** | Ten doses of 3.84E-3 kg/ha applied on:<br>10/01, 15/02, 24/03, 29/04, 05/06, 11/07, 17/08, 22/09, 29/10, 04/12 |
| **Application Method** | Direct to soil surface – UC 3 HOUSE |
| **Surrogate crop** | Alfalfa only (as surrogate for grass) |
| **Key soil scenarios** | 4 EU soil scenarios are considered as critical to GB for decision making :<br>CHATEAUDUN,<br>HAMBURG,<br>KREMSMUNSTER,<br>OKEHAMPTON. |
| **Molar Mass** | 200 g/mol (notional average of all grades) |
| **Vapour Pressure** | 0.5 Pa at 25 °C |
| **Water Solubility** | 8.11 mg/l at 25 °C |
| **Kom (as Koc / 1.724)** | 5413.6 L/Kg (based on Koc of 9333 L/Kg) |

| | |
|---|---|
| **Freundlich Exponent** | **1.0** [based upon guidance under ENV 22 of TAB v2.0 (Aug 2018), as a composite Koc value is derived from estimation and not OECD 106 study data] |
| **$DT_{50}$ Soil** | 387 days at 20 °C - AR modelling data set |
| **Molar activation energy** | 65.4 kJ/mol [ENV 2.1 of TAB v2.1 indicates that recommended default value in FOCUS PEARL 4.4.4.should be applied to comply with REACH Guidance document 7b and EFSA Opinion on choice of Q10] |
| **Coefficient for uptake in plants** | 0 (worst case) |

The following values were obtained in FOCUS PEARL 4.4.4 (80th percentile for annual average concentrations) as predicted groundwater concentrations of creosote, following treatment of external house timbers above ground (UC 3) in rural locations :

| Soil scenario (GB relevant) | GW level in µg/l : creosote |
|---|---|
| Chateaudun | 0.000000 |
| Hamburg | 0.000000 |
| Kremsmunster | 0.000000 |
| Okehampton | 0.000000 |

Levels of creosote reaching groundwater from non-residential cladding etc fall well below the drinking water trigger of 0.1 µg/l generically set for “pesticidal actives” and can be considered as acceptable based on standard modelling.

As noted above, the applicability of the FOCUS models to complex DNAPL mixtures such as creosote is associated with a degree of uncertainty. The FOCUS modelling results suggest negligible leaching risk for the scenarios assessed above. However historic contamination of groundwater resources has been reported to occur in and around industrial treatment facilities in the past. This is likely to have occurred as a result of large scale emissions to soil in unbunded facilities. Modern industrial wood preservation facilities are expected to have measures in place to prevent soil (and water) exposure. However this may also indicate that the standard FOCUS models potentially underestimate the leaching risk.

As an overall conclusion, noting the uncertainties in the groundwater assessment based on FOCUS models :

- UC 3 railway sleeper scenario : higher tier PEARL 4.4.4 modelling

demonstrates that groundwater risks are likely to be acceptable (ie. below 0.1 µg/l);

- UC 3 house and fence scenarios : higher tier PEARL 4.4.4 modelling demonstrates that groundwater risks are likely to be acceptable (ie. below 0.1 µg/l) ;

- All other UC 3 and UC 4a use patterns where ground will be contaminated from leachate were only assessed based on porewater screening which predicts values above 0.1 µg/l. The tier 1 groundwater levels are unacceptable and in light of significant failures based on soil risk, higher tier modelling has not been undertaken to refine these risks.

  However, the level of refinement afforded by the FOCUS models in comparison to the tier 1 screening approach was large, where for example the tier 1 PECgw value for the House scenario was reduced from 1.9 µg/l down to <0000001 µg/l in all 4 GB relevant scenarios using FOCUS PEARL 4.4.4. Therefore it would be expected that higher tier FOCUS modelling would demonstrate acceptable risks from all UC 3 and UC4 scenarios where the highest tier 1 concentration of 37.1 µg/l was predicted for the transmission pole scenario (noting the general uncertainty in the applicability of the FOCUS models to complex mixtures such as creosote).

### *13.6. Primary and secondary poisoning*

The conclusions drawn from the original approval of creosote (2010) remain valid as no new data are available regarding primary and secondary poisoning.

However, it should be noted that creosote is a UVCB substance containing PBT and vPvB constituents. As such, the standard quantitative approach to environmental risk assessment may not provide sufficient confidence that the environmental compartments are adequately protected and the presence of PBT and vPvB constituents leads to additional uncertainty in the estimation of risks to the environment. Therefore, based on the currently available risk assessment methodologies it cannot be demonstrated that there are no unacceptable effects to the environment, including via primary and secondary poisoning.

### *13.7. Aggregated exposure (combined for relevant emission sources)*

[Guidance in the TAB under ENV 7 of TAB v1.3 (August 2017) indicates that aggregated exposure assessment should be performed covering all relevant PTs with identical emission routes, based upon decisions reached at ENV-WG-III-2014 (and clarified at ENV-WG-III-2016). Although relevant, detailed guidance is not finalised, the decision tree currently presented in section 4.7 (page 208) of “ECHA Guidance on BPR : Vol IV, Parts B+C (Environment – Assessment and Evaluation) - October 2017” should be followed as an interim measure. This is intended to aid discussion on the need for estimation of aggregated exposure.]

Creosote is used globally in the preservation of wood, to offer “long lasting” protection of structural timbers used for foundations, marine pilings, posts, railway ties / sleepers,

and utility poles. Based upon the decision making scheme outlined in the EU flow diagram for estimating “need of aggregated exposure”, >10% of total use will be as a biocidal active and therefore aggregated exposure must be considered.

However, no consideration of aggregated exposure can reliably be made as existing guidance is not sufficient to assess a material which has been shown to be an UVCB substance containing PBT and vPvB constituents. It may be considered that chemical substances with PBT/vPvB properties have the potential to give rise to effects after a longer period of time and/or at a greater distance than chemicals which do not have these properties. As such, there may be temporal and/or spatial scale protection goals that are not covered by the standard quantitative risk assessment methodologies (i.e. PEC/PNEC comparison)

In the absence of relevant guidance on aggregated exposure for complex mixtures such as creosote, no further consideration of this principle can be undertaken.

**Conclusion on the need for ΣPEC / PNEC values**

Although PT 8 emissions modelling will predict numerous scenarios where active substance can reach the “same” environmental compartments, PECs are derived as a local release at the specific site where treated timber remains in-service. Therefore, emissions are not expected at the same location from multiple treatments (i.e. losses from noise barrier timbers are extremely unlikely to reach the same area of soil or surface water body where other treated timber may reside).

As such, aggregated exposure for use of treated timber in UC 3 - UC 5 will not be undertaken. Each scenario will be assessed to determine their local releases to soil or water body and acceptability will be determined for each individual scenario.

No additional calculations are required in this section of the CAR.

## 14. Risk characterisation for the physico-chemical properties

No new information has become available at renewal. The conclusions from the original approval of creosote (2010) remain valid.

## 15. Measures to protect man, animals and the environment

Risk Mitigation Measures to protect man are detailed in Sections 12.3.3., 12.4.3. and 12.5.3.

Risk Mitigation Measures to protect animals and the environment are largely based on assessments detailed in Section 9. These Risk Mitigation Measures are not exhaustive and additional measures may need to applied as a result of assessments at product authorisation stage:

- *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). Any losses of the product must be collected for reuse or disposal as hazardous waste in accordance with local requirements.*

- *Freshly treated timber must 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 must be collected for reuse or disposal as hazardous waste in accordance with local requirements.*

- *In case of temporary storage of treated timber at sites other than industrial impregnation facilities, timber must be stored on an impermeable hard standing or under shelter (e.g. roof or covered with a tarpaulin) and, if stored in residential or recreational areas, any access by general public must be restricted (e.g. using a fence or a cover).*

- *During in situ brush application treatments, the soil adjacent to the treated surface must be protected with an impermeable cover and any spillage should be collected to avoid emissions to soil and disposed of as hazardous waste in accordance with local requirements.*

- *The biocidal product may only be applied to timber which will not be used above or adjacent to surface waters (WITH THE EXCEPTION OF RAILWAY SLEEPERS).*

Measures to protect man, animals and the environment concerning the use of creosote and creosote treated articles should also refer to REACH.

Restrictions under REACH are measures for protecting human health and/or the environment from risks posed by chemicals on their own, in mixtures or in articles. REACH restrictions limit, ban or set conditions on the manufacture, placing on the market or use of a substance or group of substances.

The provisions for creosote are given in Annex XVII of UK REACH regulation, see entry 31 (and summarised on the HSE website).

As a summary; the restriction permits creosote for specified industrial uses. Wood that has already been legally treated with creosote for industrial uses cannot be used in parks, gardens, playgrounds or certain outdoor facilities where there is a higher risk of skin contact. It also cannot be used inside buildings or for garden furniture or toys.

# Part D – Appendices

## 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, repellent |

***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.<br><br>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.<br><br>European Standard EN 13991:2003 specifies maximum content for (Grade B and C):<br><br>Water extractable phenols: max 3%<br><br>Matter insoluble in toluene: max 0.4%<br><br>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)<br><br>≥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).<br><br>Extrapolated:<br><br>20 °C<br><br>0.4 Pa (Grade B)<br><br>0.3 Pa (Grade C)<br><br>25 °C<br><br>0.66 Pa (Grade B)<br><br>0.50 Pa (Grade C)<br><br>50 °C<br><br>4.88 Pa (Grade B)<br><br>3.41 (Grade C)<br><br>100 °C<br><br>120 Pa (Grade B)<br><br>72.6 Pa (Grade C) |
| **Henry's law constant (Pa $m^3$ $mol^{-1}$)** | Not possible to determine for the complex creosote mixture<br><br>Range for single components (literature data for 18 PAHs):<br><br>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:<br><br>At a loading of 100 mg creosote/l water:<br><br>2.25-8.11 mg/l (Grade B, Grade B-composite and Grade C)<br><br>At a loading of 10 g creosote/l water:<br><br>191 mg/l (Grade B-composite)<br><br>30.3 mg/l (Grade B)<br><br>27.7 mg/l (Grade C)<br><br>Range for single components (literature data for 18 PAHs):<br><br>0.26 µg/l (benzo[ghi]perylene) – 31.7 mg/l (naphthalene)<br><br>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:<br><br>2.7 (o:w 8:1)-3.7 (o:w 1:1.25)<br><br>o:w = octanol to water ratio |

| | |
|---|---|
| **Dissociation constant** | Not possible to determine for the complex creosote mixture<br><br>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) |
| **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 |
| **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, based on other data points |
| **Substances and mixtures which in contact with water emit flammable gases** | Not applicable, based on proposed use and not diluted |
| **Oxidising liquids** | Non-oxidising based on chemical structure of creosote |
| **Oxidising solids** | Not applicable as 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 or relative self-ignition temperature** | ≥ 450 °C (Grade B and C) |
| **Relative self-ignition temperature for solids** | Not applicable as creosote is not a solid |
| **Dust explosion hazard** | Not applicable as creosote is not a solid |

***Classification and proposed labelling***

| | |
|---|---|
| **with regard to physical hazards** | None |

| | |
|---|---|
| **with regard to human health hazards** | H350: Carc. 1B<br>H360F: Repr. 1B<br>H361d: Repr. 2<br>H315: Skin irrit. 2<br>H317: Skin sens. 1<br>H319: Eye Irrit 2 |
| **with regard to environmental hazards** | H400: Aquatic acute 1<br>H410: Aquatic chronic 1<br>M=10 |

## *Chapter 2: Methods of analysis*

### *Analytical methods for the active substance*

| | |
|---|---|
| **Technical active substance (principle of method)** | GC-FID<br><br>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)** | Soil<br><br>No specific method has been submitted. Soxhlet extraction in combination with e.g. GC-FID analysis has been proposed. However, no validation data has been provided in support of the proposal.<br><br>Therefore further information is required to fulfil this data requirement. |
| **Air (principle of method and LOQ)** | 11 PAHs in air<br><br>GC-FID. LOQ: 19.1-25.8 µg/air sampling tube.<br><br>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:<br><br>GC-FID or HPLC-UV/FD (US EPA method 610)<br><br>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))<br><br>6 PAHs in drinking water<br><br>HPLC-FD (DIN 38407-8), LOQ: 0.005 µg/l<br><br>Components of creosote in water (deionized)<br><br>GC-FID, able to quantify 68 components of creosote, LOD: 1 µg/l, LOQ: 3 µg/l<br><br>Sediment<br><br>24 PAHs in sediment<br><br>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.<br><br>Marine water and sediment – no specific method submitted but exposure is possible through UC 5: pressure impregnation: Preventive treatment of wood to be used for marine installations.<br><br>Therefore further information is required to fulfil this data requirement. |

| | |
|---|---|
| **Body fluids and tissues (principle of method and LOQ)** | Urine and faeces<br><br>1-OH-pyrene in urine<br><br>HPLC-FD, LOQ: 8.73 µg/l<br><br>Phenanthrene, pyrene and chrysene and corresponding OH-metabolites in urine and faeces<br><br>GC-FID/MS, LOQ not stated, LOD: 0.1 ng injected<br><br>These residue definitions for urine and faeces and associated monitoring methods are considered sufficient for the purposes of the regulatory process as the residue definitions in these compartments are relatively simple and the two matrices can be collected with non-invasive procedures. |

| | |
|---|---|
| **Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)** | GC-HRMS for the 16 EPA priority PAHs and 1- and 2-methylnaphthalene (only basic details of the method provided - clean up on a silica/alumina column after saponification, extraction prior to analysis).<br><br>Limited validation recovery data with an apple sample with individual PAH amounts of 2.5 µg/kg for GC MS/MS and GC-HRMS<br><br>Further details relating to the methods and associated limited validation data provided in Appendix VII (full residues evaluation).<br><br>Various LOQs according to component and sampling site in the fruit trees residues studies. LOQs of 0.5 µg/kg or 0.1 µg/kg (for many of the components, but not supported by associated validation to be able to confirm this method and the LOQs as a method of analysis suitable for monitoring purposes). LOQs for naphthalene, 1- and 2-methylnaphthalene, acenaphthene, acenaphthylene and anthracene varied depending on substance and sampling site. |
| **Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)** | No data on methods of analysis are available for products of animal origin; a monitoring method which provides full details of the analytical method with suitable acceptable validation data (including recovery rates and the limit of quantification and detection for the active substance and residues) in relevant livestock matrices would be needed if creosote is renewed and the agricultural fencing uses are part of any onward approval.<br><br>Although there are existing MRLs set for PAHs in fish and shellfish products, monitoring methods are not required as marine installation applications are not in use in GB. |

## *Chapter 3: Impact on human health*

### *Absorption, distribution, metabolism and excretion in mammals*

| | |
|---|---|
| **Rate and extent of oral absorption:** | Assumed to be 100% |
| **Rate and extent of dermal absorption*:** | 10% |
| **Rate and extent of inhalation absorption:** | Assumed to be 100% |
| **Distribution:** | Widely distributed<br><br>Pyrene (as model PAH): highest levels in |
| **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 |

*The dermal absorption value is applicable for the active substance and might not be usable in product authorisation.

### *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***

| | |
|---|---|
| **Skin corrosion / irritation** | Irritating based on animal data<br><br>Irritating (Cat 2; H315 proposed) |

***Eye irritation***

| | |
|---|---|
| **Eye irritation** | Irritating based on human data<br><br>Irritating (Cat 2; H319 proposed) |

***Respiratory tract irritation***

| | |
|---|---|
| **Respiratory tract irritation** | No data |

***Skin sensitisation***

| | |
|---|---|
| **Skin sensitisation (test method used and result)** | Positive (Maximization)<br><br>Negative (Buehler)<br><br>Overall, concluded to be a skin sensitiser (Cat 1; H317 proposed) |

***Respiratory sensitisation***

| | |
|---|---|
| **Respiratory sensitisation (test method used and result)** | No data |

***Repeated dose toxicity***

**Short-term**

| | |
|---|---|
| **Species / target / critical effect** | No data |
| **Relevant oral NOAEL / LOAEL** | No data |
| **Relevant dermal NOAEL / LOAEL** | No data |
| **Relevant inhalation NOAEL / LOAEL** | No data |

**Sub-chronic**

| | |
|---|---|
| **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 NOAEL / LOAEL** | 22/128 mg/m3 (90 d) |

**Long-term**

| | |
|---|---|
| **Species / target / critical effect** | No data |
| **Relevant oral NOAEL / LOAEL** | No data |
| **Relevant dermal NOAEL / LOAEL** | No data |
| **Relevant inhalation NOAEL / LOAEL** | No data |

***Genotoxicity***

| | |
|---|---|
| **Genotoxicity** | Genotoxicity cannot be excluded |

***Carcinogenicity***

| | |
|---|---|
| **Species / type of tumour** | Mouse (dermal): skin tumours<br>(papilloma and squamous-cell carcinoma)<br>Carc Cat 1B; H350 |
| **Relevant NOAEL / LOAEL** | T25 = 260 mg/kg bw/d |

***Reproductive toxicity***

**Developmental toxicity**

| | |
|---|---|
| **Species/ Developmental target / critical effect** | Rat, rabbit/ embryonal / post-implantation loss (Repr 2: H361d proposed) |
| **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 (Repr 1B: H360F proposed) |
| **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***

| | |
|---|---|
| **Endocrine disruption** | No data |

***Medical data***

| | |
|---|---|
| **Medical data** | Fatal cases after ingestion of creosote involve the amount of about 7 g for adults and 1-2 g for children.<br><br>Overall, the body of epidemiological data does not indicate an apparent elevated cancer risk for creosote workers. |

***Summary***

| Reference Value | Value | Study | Safety factor |
|---|---|---|---|
| **$AEL_{long\text{-}term}$** | 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 | N/A | N/A |

| Reference Value | Value | Study | Safety factor |
|---|---|---|---|
| **$AEL_{medium\text{-}term}$** | 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 | N/A | N/A |
| **$AEL_{short\text{-}term}$** | 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 | N/A | N/A |
| **ADI (if residues in food or feed)** | By definition, ADI gives a safety level of daily intake of a substance via ingestion. | N/A | N/A |
| **ARfD** | Not applicable as creosote is a genotoxic carcinogen | N/A | N/A |
| **$DMEL_{systemic_workers}$** | 8.4 µg/kg bw/d | Dermal mouse cancer study | 25,000 |

| Reference Value | Value | Study | Safety factor |
|---|---|---|---|
| **$DMEL_{systemic_general\ public}$** | 0.3 µg/kg bw/d | Dermal mouse cancer study | 250,000 |
| **$DMEL_{oral_consumers}$** | 0.3 µg/kg bw/d | Dermal mouse cancer study | 250,000 |

***MRLs***

| | |
|---|---|
| **Relevant commodities** | Existing MRLs relevant to creosote constituents<br><br>No existing MRLs specific to fruits, grapes or hops, and no MRLs covering all products of animal (livestock) origin (except MRLs for some relevant PAHs in for fat and smoked meat and smoked meat products).<br><br>There are existing MRLs for some relevant PAHs in infant foods<br><br>For further details on existing MRLs see section 12.2.3<br><br>MRLs are not being proposed as a result of this assessment of the main representative dietary exposure scenarios, as outlined in section 8.7.1 :<br><br>Agricultural fencing/equestrian fencing treated with creosote (livestock)<br><br>Agricultural tree stakes/supports treated with creosote (fruits, grapes ( vineyard), and hops). |

***Reference value for groundwater***

| | |
|---|---|
| **According to GB BPR Annex VI, point 68** | NA |

***Dermal absorption***

| | |
|---|---|
| **Study (*in vitro / vivo*), species tested** | Not available |
| **Formulation (formulation type and including concentration(s) tested, vehicle)** | Creosote |
| **Dermal absorption values used in risk assessment** | 10% |

***Acceptable exposure scenarios (including method of calculation)***

| | |
|---|---|
| **Formulation of biocidal product** | Not considered in this assessment |
| **Intended uses** | Wood preservative |
| **Industrial users** | None |
| **Professional users** | None |
| **General public users** | None |
| **General public bystanders** | None |
| **Exposure via residue in food** | None |

## *Chapter 4: Fate and behaviour in the environment*

### *Route and rate of degradation in water*

| | |
|---|---|
| **Hydrolysis of active substance and relevant metabolites ($DT_{50}$) (state pH and temperature)** | Not applicable for creosote (PAH compounds not expected to be hydrolytically degraded). |
| **Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites** | Not applicable for creosote.<br><br>Direct photochemical transformation (latitude 40°N, midday, midsummer) for different PAH compounds in creosote ranged between <1h to 71 h. :<br><br>One major transformation product of PAHs seems to be quinone derivatives. |
| **Readily biodegradable (yes / no)** | No |
| **Biodegradation in freshwater** | Not applicable for creosote.<br><br>Mineralisation half-lives (at 22 °C) ranged between 30.8 to 140 d and total percentage mineralised of 14C-labelled PAHs after 56 days ranged between <0.2 to 54.5%. |
| **Non-extractable residues** | Not applicable for creosote.<br><br>Between approx. 2% for naphthalene / methylnaphthalene to 7.5% for phenanthrene (56 days). |

| | |
|---|---|
| **Distribution in water / sediment systems (active substance)** | Not applicable for creosote.<br><br>For naphthalene, methylnaphthalene, phenanthrene and pyrene:<br><br>Between 3.1 and 8.4% was found in the water phase and between 8.2 and 75% was found in the sediment phase.<br><br>(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***

| | |
|---|---|
| **Mineralisation (aerobic)** | No data |
| **Laboratory studies (range or median, with number of measurements, with regression coefficient)** | Not applicable for creosote.<br><br>For PAHs half-lives were determined to range between 2.2 and 387 d(highest value of two soils) at 20 °C.<br><br>The kinetic calculations resulting in first order rate constants and half-lives gave $r^2$ 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**<br>**$Ka_{oc}$ , $Kd_{oc}$**<br>**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.<br><br>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.<br><br>For Composite Grade B the Log Kow = 4.12, the Log Koc = 3.67 and the proportion of creosote used in the estimate = 61%<br><br>For Grade B the Log Kow = 4.43, the Log Koc = 3.97 and the proportion of creosote used in the estimate = 58%<br><br>For Grade C the Log Kow = 4.63, the Log Koc = 4.17 and the proportion of creosote used in the estimate = 53%<br><br>No pH dependence of partition coefficients.<br><br>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.<br><br>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 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.<br><br>Half-lives of selected PAHs due to gas-phase reactions with hydroxyl (OH) radicals ranged between 0.76 h to 6.9 h; reactions with nitrate (NO3) radicals ranged between 4.2 minutes and 10 years; all for hypothetical summertime conditions in clean air.<br><br>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. |

| | |
|---|---|
| **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 GB 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<br><br>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 were reported.<br><br>At a distance of 7.6 cm from the pole the |

| | |
|---|---|
| | median creosote concentration was 3320 mg/kg wet weight (assuming the proportion of the PAHs analysed was 40% of the creosote content.<br><br>At a distance of 122 cm from the pole the median creosote concentration was 0.25 mg/kg wet weight. This value represents background levels of the sum of PAHs.<br><br>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.<br><br>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.<br><br>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 ([redacted] 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. |

| | |
|---|---|
| **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)*

**Fish**

| Species | Test substance | Timescale | Endpoint | Toxicity |
|---|---|---|---|---|
| *O. latipes (fresh water)* | creosote | 96 h<br>semi-static | $LC_{50}$ | 0.7 mg/l (measured conc. of 19 PAHs) |
| *Pagrus major* (seawater) | creosote | 96 h<br>semi-static | $LC_{50}$ | 0.7 mg/l (measured conc. of 19 PAHs) |
| *Brachydanio rerio* | PAH-mixture | 42 d | $NOEC_{growth}$ | 0.0021 mg Σ6PAHs/l (m) |
| *Clupea pallasi* | creosote from treated wood | 9 d | $NOEC_{hatching\ success}$ | 0.001 mg creosote (Σ Aromatic compounds)/l |
| *B. rerio* | phenanthrene/ fluoranthene | 28/41 d | $NOEC_{reproduction}$ | 0.011/0.0044 mg/l (estimated/m) |
| *P. promelas* | anthracene | 77 d | $NOEC_{reproduction}$ | 0.006 mg/l (m) |

**Invertebrates**

| Species | Test substance | Timescale | Endpoint | Toxicity |
|---|---|---|---|---|
| *Daphnia magna* | creosote | 48 h | $EC_{50}$ | 1.14 mg/l (n) |

| Species | Test substance | Timescale | Endpoint | Toxicity |
|---|---|---|---|---|
| *Mysidopsis bahia* | creosote | 96 h | $LC_{50}$ | 0.018 mg/l (n) |
| *Daphnia magna* | anthracene, fluorene, phenanthrene | 21 d | $NOEC_{reproduction}$ | 0.002, 0.015, and 0.018 mg/l |
| zooplankton community | creosote from treated wood | 83 d | $NOEC_{abundance}$ | 0.011 mg creosote (Σ15PAHs)/l |

**Algae**

| Species | Test substance | Timescale | Endpoint | Toxicity |
|---|---|---|---|---|
| (*Desmodesmus subspicatus*) | creosote | 72 h | $E_rC_{50}$ | 2.1 mg/l (measured TOC) |
| (*Desmodesmus subspicatus*) | creosote | 72 h | NOEC | 0.9 mg/l (measured TOC) |

**Sediment dwelling organisms**

| Species | Test substance | Timescale | Endpoint | Toxicity |
|---|---|---|---|---|
| Benthic community | creosote from treated wood pilings | 1-4 years | NOEC abundance / diversity | creosote (Σ15PAHs): 10 mg/kg dw = 22 mg/kg ww<br><br>phenanthrene: 2 mg/kg dw = 4.4 mg/kg ww<br><br>fluoranthene: 3 mg/kg dw = 6.5 mg/kg ww<br><br>(in ww after conversion to TGD standard susp. matter) |

**Micro-organisms**

| Species | Test substance | Timescale | Endpoint | Toxicity |
|---|---|---|---|---|
| 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***

| | |
|---|---|
| **Acute toxicity to earthworms (*E. fetida*)** | PAH- or creosote-contaminated soil:<br><br>$LC_{50}$ (14d): 286-1354 (ΣPAH) (ww) (mg/kg)<br><br>(after conversion to standard TGD soil) |

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

dw = dry weight, ww = wet weight

***Effects on soil micro-organisms***

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

***Effects on terrestrial plants***

| | |
|---|---|
| **Acute toxicity to lettuce (*L. sativa*)** | PAH- contaminated soil:<br><br>$EC_{50}$ (5 d): 600 (dw) = 181 (ww)<br><br>$NOEC_{seed\ germination}$ (5 d): 180 (dw) = 54 (ww) (Σ 9PAH)<br><br>(in ww after conversion to standard TGD soil) |
| **Acute toxicity to tomato** | PAH- mixture:<br><br>$EC_{50growth\ inhibition}$ (20 d): 100 (dw) = 241 (ww)<br><br>$NOEC_{growth\ inhibition}$ (20 d): 10 (dw) = 24 (ww) (Σ 4PAH/creosote)<br><br>(in ww after conversion to standard TGD soil) |

| | |
|---|---|
| **Acute toxicity to red clover, ryegrass, mustard** | phenanthrene, pyrene, fluorene, carbazole, dibenzofuran (tested ind.) fluoranthene:<br><br>$EC_{50growth\ inhibition}$ (14 d): >1000 (dw) = 1100 (ww)<br><br>$NOEC_{growth\ inhibition}$ (14 d): 10 (dw) = 11.1 (ww)<br><br>(in ww after conversion to standard TGD soil) |
| **Acute toxicity to oat** | anthracene:<br><br>$NOEC_{growth\ inhibition}$ (14 d): 10 (dw) = 15 (ww)<br><br>(in ww after conversion to standard TGD soil) |

***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***

| | |
|---|---|
| **Bioconcentration factor (BCF)** | naphthalene:<br>~70 – 1000<br>1-methyl-naphthalene:<br>~100<br>2-methyl-naphthalene:<br>~140 – 4300<br>phenanthrene:<br>~1600<br>anthracene:<br>~750 – 5000<br>fluoranthene:<br>~380<br>fluorene:<br>~540<br>pyrene:<br>~50 – 70 |
| **Degradation time ($DT_{50}$)** | naphthalenes:<br>2 days (in oyster)<br>anthracene:<br>3 days (in oyster)<br>fluoranthene:<br>5 days (in oyster) |

| | |
|---|---|
| **Degradation time ($DT_{90}$)** | Most PAHs in creosote:<br>2-5 days (in fish) |
| **Level of metabolites (%) in organisms accounting for > 10 % of residues** | No data |

## *Chapter 6: Other end points*

## Appendix II: Human exposure calculations

The following risk assessment calculation spreadsheets are available on the HSE website as additional information.

- Appendix II – bfr-calculator-for-estimating-livestock-exposure-to-active-substances-used-in-biocidal-products creosote (210kg $m^3$)
- Appendix II – bfr-calculator-for-estimating-livestock-exposure-to-active-substances-used-in-biocidal-products creosote (50 L $m^3$)

### *Scenario 1*

*Scenario 1. Industrial use - primary exposure during vacuum pressure treatment process*

Tier 2a assessment

Dermal

Potential body exposure (mg) = potential body exposure indicative value (mg/cycle) x number of cycles = 158 mg/cycle x 3 cycles = 474 mg

Exposure for 3 cycles 474 mg x 10 % (coated coveralls) = 47.4 mg

Potential hand exposure = potential hand exposure indicative value (new gloves worn each cycle) (mg/cycle) x number of cycles = 130 mg/cycle x 3 cycles = 390 mg

Total dermal exposure to the product (with new gloves and coated coveralls) = 47.4 mg + 390 mg = 437.4 mg

Dermal exposure to active substance (mg/kg bw/day) = total dermal exposure to the product (mg) x active substance (% w/w) x dermal absorption (%) / body weight (kg)

Dermal exposure to creosote = 437.4 mg x 100% x 10% / 60 kg = 0.729 mg/kg bw/day

Inhalation

Potential inhalation exposure = Indicative value (mg/$m^3$) x duration (h) x inhalation rate ($m^3$/h) = 0.6 mg/$m^3$ x 0.5 h x 1.25 $m^3$/h = 0.375 mg of inhaled product

Inhalation exposure to active substance (mg/kg bw/day) = total inhalation exposure to the product (mg) x active substance (% w/w) x inhalation absorption (%) / body weight (kg)

Inhalation exposure to creosote = 0.375 mg x 100% x 100% / 60 kg = 0.00625 mg/kg bw/day

Tier 2b

Dermal

Potential body exposure (mg) = potential body exposure indicative value (mg/cycle) x number of cycles = 158 mg/cycle x 1 cycle x 5% (Impermeable coveralls) = 7.9 mg

Potential hand exposure = potential hand exposure indicative value (new gloves worn each cycle) (mg/cycle) x number of cycles = 130 mg/cycle x 1 cycle = 130 mg

Total dermal exposure to the product (with gloves) = 7.9 mg + 130mg= 137.9 mg

Dermal exposure to active substance (mg/kg bw/day) = total dermal exposure to the product (mg) x active substance (% w/w) x dermal absorption (%) / body weight (kg)

Dermal exposure to creosote = 137.9 mg x 100%w/w x 10% / 60 kg = 0.2298 mg/kg bw/day

Inhalation

Potential inhalation exposure = Indicative value (mg/m$^3$) x duration (h) x inhalation rate (m$^3$/h) = 0.6 mg/m$^3$ x 0.5 h x 1.25 m$^3$/h = 0.375 mg of inhaled product for 3 cycles

Therefore 0.125mg for 1 cycle

Inhalation exposure to active substance (mg/kg bw/day) = total inhalation exposure to the product (mg) x active substance (%w/w) x inhalation absorption (%) / body weight (kg)

Inhalation exposure to creosote = 0.125 mg x 100%w/w x 100% / 60 kg = 0.00208 mg/kg bw/day

Assume RPE used with APF 20 (reduction of 95%) = 0.000104 mg/kg

### *Scenario 2*

*Scenario 2. Industrial use - primary exposure during Hot and Cold impregnation treatment process*

As discussed in the main body of the assessment. Exposure is anticipated to be equivalent to the vacuum pressure treatment process The calculations from Scenario 1 apply.

### *Scenario 3*

*Scenario 3. Industrial use – Primary exposure during cleaning out dipping tank vessels after use*

As discussed in the main body of the assessment. Exposure is anticipated to be at least equal to the exposures of actually treating the wood. The calculations are presented below assuming new gloves, impermeable coveralls and RPE (APF 20).

Dermal

Potential body exposure (mg) = potential body exposure indicative value (mg/cycle) x number of cycles = 158 mg/cycle x 1 cycle x 5% (Impermeable coveralls) = 7.9 mg

Potential hand exposure = potential hand exposure indicative value (new gloves worn each cycle) (mg/cycle) x number of cycles = 130 mg/cycle x 1 cycle = 130 mg

Total dermal exposure to the product (with gloves) = 7.9 mg + 130mg= 137.9 mg

Dermal exposure to active substance (mg/kg bw/day) = total dermal exposure to the product (mg) x active substance (% w/w) x dermal absorption (%) / body weight (kg)

Dermal exposure to creosote = 137.9 mg x 100 %w/w x 10 % / 60 kg = 0.2298 mg/kg bw/day

Inhalation

Potential inhalation for entire cycle, 180 mins which equates to 3hr in calculation.

Potential inhalation exposure = Indicative value (mg/m$^3$) x duration (h) x inhalation rate (m$^3$/h) = 0.6 mg/m$^3$ x 3 h x 1.25 m$^3$/h = 2.25 mg of inhaled product for 1 cycle

Inhalation exposure to active substance (mg/kg bw/day) = total inhalation exposure to the product (mg) x active substance (%w/w) x inhalation absorption (%) / body weight (kg)

Inhalation exposure to creosote = 2.25 mg x 100% w/w x 100% / 60 kg = 0.0375 mg/kg bw/day

Assume RPE used with APF 20 (reduction of 95%) = 0.001875 mg/kg

### *Scenario 4*

*Scenario 4. Professional / Industrial use – Primary exposure – Handling Wet Treated Wood*

As discussed in the main body of the assessment. Exposure is anticipated to be less than or equal to the exposures of actually treating the wood. The calculations from Scenario 1, tier 2b apply, as guidance indicates that a single event per day would apply.

### *Scenario 5*

*Scenario 5. Professional use – Primary exposure – Brush application (outdoor)*

Exposure Calculator for Scenario 5 - Application by brush Tier 1 no PPE/RPE

**Potential dermal hand exposure**

| | **Value** | **Units** |
|---|---|---|
| Indicative Value | 54.17 | mg/m$^2$ |

| | Value | Units |
|---|---|---|
| Application Area/day | 31.6 | $m^2$ |
| Potential Dermal Deposit | 1711.772 | mg |
| Glove Penetration | 100 | % |
| Actual Dermal Deposit | 1711.772 | mg |

**Potential dermal body exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 23.82 | $mg/m^2$ |
| Application Area/day | 31.6 | $m^2$ |
| Potential Dermal Deposit | 752.712 | mg |
| Coverall Penetration | 100 | % |
| Actual Dermal Deposit | 752.712 | mg |
| Total Active Substance Deposit | 2464.484 | mg |
| Dermal Penetration | 10 | % |
| Active substance via the skin | 246.4484 | mg |

**Potential Inhalation Exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 0.16 | $mg/m^2$ |
| Application Area/day | 31.6 | $m^2$ |
| Potential Inhalation Exposure | 5.056 | mg/day |
| RPE Penetration | 100 | % |
| Actual Inhalation Exposure | 5.056 | mg/day |

**Dose**

| | Value | Units |
|---|---|---|
| Total Per Day | 251.5044 | mg |
| Operator body weight | 60 | kg |
| **Systemic Dose** | 4.19174 | mg/kg bw/day |

Exposure Calculator for Scenario 5 - Application by brush Tier 2a gloves, coated coveralls

**Potential dermal hand exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 54.17 | $mg/m^2$ |
| Application Area/day | 31.6 | $m^2$ |

| | Value | Units |
|---|---|---|
| Potential Dermal Deposit | 1711.772 | mg |
| Glove Penetration | 10 | % |
| Actual Dermal Deposit | 171.1772 | mg |

**Potential dermal body exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 23.82 | $mg/m^2$ |
| Application Area/day | 31.6 | $m^2$ |
| Potential Dermal Deposit | 752.712 | mg |
| Coverall Penetration | 10 | % |
| Actual Dermal Deposit | 75.2712 | mg |
| Total Active Substance Deposit | 246.4484 | mg |
| Dermal Penetration | 10 | % |
| Active substance via the skin | 24.64484 | mg |

**Potential Inhalation Exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 0.16 | $mg/m^3$ |
| Application Area/day | 31.6 | $m^2$ |
| Potential Inhalation Exposure | 5.056 | mg/day |
| RPE Penetration | 100 | % |
| Actual Inhalation Exposure | 5.056 | mg/day |

**Dose**

| | Value | Units |
|---|---|---|
| Total Per Day | 29.70084 | mg |
| Operator body weight | 60 | kg |
| **Systemic Dose** | 0.495014 | mg/kg bw/day |

Exposure Calculator for Scenario 5 - Application by brush Tier 2b with New Gloves, Impermeable coveralls and suitable RPE

**Potential dermal hand exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 54.17 | $mg/m^2$ |
| Application Area/day | 31.6 | $m^2$ |

| | Value | Units |
|---|---|---|
| Potential Dermal Deposit | 1711.772 | mg |
| Glove Penetration | 5 | % |
| Actual Dermal Deposit | 85.5886 | mg |

**Potential dermal body exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 23.82 | $mg/m^2$ |
| Application Area/day | 31.6 | $m^2$ |
| Potential Dermal Deposit | 752.712 | mg |
| Coverall Penetration | 5 | % |
| Actual Dermal Deposit | 37.6356 | mg |
| Total Active Substance Deposit | 123.2242 | mg |
| Dermal Penetration | 10 | % |
| Active substance via the skin | 12.32242 | mg |

**Potential Inhalation Exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 0.16 | $mg/m^3$ |
| Application Area/day | 31.6 | $m^2$ |
| Potential Inhalation Exposure | 5.056 | mg/day |
| RPE Penetration | 5 | % |
| Actual Inhalation Exposure | 0.2528 | mg/day |

**Dose**

| | Value | Units |
|---|---|---|
| Total Per Day | 12.57522 | mg |
| Operator body weight[2] | 60 | kg |
| **Systemic Dose** | 0.209587 | mg/kg bw/day |

Exposure Calculator for Scenario 5 - Application by brush Tier 2c with New Gloves, Impermeable coveralls and suitable RPE, reduced exposure time to 1 hour

**Potential dermal hand exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 54.17 | $mg/m^2$ |
| Application Area/day | 7.89 | $m^2$ |

| | Value | Units |
|---|---|---|
| Potential Dermal Deposit | 427.66 | mg |
| Glove Penetration | 5 | % |
| Actual Dermal Deposit | 21.38 | mg |

**Potential dermal body exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 23.82 | $mg/m^2$ |
| Application Area/day | 7.89 | $m^2$ |
| Potential Dermal Deposit | 187.94 | mg |
| Coverall Penetration | 5 | % |
| Actual Dermal Deposit | 9.397 | mg |
| Total Active Substance Deposit | 30.78 | mg |
| Dermal Penetration | 10 | % |
| Active substance via the skin | 3.0777 | mg |

**Potential Inhalation Exposure**

| | Value | Units |
|---|---|---|
| Indicative Value | 0.16 | $mg/m^2$ |
| Application Area/day | 7.89 | $m^2$ |
| Potential Inhalation Exposure | 1.2624 | mg/day |
| RPE Penetration | 5 | % |
| Actual Inhalation Exposure | 0.06312 | mg/day |

**Dose**

| | Value | Units |
|---|---|---|
| Total Per Day | 3.14082 | mg |
| Operator body weight | 60 | kg |
| **Systemic Dose** | 0.052347 | mg/kg bw/day |

***Scenario 6***

*Scenario 6. Professional use – Primary exposure – Cleaning Brushes - application (outdoor)*

Exposure Calculator for Scenario 6 – Cleaning Brushes. Tier 1 no PPE/RPE, Tier 2a Gloves and Tier 2b New gloves (as stipulated in main body of text).

| **Activity** | **Parameters** | **Tier 1**<br>**No PPE** | **Tier 2a**<br>**PPE Gloves** | **Tier 2b**<br>**PPE New Gloves** |
|---|---|---|---|---|
| Volume of brush | 200 ml | | | |

| | | | | |
|---|---|---|---|---|
| Volume of paint remaining on brush after painting | 1/8 of 200 ml = 25 ml | | | |
| Density of paint | 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). | 25 ml x 1.17 g/ml =<br><br>29.25 g | | | |
| Concentration of a.s. in paint | 100 %w/w | | | |
| **(A)** Weight of a.s. on brush after painting | 29.25 g x 100/100 = 29.25 g (29250 mg) | 29250 mg | 29250 mg | 29250 mg |
| **(B) Residues of a.s. on brush after 1st washing** | **10 % of A** | 2925 mg | 2925 mg | 2925 mg |
| Amount of a.s. removed from the brush into the cleaning fluid | A - B | 26325 mg | 26325 mg | 26325 mg |
| **(C)** Weight of a.s. squeezed out from brush onto cloth | **50 % of B** | 1462.5 mg | 1462.5 mg | 1462.5 mg |
| Cloth absorbs 90 % of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand. | **10 % of C** | 146.25 mg | 146.25 mg | 146.25 mg |
| Penetration of a.s. through gloves | | 100% | 10 % | 5% |

| | | | | |
|---|---|---|---|---|
| Weight of a.s. on hand | | 146.25 mg | 14.625 mg | 7.3125 mg |
| Dermal absorption of a.s. | 10 % | 14.625 mg | 1.4625 mg | 0.73125 mg |
| **Weight of a.s. entering the body (1)** | | **14.625 mg** | **1.4625 mg** | **0.73125 mg** |
| **(D)** Amount of a.s. left on the brush after 1st wash and squeezing | B-C | 1462.5 mg | 1462.5 mg | 1462.5 mg |
| **(E) Residues of a.s. on brush after 2nd washing** | **10 % of D** | 146.25 mg | 146.25 mg | 146.25 mg |
| Amount of a.s. removed from the brush into the cleaning fluid | D-E | 1316.25 mg | 1316.25 mg | 1316.25 mg |
| **(F)** Weight of a.s. squeezed out from brush onto cloth | 50 % of E | 73.125 mg | 73.125 mg | 73.125 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 | 7.3125 |
| Penetration of a.s. through gloves | | 100 % | 10 % | 5% |
| Weight of a.s. on hand | | 7.3125 mg | 0.73125 mg | 0.365625 mg |
| Dermal absorption of a.s. | 10% | 10 % | 10 % | 10 % |
| **Weight of a.s. entering the body (2)** | | **0.73125 mg** | **0.073125 mg** | **0.0365625 mg** |

| | | | | |
|---|---|---|---|---|
| **(G)** Amount of a.s. left on the brush after 2nd wash and squeezing | E-F | 73.125 mg | 73.125 mg | 73.125 mg |
| **(H) Residues of a.s. on brush after 3rd washing** | **10 % of G** | 7.3125 mg | 7.3125 mg | 7.3125 mg |
| Amount of a.s. removed from the brush into the cleaning fluid | **G-H** | 65.8125 mg | 65.8125 mg | 65.8125 mg |
| **(I)** Weight of a.s. squeezed out from brush onto cloth | 50 % of H | 3.65625 mg | 3.65625 mg | 3.65625 mg |
| Cloth absorbs 90 % of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand. | **10 % of I** | 0.365625 mg | 0.365625 mg | 0.365625 mg |
| Penetration of a.s. through gloves | | 100 % | 10% | 5% |
| Weight of a.s. on hand | | 0.365625 mg | 0.0365625 mg | 0.01828125 mg |
| Dermal absorption of a.s. | 10% | | | |
| **Weight of a.s. entering the body (3)** | | 0.0365625 mg | 0.00365625 mg | 0.001828125 mg |
| **Total weight of a.s. entering the body (to 4 decimal places)** | **1 + 2 + 3** | 15.3928 mg | 1.5393 mg | 0.7696 mg |
| **Body Weight** | 60 kg | | | |

| | | | | |
|---|---|---|---|---|
| **Total Systemic Dermal Dose of Active Substance (to 4 decimal places)** | | 0.2565 mg a.s./kg bw | 0.0257 mg a.s./kg bw | 0.0128 mg a.s./kg bw |

***Scenario 7***

*Scenario 7. Professional – Primary exposure – Cutting/Sanding wood*

Systemic exposure via the inhalation route for sanding wood has been calculated using the following equation.

Systemic dose via the inhalation route (mg/kg bw/day) = volume of wood inhaled ($cm^3$) x concentration of a.s. in wood ($mg/cm^3$) x 100% absorption ÷ bodyweight (kg).

Systemic exposure via the dermal route for sanding wood has been calculated using the following equation.

Systemic dose via the dermal route (mg/kg bw/day) = active substance residue on surface ($mg/cm^3$) x area of hands ($cm^2$) x proportion of hands contaminated (%) x transfer efficiency of wood (%) x dermal absorption (%) ÷ bodyweight (kg).

Tier 1 assessment.

Systemic dose via the inhalation route (mg/kg bw/day) = 0.0938 ($cm^3$) x 210 ($mg/cm^3$) x 100% absorption ÷ 60 (kg). = 0.3283 mg/kg bw/day

Systemic dose via the dermal route (mg/kg bw/day) = 210 ($mg/cm^3$) x 410 ($cm^2$) x 20 (%) x 2(%) x 10 (%) ÷ 60 (kg). = 0.574 mg/kg bw/day

Tier 2a Assessment (Reduce to 1 hr exposure)

Systemic dose via the inhalation route (mg/kg bw/day) = 0.015625 ($cm^3$) x 210 ($mg/cm^3$) x 100% absorption ÷ 60 (kg). = 0.05469

Systemic dose via the dermal route (mg/kg bw/day) = 210 ($mg/cm^3$) x 410 ($cm^2$) x 20 (%) x 2(%) x 10 (%) ÷ 60 (kg). = 0.574 mg/kg bw/day

Tier 2b Assessment (RPE & Reduce to 1hr exposure)

Systemic dose via the inhalation route (mg/kg bw/day) = 0.015625 ($cm^3$) x 210 ($mg/cm^3$) x 100% absorption x 5 % (RPE) ÷ 60 (kg).

(Assume RPE used with APF 20 (reduction of 95 %)) = 0.002734375

Tier 2c Assessment (RPE & Reduce to 1hr exposure & gloves)

Systemic dose via the inhalation route (mg/kg bw/day) = 0.015625 ($cm^3$) x 210

(mg/cm$^3$) x 100% absorption x 5 % (RPE) ÷ 60 (kg).

(Assume RPE used with APF 20 (reduction of 95 %)) = 0.002734375

Systemic dose via the dermal route (mg/kg bw/day) = 210 (mg/cm$^3$) x 410 (cm$^2$) x 20 (%) x 2(%) x 10 (%) x 10 % (Gloves) ÷ 60 (kg). = 0.0574 mg/kg bw/day

Tier 1 – No PPE/No Refinement

| **Parameter** | **Creosote Exposure** |
|---|---|
| Concentration of a.s in the wood (mg a.s/cm$^3$) | 210 mg/cm$^3$ |
| Inhalation Absorption (%) | 100 % |
| Dermal Absorption (%) | 10 % |
| Body weight (kg) | 60 kg |
| Volume of wood dust inhaled (cm$^3$/hr) | 0.0938 cm$^3$/hr |
| Estimated inhalation uptake (mg a.s./day) | 19.698 |
| Systemic dose (inhalation) (mg a.s./ kg bw/ day) | 0.3283 |
| Area of hands (cm$^2$) | 410 cm$^2$ |
| Hand contamination (%) | 20 % |
| Transfer efficiency (%) | 2 % |
| Estimated dermal uptake (mg a.s./day) | 34.44 |
| Systemic dose (dermal) (mg a.s./kg bw/day) | 0.574 |

| Parameter | Creosote Exposure |
|---|---|
| Total systemic dose (mg/kg bw/day) | 0.9023 |

Tier 2a – No PPE / reduced exposure time 1 hour

| Parameter | Creosote Exposure |
|---|---|
| Concentration of a.s in the wood (mg a.s/$cm^3$) | 210 mg/$cm^3$ |
| Inhalation Absorption (%) | 100 % |
| Dermal Absorption (%) | 10 % |
| Body weight (kg) | 60 kg |
| Volume of wood dust inhaled ($cm^3$/hr) | 0.015625 $cm^3$/hr |
| Estimated inhalation uptake (mg a.s./day) | 3.28125 |
| Systemic dose (inhalation) (mg a.s./ kg bw/ day) | 0.0546875 |
| Area of hands ($cm^2$) | 410 $cm^2$ |
| Hand contamination (%) | 20 % |
| Transfer efficiency (%) | 2 % |
| Estimated dermal uptake (mg a.s./day) | 34.44 |
| Systemic dose (dermal) (mg a.s./kg bw/day) | 0.574 |

| Parameter | Creosote Exposure |
|---|---|
| Total systemic dose (mg/kg bw/day) | 0.6286875 |

Tier 2b – RPE with APF of 20, reduced exposure time 1 hour

| Parameter | Creosote Exposure |
|---|---|
| Concentration of a.s in the wood (mg a.s/$cm^3$) | 210 mg/$cm^3$ |
| Inhalation Absorption (%) | 100 % |
| Dermal Absorption (%) | 10 % |
| Body weight (kg) | 60 kg |
| Volume of wood dust inhaled ($cm^3$/hr) | 0.015625 $cm^3$/hr |
| Estimated inhalation uptake (mg a.s./day) | 3.28125 |
| RPE APF20 95% efficiency (mg a.s./kg bw/day) | 0.1640625 |
| Systemic dose (inhalation) (mg a.s./ kg bw/ day) | 0.002734375 |
| Area of hands ($cm^2$) | 410 $cm^2$ |
| Hand contamination (%) | 20 % |
| Transfer efficiency (%) | 2 % |
| Estimated dermal uptake (mg a.s./day) | 34.44 |

| Parameter | Creosote Exposure |
|---|---|
| Systemic dose (dermal) (mg a.s./kg bw/day) | 0.574 |
| Total systemic dose (mg/kg bw/day) | 0.576734375 |

Tier 2c – RPE with APF of 20, reduced exposure time 1 hour; Gloves

| Parameter | Creosote Exposure |
|---|---|
| Concentration of a.s in the wood (mg a.s/cm$^3$) | 210 mg/cm$^3$ |
| Inhalation Absorption (%) | 100 % |
| Dermal Absorption (%) | 10 % |
| Body weight (kg) | 60 kg |
| Volume of wood dust inhaled (cm$^3$/hr) | 0.015625 cm$^3$/hr |
| Estimated inhalation uptake (mg a.s./day) | 3.28125 |
| RPE APF20 95% efficiency (mg a.s./kg bw/day) | 0.1640625 |
| Systemic dose (inhalation) (mg a.s./ kg bw/ day) | 0.002734375 |
| Area of hands (cm$^2$) | 410 cm$^2$ |
| Hand contamination (%) | 20 % |
| Transfer efficiency (%) | 2 % |

| Parameter | Creosote Exposure |
|---|---|
| Estimated dermal uptake (mg a.s./day) | 34.44 |
| Gloves (10%) | 3.444 |
| Systemic dose (dermal) (mg a.s./kg bw/day) | 0.0574 |
| Total systemic dose (mg/kg bw/day) | 0.060134375 |

### *Scenario 8*

*Scenario 8. General Public – Primary exposure – Cutting/Sanding wood*

Member of the public is assumed to sand treated wood up to 1 hour/day. Therefore the calculations already carried out for Professional Sanding Scenario 7 Tier 2a can be used.

### *Scenario 9*

*Scenario 9. General Public Adults – Secondary exposure – Cleaning work clothes at home*

For this scenario it has been assumed that laundering coveralls after application of creosote by brush for remedial treatment is considered. The model assumes the coverall is washed after 5 days of wear.

This is considered to be a professional user applying the product containing 100% creosote to wood using a brush. To assess the exposure of professional workers when applying the product with brush, the scenario “Professional brush treatment” (no 23) described in the HEAdhoc Recommendation 6 has been followed. The calculated exposure values are in mg/m$^2$. The average application duration per m$^2$ is 7.6 min/m$^2$. Considering that the application task lasts 240 minutes, the surface of the applied area is 240 min / 7.6 min/m$^2$ = 31.6 m$^2$. The indicative values are normalised to 1% active substance. Due to the normalisation, at a product level the exposure values can be derived and for 100% creosote the indicative value for body 23.82 mg/m$^2$.

Potential body exposure for 5 days would be

Area of wood treated (240) min) x Indicative Exposure Body x 5 days

31.6 m$^2$ x 23.82 mg/m$^2$ x 5 = 3763.56 mg product

The product is 100 % creosote, therefore = 3763.56 mg creosote.

The total surface area of a medium-sized coverall is 22700 cm$^2$ (which in the

calculation gives a greater exposure to the person undertaking the laundering than for a larger sized coverall). Therefore, expressed as mg/cm$^2$, the accumulated residue of in-use product over 5 days would be 0.16580 mg/cm$^2$ creosote.

For an adult, the total area of both hands (palms and backs of hands) is 820 cm$^2$ (HEEG opinion 17) however it can be assumed that only the palms will come into contact with the contaminated coveralls (equating to a surface area of 410 cm²). It is proposed that 30 % of the dried fluid will be transferred from the coveralls to wet hands (TNsG 2002, Part 2, p. 204). Using the dermal absorption value 10 % the systemic dose for a 60 kg adult can be calculated as follows:

Systemic Dose = (AbsD x Transl x EHA x TA) / BW

Where:

AbsD = dermal absorption (%)

Transl = fraction of wood preservative translodegable from the coveralls to the skin (%)

EHA = skin surface area in contact with treated surface (cm$^2$)

TA = creosote residue on coveralls (mg/cm$^2$)

BW = bodyweight (kg)

Therefore for creosote

Systemic Dose = (10 % x 30 % x 410 cm² x 0.16580 mg/cm²) / 60 kg

= 0.03399 mg a.s./kg bw/day

In previous assessments it has been agreed that contaminated clothes should not be reworn, therefore a refinement for clothes contaminated by 1 days work has been considered.

Potential body exposure for 1 day would be

Area of wood treated (240) min) x Indicative Exposure Body x 1 day

31.6 m$^2$ x 23.82 = 752.712 mg product

The product is 100 % creosote, therefore = 752.712 mg creosote.

The total surface area of a medium-sized coverall is 22700 cm$^2$ (which in the calculation gives a greater exposure to the person undertaking the laundering than for a larger sized coverall). Therefore, expressed as mg/cm$^2$, the accumulated residue of in-use product over 1 day would be 0.03316 mg/cm$^2$ creosote.

Systemic Dose = (AbsD x Transl x EHA x TA) / BW

Therefore for Creosote

Systemic Dose = (10 % x 30 % x 410 cm² x 0.03316 mg/cm²) / 60 kg

= 0.0068 mg a.s./kg bw/day

### *Scenario 10*

*Scenario 10. General Public Adults and Infants – Secondary exposure – Contact treated poles or equestrian fences.*

Calculations for systemic exposure for this scenario are based on the following equations.

Adult

Dermal

Systemic exposure via the dermal route = (concentration of a.s. on the wood surface (mg/cm$^2$) x surface area of hand (cm$^2$) x area of hand contaminated (%) x transfer coefficient (%) x dermal absorption (%)) ÷ bodyweight (kg)

Systemic exposure via the dermal route = (23.4 (mg/cm$^2$) x 410 (cm$^2$) x 20 (%) x 2 (%) x 10 (%)) ÷ 60 (kg) = 0.06396 mg/kg bw/day

Toddler

Oral

Systemic exposure via the oral route = concentration of a.s. on the wood surface (mg/cm$^2$) x surface area of hand (cm$^2$) x area of hand contaminated (%) x transfer coefficient (%) x oral absorption (%) ÷ bodyweight (kg)

Systemic exposure via the oral route = (23.4 (mg/cm$^2$) x 115.2 (cm$^2$) x 20 (%) x 2 (%) x 100 (%)) ÷ 10 (kg) = 1.078272 mg/kg bw/day

### *Scenario 11*

*Scenario 11. General Public All Groups – Secondary exposure – Inhalation of volatilised residues indoor*

No calculations have been completed as the product is for outdoor use only and there is no anticipated inhalation exposure – this scenario is not considered in this assessment.

### *Scenario 12*

*Scenario 12. General Public All Groups – Exposure to livestock from agricultural fencing treated with creosote.*

Tier 1

The total potential Estimated Livestock Exposure has been calculated in line with the Guidance on BPR (vol III B+C; Chapter 6) and using the BfR's Livestock Exposure

Calculator. Additional details on equations Details on formulas and default values are found in section 8.7.3. For Tier 1 assessments only the total exposure (sum of all exposure routes, dermal and oral) are presented below.

**BfR output for creosote: Summary of all scenarios assessed. – Retention Rate of 50L/m$^3$**

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Beef cattle | - | 0.5887 |
| Dairy cattle | - | 0.4492 |
| Calf | - | 0.6205 |
| Fattening pig | - | 0.5402 |
| Breeding pig | - | - |
| Breeding pig | individual housing | 0.5956 |
| Breeding pig | group housing | 0.7657 |
| Sheep | - | - |
| Lamb | - | - |
| Slaughter goat | - | - |
| Lactating goat | - | - |
| Broilers | - | - |
| Broilers | free range, litter floor | 0.8416 |

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Broilers | parent broilers, free range (grating floor) | 1.0306 |
| Broilers | parent broilers in rearing, free range (grating floor) | 0.9542 |
| Laying hen | - | - |
| Laying hen | battery | 0.5123 |
| Laying hen | free range (litter floor) | 1.8442 |
| Laying hen | free range (grating floor) | 0.8483 |
| Turkey | - | - |
| Horse | - | - |
| Rabbit | - | 2.8032 |

**BfR output for creosote: Summary of all scenarios assessed. – Retention Rate of 210 kg/m$^3$**

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Beef cattle | - | 2.1168 |
| Dairy cattle | - | 1.6154 |
| Calf | - | 2.2313 |

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Fattening pig | - | 1.9425 |
| Breeding pig | - | - |
| Breeding pig | individual housing | 2.1416 |
| Breeding pig | group housing | 2.7535 |
| Sheep | - | - |
| Lamb | - | - |
| Slaughter goat | - | - |
| Lactating goat | - | - |
| Broilers | - | - |
| Broilers | free range, litter floor | 3.0265 |
| Broilers | parent broilers, free range (grating floor) | 3.7059 |
| Broilers | parent broilers in rearing, free range (grating floor) | 3.4314 |
| Laying hen | - | - |
| Laying hen | battery | 1.8421 |

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Laying hen | free range (litter floor) | 6.6316 |
| Laying hen | free range (grating floor) | 3.0505 |
| Turkey | - | - |
| Horse | - | - |
| Rabbit | - | 10.0800 |

Tier 2 assessment

The trigger value indicated in the BPR Guidance of 0.004 mg/kg bw/day for total exposure is exceeded (the values exceeding the threshold are highlighted in the red in the tables above) for all substances and several species, therefore a refinement (Tier 2 assessment) is needed.

The BfR calculator has been used with the following refinements:

- dislodgeable residues (2%) for oral exposure via licking, (BHHEM (p 171; ECHA 2015), the default value for dislodgeable residues from rough sand wood).
- dermal absorption (10%), (tox assessment), and
- and an additional factor for the barrier provided by fur/feathers (50%) (Fresenius course on Biocidal products and Dietary Risk Assessment (DRA) – 12th October 2023 (online course)

**BfR output for creosote: Summary of all scenarios assessed. – Retention Rate of 50L/m$^3$**

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Beef cattle | - | 0.0084 |

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Dairy cattle | - | 0.0076 |
| Calf | - | 0.0361 |
| Fattening pig | - | 0.0600 |
| Breeding pig | - | 0.0275 |
| Breeding pig | individual housing | 0.0275 |
| Breeding pig | group housing | 0.0275 |
| Sheep | - | 0.0000 |
| Lamb | - | 0.0000 |
| Slaughter goat | - | 0.0338 |
| Lactating goat | - | 0.0188 |
| Broilers | - | 0 |
| Broilers | free range, litter floor | 0 |
| Broilers | parent broilers, free range (grating floor) | 0 |
| Broilers | parent broilers in rearing, free range (grating floor) | 0 |

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Laying hen | - | 0 |
| Laying hen | battery | 0 |
| Laying hen | free range (litter floor) | 0 |
| Laying hen | free range (grating floor) | 0 |
| Turkey | - | 0 |
| Horse | - | 0.0146 |
| Rabbit | - | 0.0731 |

**BfR output for creosote: Exposure by route. – Retention Rate of 50L/m$^3$**

| Animal species | Additional housing information (if available) | Oral – Animals licking surfaces (mg/kg bw/day) | Oral – Chewing on wooden stall edgings (mg/kg bw/day) | Dermal – Rubbing against surfaces (mg/kg bw/day) |
|---|---|---|---|---|
| Beef cattle | - | 0 | 0 | 0.00842 |
| Dairy cattle | - | 0 | 0 | 0.00756 |
| Calf | - | 0.0234 | 0 | 0.01272 |
| Fattening pig | - | 0.0468 | 0 | 0.01316 |

| Animal species | Additional housing information (if available) | Oral – Animals licking surfaces (mg/kg bw/day) | Oral – Chewing on wooden stall edgings (mg/kg bw/day) | Dermal – Rubbing against surfaces (mg/kg bw/day) |
|---|---|---|---|---|
| Breeding pig | - | 0.0180 | 0 | 0.00945 |
| Breeding pig | individual housing | 0.0180 | 0 | 0.00945 |
| Breeding pig | group housing | 0.0180 | 0 | 0.00945 |
| Sheep | - | 0 | 0 | 0 |
| Lamb | - | 0 | 0 | 0 |
| Slaughter goat | - | 0 | 0 | 0.03375 |
| Lactating goat | - | 0 | 0 | 0.01880 |
| Broilers | - | 0 | 0 | 0 |
| Broilers | free range, litter floor | 0 | 0 | 0 |
| Broilers | parent broilers, free range (grating floor) | 0 | 0 | 0 |

| Animal species | Additional housing information (if available) | Oral – Animals licking surfaces (mg/kg bw/day) | Oral – Chewing on wooden stall edgings (mg/kg bw/day) | Dermal – Rubbing against surfaces (mg/kg bw/day) |
|---|---|---|---|---|
| Broilers | parent broilers in rearing, free range (grating floor) | 0 | 0 | 0 |
| Laying hen | - | 0 | 0 | 0 |
| Laying hen | battery | 0 | 0 | 0 |
| Laying hen | free range (litter floor) | 0 | 0 | 0 |
| Laying hen | free range (grating floor) | 0 | 0 | 0 |
| Turkey | - | 0 | 0 | 0 |
| Horse | - | 0 | 2.7159E-03 | 0.01185 |
| Rabbit | - | 0 | 7.3125E-02 | 0 |

**BfR output for creosote: Summary of all scenarios assessed. – Retention Rate of 210 kg/m$^3$**

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Beef cattle | - | 0.0302 |

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Dairy cattle | - | 0.0271 |
| Calf | - | 0.1297 |
| Fattening pig | - | 0.2153 |
| Breeding pig | - | 0.0985 |
| Breeding pig | individual housing | 0.0985 |
| Breeding pig | group housing | 0.0985 |
| Sheep | - | 0.0000 |
| Lamb | - | 0.0000 |
| Slaughter goat | - | 0.1212 |
| Lactating goat | - | 0.0675 |
| Broilers | - | 0 |
| Broilers | free range, litter floor | 0 |
| Broilers | parent broilers, free range (grating floor) | 0 |
| Broilers | parent broilers in rearing, free range (grating floor) | 0 |

| Animal species | Additional housing information (if available) | Sum of all routes of exposure (mg/kg bw/day) |
|---|---|---|
| Laying hen | - | 0 |
| Laying hen | battery | 0 |
| Laying hen | free range (litter floor) | 0 |
| Laying hen | free range (grating floor) | 0 |
| Turkey | - | 0 |
| Horse | - | 0.0523 |
| Rabbit | - | 0.2625 |

**BfR output for creosote: Exposure by route. – Retention Rate of 210 kg/m$^3$**

| Animal species | Additional housing information (if available) | Oral – Animals licking surfaces (mg/kg bw/day) | Oral – Chewing on wooden stall edgings (mg/kg bw/day) | Dermal – Rubbing against surfaces (mg/kg bw/day) |
|---|---|---|---|---|
| Beef cattle | - | 0 | 0 | 0.03024 |
| Dairy cattle | - | 0 | 0 | 0.02714 |
| Calf | - | 0.0840 | 0 | 0.04568 |
| Fattening pig | - | 0.1680 | 0 | 0.04725 |

| Animal species | Additional housing information (if available) | Oral – Animals licking surfaces (mg/kg bw/day) | Oral – Chewing on wooden stall edgings (mg/kg bw/day) | Dermal – Rubbing against surfaces (mg/kg bw/day) |
|---|---|---|---|---|
| Breeding pig | - | 0.0646 | 0 | 0.03392 |
| Breeding pig | individual housing | 0.0646 | 0 | 0.03392 |
| Breeding pig | group housing | 0.0646 | 0 | 0.03392 |
| Sheep | - | 0 | 0 | 0 |
| Lamb | - | 0 | 0 | 0 |
| Slaughter goat | - | 0 | 0 | 0.12115 |
| Lactating goat | - | 0 | 0 | 0.06750 |
| Broilers | - | 0 | 0 | 0 |
| Broilers | free range, litter floor | 0 | 0 | 0 |
| Broilers | parent broilers, free range (grating floor) | 0 | 0 | 0 |

| Animal species | Additional housing information (if available) | Oral – Animals licking surfaces (mg/kg bw/day) | Oral – Chewing on wooden stall edgings (mg/kg bw/day) | Dermal – Rubbing against surfaces (mg/kg bw/day) |
|---|---|---|---|---|
| Broilers | parent broilers in rearing, free range (grating floor) | 0 | 0 | 0 |
| Laying hen | - | 0 | 0 | 0 |
| Laying hen | battery | 0 | 0 | 0 |
| Laying hen | free range (litter floor) | 0 | 0 | 0 |
| Laying hen | free range (grating floor) | 0 | 0 | 0 |
| Turkey | - | 0 | 0 | 0 |
| Horse | - | 0 | 9.7493E-03 | 0.04253 |
| Rabbit | - | 0 | 26250E-01 | 0 |

## Appendix III: Environmental emission (and exposure) calculations

The following risk assessment calculation spreadsheets for Use Classes 3, 4a, 4b and 5 are available on the HSE website as additional information.

- Appendix III – Evaluation - Supplemental modelling for sediment_water partitioning - Creosote - Renewal - PT 8
- Appendix III – Evaluation - Supplemental PT 8 modelling for fruit stake application - Creosote - Renewal - PT 8
- Appendix III - Evaluation - Supplemental STP modelling for noise barrier scenario - Creosote - Renewal - PT 8
- Appendix III - Supplemental PT 8 modelling for general emissions assessment in UC 3 to UC 5

## Appendix IV: List of terms and abbreviations

NESTI - National estimate of short term intake

IESTI - International estimate of short term intake

NEDI - National estimate of dietary intake

IEDI - International estimate of dietary intake

## Appendix V: Overall reference list (including data owner and confidentiality claim)

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| - | DHV | 2013b | Data information: Impregnation process, technical data, application modalities, scenarios / 2013<br><br>[DHV 2013b_VDI_Impreg process_20130227_rev20130920(en_de).pdf]<br><br>Unpublished | No | Yes | Deutscher Holzschutzverband (DHV) [German Wood Protecting Association] |
| - | [redacted] et al. | 2009 | Arbeitsplatzbelastungen bei der Verwendung von bioziden Produkten -<br>Teil 4: Holzschutzmittel (German)<br><br>Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) Dortmund<br><br>Projekt F 1809<br><br>Published | No | No | Public |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| - | [redacted] | 2011 | Biomonitoring bei der Holzimprägnierung mit Steinkohlenteerölen - 1-Hydroxy-pyren im Urin als Marker für die innere Belastung mit polyzyklischen aromatischen Kohlenwasserstoffen<br><br>Zbl. Arbeitsmed., 61, 4 – 11<br><br>Published | No | No | Public |
| - | [redacted] et al. | 2012 | Determination of the dermal exposure to hazardous substances during impregnation with wood preservatives (Engl. translation) (publication)<br><br>Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) Dortmund/Germany<br><br>Projekt F 2053<br><br>Published | No | No | Public |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| - | VDI | 2012 | Anforderungen an Hölzer nach ihrer Behandlung im Heiss-Kalt-Einstelltränkverfahren. (Draft), included in DHV 2013b<br><br>Verein Deutscher Ingenieure (VDI) [via DHV 2013b]<br><br>VDI-Richtlinie 3462<br><br>Published | No | No | (Not yet) public |
| - | WPA | 2013 | Creosote: Brush Application, April 2013 | No | No | The Wood Protection Association/ UK |
| - | [redacted] | 2002 | Evaluation de l'exposition aux hydrocarbures aromatiques polycycliques lors de l'usinage de traverses créosotées / 4ème trimestre 2002.<br><br>SNCF – Informations médicales | No | Yes | Société Nationale des Chemins de Fer français (SNCF) |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | No 208 | | | |
| - | [redacted] | 2014 | Additional Information about Biomonitoring in Workers Processing Creosoted Wood.<br><br>Société Nationale des Chemins de Fer français (SNCF) | No | Yes | Société Nationale des Chemins de Fer français (SNCF) |
| - | [redacted] | 2012 | Status Report on Soil Contamination in the Proximity of Creosote-Treated In-Service Utility Poles in Sweden., AB / 40989<br><br>21 March 2012<br><br>Pöyry Swedpower<br><br>Project No. 3219500 | No | Yes | International Research Group on Wood Preservation (IRG) / - Wood-Preservation Industry of Europe (WEI) (Brussels) / - Creosote Council Europe (CCE) (Brussels) |
| - | CCE | 2013 | Creosote (PT8): Addendum DOCUMENT II B | No | Yes | Creosote Council Europe (CCE) |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | | | | (Brussels) |
| - | DHV | 2013a | Kreosot für die Verwendung im Agrar(Industrie-)bereich – Daten und Informationen / 13. Jan. 2013<br><br>Translation:<br><br>Creosote for agricultural(industrial) applications – data and information / 13. Jan. 2013<br><br>Deutscher Holzschutzverband (DHV), Bingen/ Germany | No | Yes | Deutscher Holzschutzverband (DHV) [German Wood Protecting Association] |
| - | DIN | 1978 | Imprägnierte Holzpfähle (included in DHV 2013a)<br><br>Deutsche Normen<br><br>68 810<br><br>Published | No | No | Public |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| - | [redacted] | 1997 | Losses of CCA Components and Creosote from treated timber to soil /1997<br><br>The International Research Group on Wood Preservation (IRG)<br><br>IRG/WP 97-50098 | No | Yes | International Research Group on Wood Preservation (IRG) / Wood-Preservation Industry of Europe (WEI) (Brussels) / Creosote Council Europe (CCE) (Brussels) |
| - | [redacted] | 1994 | Analysis of creosoted posts after 40 years of exposure / 1994<br><br>The International Research Group on Wood Preservation (IRG)<br><br>IRG/WP 94-50035 | No | Yes | International Research Group on Wood Preservation (IRG) / Wood-Preservation Industry of Europe (WEI) (Brussels) / Creosote Council Europe (CCE) (Brussels) |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| - | [redacted] | 2013 | Impact des traverses créosotées sur les ballasts et les sols au droit des voies ferrées / 28 Feb. 2013<br><br>Deutscher Holzschutzverband (DHV), Bingen/ Germany<br><br>FF0700.22-RN008 | No | Yes | Société Nationale des Chemins de Fer français (SNCF) |
| - | [redacted] | 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,<br>05 May 2008<br><br>Translation:<br><br>Creosoted sleepers and their role in migration of creosote to the ground – Leaching of PAH from the surface of creosoted sleepers. Varia 587, 2008 | No | Yes | Trafikverket, Sweden |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | Statens Geotekniska Institute<br><br>Dnr Banverket S 05-3053/AL50 | | | |
| - | [redacted] | 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<br><br>**Annex:** Methods and Results Tables<br><br>Statens Geotekniska Institute, Varia 588<br><br>Dnr Banverket S 05-3053/AL50 | No | Yes | Trafikverket, Sweden |
| - | [redacted] | 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<br><br>Translation: | No | Yes | Trafikverket, Sweden |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | Creosoted sleepers and their role in migration of creosote to the ground - Sorption and desorption tests of PAH. Varia 588, 2008<br><br>Statens Geotekniska Institute, Varia 588<br><br>Dnr Banverket S 05-3053/AL50 | | | |
| - | [redacted] | 2008b | Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Fastläggnings- och desorptionstest av PAH<br><br>Annex: Methods and Results Tables<br><br>Statens Geotekniska Institute, Varia 588<br><br>Dnr Banverket S 05-3053/AL50 | No | Yes | Trafikverket, Sweden |
| - | [redacted] | 2003 | Biodegradation and general aspects of bioavailability, in: PAHs – An Ecotoxicological Perspective (ed. Douben PET),<br><br>Ecological & Environmental Toxicology Series, pp. 81-96, John Wiley & Sons Ltd., Chichester/ | No | No | Public |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | England | | | |
| - | [redacted] | 2009a | Daphnia sp., Acute Immobilisation Test according to OECD 202 of Wash Oil, 18 March 2009<br><br>Steinbeis-Transferzentrum, Reutlingen/Germany<br><br>STZ 08-07-004<br><br>GLP | No | Yes | CCSG/CCE (Brussels) |
| - | [redacted] | 2009b | Daphnia sp., Acute Immobilisation Test according to OECD 202 of Anthracene Oil (BaP > 50 ppm),<br>25 March 2009<br><br>Steinbeis-Transferzentrum, Reutlingen/Germany<br><br>STZ 09-07-004 | No | Yes | CCSG/CCE (Brussels) |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | GLP | | | |
| - | Eidgenössische 2025 Technische Hochschule Zürich (CH) | 2025 | Environmental risk assessment –<br><br>The route of degradation and identification of several metabolites<br><br>http://eawag-bbd.ethz.ch/<br><br>Published | No | No | Public |
| - | CCE | 2015 | DOC-IIB_Addendum human and environ exposure_rev.2015-05-11 | No | Yes | Creosote Council Europe, Brussels |
| - | CCE | 2013 | DOC-IIC_ Addendum human and environ RA_rev20131016 | No | Yes | Creosote Council Europe, Brussels |
| - | CCE | 2015 | Use of wooden post/stakes in agriculture: vineyards, in: DOC-IIB_Addendum human and environ exposure_rev.2015-05-11 | No | Yes | Creosote Council Europe, Brussels |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | CCE 2013_Field studies_Vineyard model<br><br>DOC-IIB_add_Chapter 8.3.2.2.4-4 / 2013-04-26 | | | |
| - | CCE | 2013 | Environmental exposure data (field, vineyard) [in: DOCIIIA2.10.2-16_DHV_ agriculture_env exp_rev2]<br><br>CCE 2013_Field studies_Vineyard model<br><br>DOC-IIIA2.10.2/16 | No | Yes | Creosote Council Europe, Brussels |
| - | DHV | 2013 | Kreosot für die Verwendung im Agra(Industrie-)bereich – Daten und Informationen;<br><br>Translation:<br><br>Creosote for agricultural(industrial) applications – data and information<br><br>Deutscher Holzschutzverband (DHV), Bingen/ Germany | No | Yes | Deutscher Holzschutzverband (DHV) [German Wood Protecting Association] [http://www.holzschutz.com] |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | 2013-01-20- | | | |
| - | CCE | 2015 | The use of hop poles, UC 4a<br><br>CCE 2015_Field studies_ use of hop poles_model<br><br>42135 | No | Yes | Creosote Council Europe, Brussels |
| - | CCE | 2013 | Environmental exposure data (field, vineyard) [in: DOCIIIA2.10.2-16_DHV_agriculture_env exp_rev2.pdf]<br><br>CCE 2013_Field studies_Vineyard model<br><br>DOC-IIIA2.10.2/16 | No | Yes | Creosote Council Europe, Brussels |
| - | CCE | 2016 | Use Scenario – Timber Foundation Block for Steel-Utility Poles – UC 4a (CCE 2015, modified)<br><br>CCE 2016_Field studies_Timber foundation | No | Yes | Creosote Council Europe, Brussels |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | model(1)_SE<br><br>Revision date:2016-10-22 | | | |
| - | CCE | 2016 | Excerpt from DOC-IIB: (KEMI 2010)<br>PEC – exposure to groundwater from in-service use<br><br>CCE 2016_Field studies_Timber foundation model(1)_SE<br><br>Revision date:2016-10-22 | No | Yes | Creosote Council Europe, Brussels |
| - | CCE | 2016 | Use Scenario – Timber Foundation Block for Wooden-Utility Poles – UC 4a<br><br>CCE 2016_Field studies_Timber foundation model(2)_UK<br><br>6 October 2016 | No | Yes | Creosote Council Europe, Brussels |
| - | [redacted] | 2015 | Technical Report: Wood Pole Foundations (Creosote Registration under Biocidal | No | No | Wood Protection Association (WPA), |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | Products Regulations)<br><br>Wood Protection Association (WPA)<br><br>13 July 2015 | | | UK |
| - | CCE | 2016 | Excerpt from DOC-IIB: (KEMI 2010)<br>PEC – exposure to groundwater from in-service use<br><br>CCE 2016_Field studies_Timber foundation model(2)_UK<br><br>Revision date:2016-10-22 | No | Yes | Creosote Council Europe, Brussels |
| - | CCE | 2016 | Use Scenario – Noise Barrier – UC 3<br><br>CCE 2016_Field studies_noise barrier_model | No | Yes | Creosote Council Europe, Brussels |
| - | CCE | 2016 | Excerpt from DOC-IIB: (KEMI 2010)<br>PEC – exposure to groundwater from in-service use | No | Yes | Creosote Council Europe, Brussels |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | CCE 2016_Field studies_Timber foundation model(1)_SE<br><br>Revision date:2016-10-22 | | | |
| - | CCE | 2016 | USE scenario - Landscape retaining wall from timber – UC 4a<br><br>CCE 2016_Field studies_landscape wall_model | No | Yes | Creosote Council Europe, Brussels |
| - | CCE | 2016 | Excerpt from DOC-IIB: (KEMI 2010) PEC – exposure to groundwater from in-service use<br><br>CCE 2016_Field studies_landscape wall_model<br><br>Revision date:2016-10-22 | No | Yes | Creosote Council Europe, Brussels |
| - | [redacted] | 2009 | Fish, acute toxicity test according to OECD 203 of Wash Oil. | Yes | Yes | Coal Chemicals Sector Group |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | [redacted]<br>Report No. [redacted], 17 March 2009 | | | CEFIC (CCSG), Brussels, Belgium |
| - | [redacted] | 2015 | Creosote - Efficacy and intended retentions, Rev. 3<br>Wood Protection Association (WPA), UK<br>42073 | No | Yes | Wood Protection Association (WPA), UK |
| - | [redacted] | 2000 | Marine performance of preservative treated southern pine panels, Part 1: Exposure in Newport, Oregon<br>International Research Group on Wood Preservation (IRG), Sweden<br>IRG/WP 00-10368;36660 | No | No | International Research Group on Wood Preservation (IRG), Sweden |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| - | [redacted] | 2000 | Marine performance of preservative treated southern pine panels, Part 2: Exposure at Mourilyan Harbour, Queensland, Australia<br><br>International Research Group on Wood Preservation (IRG), Sweden<br><br>IRG/WP 00-10368;36660 | No | No | International Research Group on Wood Preservation (IRG), Sweden |
| - | [redacted] | 1975 | Results of stake tests on wood preservatives (Progress report to 1974)<br><br>British Research Establishment (BRE), archived under IRG/WP 361<br><br>BRE CP 86/75; 27668 | No | No | International Research Group on Wood Preservation (IRG), Sweden |
| - | Anonymous | 1997 | Sosnowe, dębowe i bukowe materiały drzewne nawierzchni kolejowej nasycane olejem impregnacyjnym /<br>Title (Engl.): *Oil Impregnated Pine-wood, Oak-wood And Beech-wood Sleepers, Switch And* | No | No | Polish Committee for Standardization, Poland |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | *Bridge Sleepers For Railways.*<br><br>PKN Polski Komitet Normalizacyjny / Poland<br><br>PN-D-95014<br><br>Published | | | |
| - | Anonymous | 1974 | Materiały z okrągłego drewna sosnowego nasycone olejem impregnacyjnym metodą oszczędnościową /<br>Title (Engl.): *Materials made of round pine wood treated with impregnating oil by applying the empty –cell Rueping method*<br><br>Norma branżowa / Industry Standard Poland 1974<br><br>BN-74/9221-07<br><br>Published | No | No | Polish Committee for Standardization, Poland |
| - | Anonymous | 2011 / | Preservation of wood – Code of practice 2011 | No | No | BSI, Great Britain |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | 2014 | and A1.2014<br><br>The British Standards Institution<br><br>BS 8417, 2011<br><br>Published | | | |
| - | Anonymous | 2007 | Imprägnierung von Eisenbahnschwellen aus Holz mit Kreosot (Steinkohlenteeröl) / Title (Engl.): *Impregnation of wood railway sleepers with creosotes (coal tar based oil)*<br><br>DIN Deutsches Institut für Normung e.V., Berlin<br><br>DIN 68811: 2007-01<br><br>Published | No | No | DIN, Germany |
| - | Anonymous | 2011 | Nordic wood preservation classes and product requirements for preservative-treated wood, Part 1: Pine and other permeable softwoods, | No | No | NPWC |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | NWPC Document No. 1<br><br>Nordic Wood Preservation Council (NPWC)<br><br>40544<br><br>Published | | | |
| - | Anonymous | 2015 | Förteckning över godkända träskyddsmedel (Inventory of approved wood preservatives)<br><br>Nordic Wood Preservation Council (NPWC)<br><br>42023<br><br>Published | No | No | NPWC |
| - | CCE | 2016 | Screening of PAH residues on fruit grown in orchards constructed with creosote- treated stakes<br><br>Creosote Council Europe | No | No | Creosote Council Europe (CCE) |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | 20160602 | | | |
| - | CEHTRA | 2018 | Endocrine Disruption Assessment of Creosote under Biocides Product Regulation (EU)<br><br>CEHTRA SAS (Consultancy for Environmental & Human Toxicology & Risk Assessment), France<br><br>No 528/2012, study no. CFR/CCE/BPR/1801, report no. CFR-18.066 | No | Yes | Creosote Council Europe |
| - | CCE | 2018 | Risk assessment on fruit grown in orchards constructed with creosote-treated stakes, version 8<br><br>20181120 2018 study report fruit stake study v8c<br><br>Unpublished | No | Yes | Creosote Council Europe (CCE) |
| - | CCE | 2020 | Dermal contact of general public to agricultural | No | No | Creosote Council |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | and equestrian fencing (including climbing children with parameters according to HEAdhoc recommendation No. 5, 2015) | | | Europe (CCE) |
| - | [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<br><br>Arcadis (UK) Ltd., Cambridge, United Kingdom<br><br>AUK-087-FINAL<br><br>GLP, Unpublished | No | Yes | Creosote Council Europe, Brussels |
| - | [redacted] | 2019a | Bestimmung der Giftwerte gegenüber Eilarven von Hylotropes bajulus (L.) gemäß EN 47 (2016) in Kombination mit einer Auswaschbeanspruchung gemäß EN 84 (1997)<br><br>32/18/10197/01 | No | Yes | Creosote Council Europe, Brussels |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | GLP, Unpublished | | | |
| - | [redacted] | 2019b | Bestimmung der Giftwerte gegenüber Eilarven von Hylotropes bajulus (L.) gemäß EN 47 (2016) in Kombination mit einer Verdunstungsbeanspruchung gemäß EN 73 (2014)<br><br>32/18/10197/02<br><br>GLP, Unpublished | No | Yes | Creosote Council Europe, Brussels |
| - | [redacted] | 2019c | Bestimmung der vorbeugenden Wirkung gegenüber Anobium punctatum<br><br>32/18/10197/04<br><br>GLP, Unpublished | No | Yes | Creosote Council Europe, Brussels |
| - | [redacted] | 2019d | Bestimmung der vorbeugenden Wirkung gegenüber Lytcus brunneus gemäß EN 20/2 (1993) in Kombination mit einer Verdunstungs- | No | Yes | Creosote Council Europe, Brussels |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | beanspruchung gemäß EN 73 (2014); Teil 2: Anwendung durch Vollträнkung<br><br>32/18/10197/05<br><br>GLP, Unpublished | | | |
| - | [redacted] | 2020a | Bestimmung der vorbeugenden Wirkung gegenüber Anobium punctatum (de Geer) durch Beobachtung der Eiablage und des Überlebens von Larven gemäß EN 49 Teil 2 (2015) in Kombination mit einer Auswasch-beanspruchung gemäß EN 84 (1997)<br><br>32/18/10197/03<br><br>GLP, Unpublished | No | Yes | Creosote Council Europe, Brussels |
| - | [redacted] | 2020b | Bestimmung der Grenze der Wirksamkeit gegen holzzerstörende Basidiomyceten gemäß EN 113 (1996) in Kombination mit einer Auswaschbeanspruchung gemäß EN 84 (1997) | No | Yes | Creosote Council Europe, Brussels |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | 32/18/10197/06A<br><br>GLP, Unpublished | | | |
| - | [redacted] | 2020c | Bestimmung der Grenze der Wirksamkeit gegen holzzerstörende Basidiomyceten gemäß EN 113 (1996) in Kombination mit einer Verdunstungsbeanspruchung gemäß EN 73 (2014)<br><br>32/18/10197/07A<br><br>GLP, Unpublished | No | Yes | Creosote Council Europe, Brussels |
| - | [redacted] | 2019 | Livestock Exposure Assessment for Creosote, Covance Project Number RG61YB, 17 September 2020 (6 pages)<br><br>Performed by COVANCE CRS (Switzerland) Ltd., Rheinstrasse 74,4414 Füllinsdorf, Switzerland Sponsor: CCE<br><br>RG61YB 2019-09-17 | No | Yes | Creosote Council Europe, Brussels |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | Unpublished | | | |
| - | Anonymous | 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<br><br>Creosote Council Europe, Brussels<br><br>Unpublished | No | Yes | Creosote Council Europe, Brussels |
| - | Anonymous | 2020 | Consumer risk assessment for the Report, not dated<br><br>Creosote Council Europe, Brussels<br><br>Unpublished | No | Yes | Creosote Council Europe, Brussels |
| - | Anonymous | 2020 | Livestock: Residues in cattle (as model) after grass ingestion in the vicinity of creosote-treated fences, not dated | No | Yes | Creosote Council Europe, Brussels |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | Creosote Council Europe, Brussels<br><br>Unpublished | | | |
| - | CCE | 2020 | Risk assessment on fruit grown in orchards constructed with creosote-treated stakes (CCE)<br><br>Creosote Council Europe, Brussels<br><br>Version 8, 20/11/2018 (40 pages)<br><br>Unpublished | No | Yes | Creosote Council Europe, Brussels |
| - | [redacted] | 2022 | Magnitude of the Residue Determination of Polycyclic Aromatic Hydrocarbons (PAH) following the use of creosote treated wooden stakes on stone fruit in the United Kingdom<br><br>AUK-090-FINAL Study<br><br>Arcadis (UK) Ltd., Cambridge, United Kingdom | No | Yes | Creosote Council Europe, Brussels |

| Section No. / Reference No. | Author(s) | Year | Title, Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published | Vertebrate study (Yes / No) | Data protection claimed (Yes / No) | Owner |
|---|---|---|---|---|---|---|
| | | | April 2022<br><br>GLP, Unpublished | | | |

## Appendix VI: Socioeconomic assessment

The socioeconomic assessment performed as part of the assessment of creosote is split into two parts, Part I: Availability of Suitable Alternatives: Technical and Economic Feasibility of Substitution Assessment Report, and Part II: Consideration of Disproportionate Impacts (GB BPR Art 5(2)(c)) and Availability of Suitable Alternatives, July 2025 (Update of 2018 and 2016 Assessment Report).

Creosote has a mandatory classification in accordance with assimilated Regulation (EC) No 1272/2008 (GB CLP) 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 assimilated Regulation (EC) No 2006/1907 (UK REACH). As such, creosote meets the criterion for exclusion under Article 5(1)(a) (c) and (e) of assimilated Regulation (EU) 528/2012 (GB BPR).

An active substance meeting the exclusion criteria can still be approved as an active substance if it meets the requirements of Article 5(2). The analysis in this report seeks to confirm specifically whether the condition under Article 5(2)(c) is met, which states that approval can be given if “not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance”.

It should also be noted that creosote also meets the criteria for nomination as a candidate for substitution under Article 10(1)(a) (d) and (e).

Within Article 23, a biocidal product containing an active substance that is a candidate for substitution can be placed on the market or used so long as there is, for the uses of the product specified in the authorisation application, no other authorised biocidal product or non-chemical control or prevention method that already exists and which presents a significantly lower risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages. In this respect, components of the work carried out for this report thus also serve for the assessment of whether there are significant economic or practical disadvantages associated with alternatives.

### Part I: Availability of Suitable Alternatives: Technical and Economic Feasibility of Substitution Assessment Report, July 2025 (Update of 2018 and 2016 Assessment Report)

#### *1. Background*

In the absence of GB BPR guidance, it is not clear whether the burden of proof required to justify that there are no appropriate alternatives should rely on information demonstrating that possible alternatives are not technically or economically feasible, or on the lack of information demonstrating that there are alternatives that are technically and economically feasible. For the purpose of this report, whilst the assessment is primarily based on consideration of the former (strong) approach, the conclusions are ultimately determined on the basis of the latter (weak) approach. It is also not clear how to interpret the term ‘economic feasibility’ in the context of an applicant’s application for approval or renewal of an active substance. It should be noted that the ‘term ‘economic

feasibility' has no technical (from the perspective of economic science) or legal definition, thus rendering it open to multiple interpretations. HSE has therefore followed the approach taken under UK REACH. Specifically, the suitability of alternatives (in terms of technical and economic feasibility and availability) is considered under the Authorisation provisions of Title VII. In line with these provisions, there is a requirement to show that there are no suitable alternatives when granting an authorisation to use a substance included in Annex XIV. An assessment of the fulfilment of this requirement is carried out in accordance with the approach under UK REACH (EUR 2006/1907) relating to the analysis of technical and economic feasibility. This seeks to evaluate whether a suitable alternative substance or technology can be used instead of a substance of concern, and is used where companies must demonstrate that there are no suitable alternatives before being granted permission to use a substance of concern under REACH. As such, this is relevant and appropriate to the consideration of substances of concern under GB BPR.

The following sections provide the justification of HSE's conclusions regarding the technical and economic feasibility of substitution. The evaluation and conclusions reached are based on the information available to HSE at the time of writing in July 2025. The evaluation is an update of the Technical and Economic Feasibility Assessment Report of February 2018, which was itself an updated version of the August 2016 Report.

## *2. Justification of the suitability of alternatives to creosote*

### *2.1. To what extent is the technical and economic feasibility of alternatives to creosote described and compared in those uses seeking renewal.*

The applicant has submitted a package of documents that constitute an analysis of technical and economic feasibility of alternatives. Alongside the applicant's package of documents is additional information on candidates for substitution submitted as part of various consultations by the EU and the HSE consultation undertaken in 2024 specifically in consideration of this application for approval of creosote

The various documents and submissions relate to the main function of creosote as a biocide in the context of the general uses being considered for renewal. This is as a preservative treatment to protect wood in situations where it can become and remain wet or where wood destroying fungi and insects are present. Wood treated with creosote is frequently used in safety-critical and economically important situations where confidence in performance and long-service life are key functional requirements. Indeed, the service life expectation for wood treated with creosote is the fundamental characteristic associated with its continued demand as a biocide for most of the use classes concerned.

The overall package of documents submitted by the applicant describe to varying degrees across the different use classes concerned, the technical and/or economic feasibility of a number of alternatives to creosote. The alternatives considered are thought to represent the main alternatives which have been identified, through desk-based literature review, stakeholder questionnaires (e.g. on user experiences) and through consultation, as potential alternatives for the uses concerned. The alternatives also reflect the ongoing search for alternatives as a result of existing public and

legislative pressures to substitute creosote. As such they can be considered to encompass a wide range and breadth of known substitution possibilities, including options that were available in the past. However, a significant deficiency in the documents submitted by the applicant is that the list of alternatives considered do not fully encompass the latest information on alternatives. In particular the formal socioeconomic studies containing analyses of alternatives are from 2016 and hence do not include consideration of alternatives that have recently been developed, authorised and which are available on the UK and EU market. Nevertheless, information on these alternatives has been incorporated into HSE's consideration

Although a large number of documents across all uses have been submitted by the applicant, the studies submitted by the applicant which contain formal socioeconomic analyses of alternatives focus on substitution options for fencing, tree stakes and wood poles. The options considered are based on either making the function performed by wood impregnated with creosote redundant (i.e., by eliminating the need for wood impregnated with creosote, e.g., by using an alternative material), or finding an alternative substance/biocide that can perform the same function (i.e., preservation of wood) as creosote. The studies undertake a comparison in which the selection of alternatives has to some extent been based on formal screening criteria identified for some of the different use classes. In the case of other use classes, the submissions comparing alternatives have based the selection of alternatives on substitution possibilities previously identified in the literature and knowledge base, and which have proven some degree of feasibility as possible substitutes and/or have already been the subject of previous research and development work on substitution in the use areas concerned.

In the socioeconomic studies submitted by the applicant which formally compare creosote and the alternatives, the selected alternatives were taken forward for more detailed evaluation across the different use classes. The descriptions and analyses related to technical feasibility were concerned with the ability of the alternatives to meet certain technical properties and requirements. These properties are essentially aspects of the performance and length of service life requirements in the use classes considered by the studies. The descriptions and analysis related to economic feasibility concern the costs of switching to the alternatives, including as relevant to each use class, indications of the raw material substitution costs, process, transportation and installation costs, as well as lifetime investment costs (i.e. related to length of service life of the alternative). In addition, the applicant has included a number of life-cycle analyses related to some of the use classes, which compare the alternatives across a number of additional criteria (environmental and other technical). As already noted however, the analysis in these documents does not include consideration of the latest developments regarding alternatives that are now available on the market.

The descriptions, assessment and discussion of technical and economic feasibility across the rest of the submissions vary greatly in their comprehensiveness and depth. At times it is difficult to discern between information based on assertion and that based on a sound evidential footing. This has made the evaluation of the evidence more difficult, leading to some uncertainty regarding the conclusions about the suitability of the alternatives in some cases.

It should also be noted that the technical feasibility considerations often relate to standards and guidelines governing material specifications, and for which it is not entirely clear whether these standards are essentially a form of type approval/certification (and hence possibly a customer requirement rather than a pure technical constraint). Irrespective, the arguments related to technical feasibility can often be classed as economic feasibility considerations, since they ultimately concern the cost implications of switching to alternatives. In this respect, the analysis is for some of the use classes relatively more quantitative (for example, including specific estimates of the additional costs of the alternatives), whilst in other cases it is based on more qualitative argumentation. These provide an indication of the likely direction of the economic impacts of substitution, though the description and/or derivation of its magnitude are often lacking and too brief for detailed scrutiny.

Evidence from the various consultation exercises has also been included and whilst much of this consists of largely supportive position statements, some of it contains more substantive technical evidence either in support of or disputing the technical and economic feasibility of alternatives. A number of these submissions also contain the latest evidence on alternatives and thus can be used to complement the more dated information on alternatives.

**In summary, HSE finds the descriptions and comparison of alternatives submitted by the applicant to be generally acceptable, though there are deficiencies in terms of it being up to date. However, further information in this respect has been submitted in the HSE 2024 consultation. Across the various submissions from the applicant and stakeholders, there are competing claims primarily about the technical substitution constraints for some of the use classes. Moreover, the claims in the various submissions regarding economic feasibility of alternatives are difficult to fully scrutinise and confirm given the lack of transparency in how costings were undertaken and compared on a like for like basis. Nevertheless, it is possible to draw conclusions on the basis of the weight of evidence across the various submissions.**

### *2.2. Are the alternatives technically and economically feasible?*

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 UK REACH Annex XVII (31). 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.

Within the package of documents submitted for analysis by the applicant, possible alternatives that can be considered as substitutes for creosote in the uses seeking approval are described and discussed. Alternatives to creosote-treated wood vary by

use. Alternative materials and products involve trade-offs in structural qualities/technical characteristics, cost, and effectiveness. The information provided sets out evidence that supports the applicant's position that although in principle there are alternatives available to replace the use of creosote, these are not suitable in terms of their technical and economic feasible at the time of writing.

HSE largely concurs with this position for the use classes indicated based on its assessment of the information provided by the applicant as well as through various consultations, including one undertaken by HSE in 2024. The evidence supporting this conclusion is at times equivocal and relies heavily on actual user experience. There is nevertheless a shortage of evidence demonstrating that other alternatives are indeed either completely suitable and or available in sufficient quantities in practice under all circumstances and for all uses seeking renewal. The assessment below considers the evidence submitted by the applicant and the various consultation on the technical and economic feasibility of alternatives in each of the main use class areas, following which the overall conclusions of the assessment are presented.

### 2.2.1. Railway sleepers

The main reason for the use of wooden railway sleepers is their light weight and corresponding ease of maintenance. Another benefit is the dynamic interaction between the rolling stock and a track with wooden sleepers. Wood sleepers have traditionally been used because they have a lower mass and greater resiliency, which results in a more resilient track with improved impact loading, and reduced amplification of these impacts. This improves track component life and improves ride quality. Wood sleepers also reduce noise and vibration, as well as having electrical isolation properties, which minimizes electrical leakage into sleepers that can disrupt signal systems.

With respect to sleepers, decay fungi are usually the organisms of concern. When properly treated with a preservative such as creosote, deterioration due to these organisms is essentially eliminated. There are also physical agents, such as ultraviolet light, heat abrasion, and exposure to alternating climatic conditions that affect the wood structure. These effects can be minimized by the use of preservatives such as creosote.

Various submissions by the applicant and stakeholders consider both the use of alternative materials (concrete, plastic, etc) as well as alternative wood preservatives as potential substitutes for the use of railway sleepers treated with biocidal products containing creosote. The life of a treated sleeper depends on the weight, speed of traffic, axle loads, track condition, climate factors, and its quality, treatment, and track maintenance. The average service life of untreated sleepers is stated to be approximately five and a half years. Treatment with creosote extends service life to an estimated average life of over thirty years.

The railway sleeper use class is a safety critical application, with exacting performance specifications related to the scope of usage across rail network applications and service life requirements. As such, there may be rail infrastructure type approval/certification requirements related to the use class, within which technical feasibility must be

considered.

According to the applicant and some railway industry stakeholders responding to the consultation, other wood preservatives are not as effective at treating wood used for sleepers, such that alternatives to treated wood appear to be the most technically feasible alternatives. In principle, concrete sleepers can be considered to be the most technically feasible given their extensive use across the UK rail network. However, wooden sleepers are still necessary for a variety of technical reasons in specialist applications. Wooden sleepers are said to have, for example, greater flexibility in terms of where they can be used (e.g. inaccessible areas, switching points, tunnels, bridges, small radius curves, etc) since they can be custom cut to individual circumstances and do not require heavy/mechanised equipment (concrete can be 3 times as heavy as wood).

According to the applicant's submission it is also not possible to mix concrete and wooden sleepers in track maintenance uses due to the different ballast requirements to ensure equal profile tracks – whilst it would be possible to replace all wooden sleepers to avoid such mixing, this would be economically infeasible (see below) since it would, according to one industry estimate, require a 3 fold increase in the number of sleepers requiring replacement per year.

In terms of their economic feasibility, although the price of concrete and wooden individual sleeper units are comparable, it is claimed that there are significant extra costs to using concrete sleepers associated with the need for extra ballast and bedding, as well as the need for specialist equipment due to their heavier weight. At the same time, the service life of concrete sleepers is apparently longer and hence there may be some circumstances in which they are economically feasible. Though, according to the applicant, it is not clear to what extent this is always the case since Network Rail, which owns and operates the UK rail infrastructure, has specifications (L2/TRK/4001/B03) that call up treatment with creosote for a 60-year service life. Moreover, there is apparently evidence that concrete sleepers chip, crack and crumble prematurely, thus lasting less than the 50-60 years that manufacturers claim. However, the evidence submitted by the applicant is insufficient to allow a detailed assessment in this respect, and in any case the technical feasibility constraints noted above are not overcome. Tuned Concrete Sleepers (TCS) are a variant with wood characteristics, which have been developed in order to serve as replacements for wooden sleepers. These appear to be a promising alternative, though the costs are apparently very high and it is not clear to what extent the various technical feasibility constraints are overcome. In this respect, testing and evaluation is ongoing (e.g. by some transport administrations in EU members states, though it is not known if such testing is being undertaken in GB).

There are also a number of other non-wood material-based alternatives to wooden sleepers (e.g. steel, aluminium, plastic, other composites) that have been considered by the applicant and other stakeholders. However, uncertainties exist as to their technical and economic feasibility at the present time. Even though some of these alternatives appear to be usable across the variety of rail track applications, it is unclear if man-made materials, such as plastic and composites, have the same combination of desirable technical factors (damping, strength, etc) and how the alternatives differ in both material cost and installation cost. Nevertheless, testing and performance

evaluation of some of these alternatives is underway or will be carried out in the future, though for the time being their approval by UK rail infrastructure bodies across all the various rail track applications is not confirmed.

A final category of alternatives concerns other chemical wood preservatives, non-treated wood and wood modification. According to users, traditional alternative wood preservatives have been largely problematic in terms of the associated service life of the sleepers and hence on their economic feasibility.

However, more recent evidence from the HSE 2024 consultation has indicated that the use of recently authorised wood treatments such as copper oil preservatives are a promising alternative to creosote. In this respect these chemical alternatives (such as Tanasote® S40) are stated by some stakeholders to have a better profile in terms of human health and the environment, as well as an overall cost advantage over creosote when taking all direct and indirect costs of transitioning - including treatment costs (taking into account application rates), transport costs, transition costs, total installation costs and disposal cost. Nonetheless, there is no evidence that these have been authorised for use by rail infrastructure bodies in this particular use class in the UK, though of course this may be due to concerns about its as yet unproven service life. It is understood that testing is being carried out on some uses, but that this is currently insufficient to conclude on its longevity, though initial results are promising, and further testing is being carried out. Furthermore, submissions to the HSE 2024 consultation have highlighted the current lack of supply capacity of such preservatives given that there are very few products which have been authorised for use, leading to concerns also about market competition. Finally, it is claimed that such oil-based preservatives present significant challenges in meeting the minimum retention rates required for sufficient efficacy, leading to potential regulatory violations. HSE has been unable to confirm the significance of these challenges and concerns.

In summary, according to the information submitted by railway industry users and assessed herein, it is accepted by HSE that there currently appear to be technical and economic feasibility constraints, particularly within the context of the safety critical rail infrastructure approval system in the UK, which justifies the conclusion that at the present time there are no established alternatives to replace creosote-treated wooden sleepers at least in the short term. However, there are promising signs that viable alternatives are being developed and indeed are already on the market, albeit at limited volumes, such that the situation with respect to their availability and suitability is expected to change within the next few years. In the context of railway sleepers as a safety critical use it has to be accepted that good evidence of availability and service life performance of the newer copper oil wood preservatives is critical. Currently, such evidence is inconclusive. Furthermore, other non-wood materials appear to have significant disadvantages in terms of technical and economic feasibility across a number of applications within the railway sleeper use class. Consequently, HSE concludes that for railway sleepers, there are currently no suitable alternatives to creosote generally available for all applications.

### 2.2.2 Transmission poles (electric power transmission and telecommunications)

Wood poles have been the traditional material for telecommunications and electrical

transmission distribution structures for many years, having a number of advantages and disadvantages with respect to other materials. Their properties are familiar to transmission and maintenance engineers, whilst their supply is good and prices generally low and relatively stable compared to other materials. The manufacturing processes of alternate materials tend to be much slower. Wood poles have solid cross-sections unlike typically, concrete, steel, and composite materials, which eliminates the possibility of buckling and provides very good compressive strength. Wood also has an inherent flexibility that allows it to deflect and absorb dynamic loads, as well as transfer loads to other poles in the line. Alternative pole materials when stressed to the bending point end up requiring replacement. Wood poles are generally climbable with climbing spurs, compared to alternative materials that may or may not have steps built into them. However, as is the case with all transmission assets, these structures require ongoing maintenance and refurbishment/replacement, the latter being driven principally by the lifespan of the asset. In this respect, the main disadvantage of wood poles is that they require preservative treatment if their service lives are to be extended. As such the substitution of creosote requires consideration of possible effects on lifespan/service life, and hence the consequential effect on the refurbishment periods associated with such transmission networks. Confidence in the performance of transmission poles is crucial given also the safety critical nature of maintenance of the transmission lines (e.g. due to the need for engineers to access the assets for maintenance, etc, and whose safety depends on the structural integrity of the poles).

The applicant’s submission has considered three principal options for the substitution of the use of creosote to treat wood transmission poles. These include the substitution of creosote with an alternative biocidal product, such as copper based actives. Alternatively, creosote treated poles may be replaced by poles manufactured from other materials, such as concrete, steel, composites etc. Finally, it is possible to move away from overhead transmission lines completely and instead adopt underground cable-based solutions.

Regarding the use of alternative biocidal preservatives, the applicant in their submission has noted that there is experience with water-based copper organic type preservatives already within the UK, where such treatment has been used for a limited number of poles, for example at playgrounds (in order to avoid contact with creosote). These alternatives can thus, in principle, be considered as technically feasible. Although these preservatives have been extensively tested in the lab and field trials, the evidence from their use suggests their performance is rather limited. It should also be noted that UK utility companies require service lives in excess of 30 years for poles, though the case of economic feasibility seems to rest on arguments for longer service lives. Traditional standards make reference to 40 years desired service lives, with some specifications referring to 60-year service lives. Certainly, as far as alternative preservatives are concerned, there is only limited evidence of performance in excess of 20 years, though further testing is currently ongoing. According to industry bodies this evidence suggests that the service life of poles treated with most water-based copper organic preservative is around half of those treated with creosote. Moreover, it is reported that a significant proportion of copper treated poles (>5%) have shown evidence of advanced decay in as little as 7 years of service. Consequently, confidence in this alternative as a more widespread alternative is affected, according to the applicant. The effect of the reduced lifespan is to increase the number of poles required

annually, with an associated increase in annual refurbishment costs (see later for quantitative estimates), leading to the conclusion that, except for some minor use circumstances, this alternative is economically infeasible.

The second substitution option proposed by the applicant concerning the replacement of creosote treated wooden poles by steel, concrete or other composite material poles is considered to be technically feasible. Certainly, in terms of steel and concrete the technology has been in use for many years and is widespread in the sector. Indeed, such poles offer certain advantages over wood poles (e.g. rigidity, invariant physical characteristics, fire retardancy). Other materials, such as fibreglass and composite are according to the applicant largely insufficiently tested, may have service life or other technical concerns, or are more expensive when compared to wood poles.

With respect to steel and concrete poles, the key problem (amongst others) with their use as an alternative appears to relate to the increased costs associated with their installation, maintenance and replacement as a result of their higher physical weight compared to wooden poles. The additional weight necessitates the use of specialised lifting and installation equipment, for which additional capital expenditure would have to be made by the sector, depending on the existing levels of mechanisation. The applicant's submission describes the various installation and operational practices associated with transmission poles and outlines the necessary changes and impacts associated with the use of concrete and steel poles. The increased cost (some estimates suggest over 200% more expensive) associated with both the purchase, installation and maintenance of such poles is again considered to be economically infeasible compared to wooden poles. However, this does not take into account the fact that concrete is said to have a longer life expectancy, though the evidence related to transmission poles made of concrete and other materials is less well documented than for creosoted wood which has a proven service life record in this respect. Irrespective, the evidence whilst somewhat uncertain, suggests such poles are largely economically infeasible.

Fibreglass and other composite material poles are increasingly being developed and proposed for use in this sector. Initial technical findings suggest that there are issues with strength properties or with inferior service life in some cases. Information on the economic feasibility of these alternative is somewhat mixed (with reports that these are 3-5 times more expensive than corresponding wooden poles), with some individual composite materials performing better than others. However, evidence of the general suitability and availability of these alternatives as a currently viable substitute across the board in this sector is lacking. Furthermore, the use of such materials would potentially require the re-specification and/or redesign of ancillary equipment and fittings in order to be compatible with the material, thereby necessitating further transitional investment costs.

The final category of alternative is the adoption of an underground network of transmission cables. Given the common presence of such cables in urban and city environments, this is clearly technically feasible at a general level, though this option becomes more technically challenging according to the natural terrain across which the network must traverse. The costs of installation have been found in the literature to be up to 15 times higher than equivalent overhead lines, though the gap has narrowed

more recently such that for level and stable ground conditions, costs are thought to be in the region of 2 to 3 times greater. Where terrain is inaccessible or otherwise environmentally challenging, costs will increase, for example as a result of lines having to be diverted, etc. Moreover, cable fault rectification may be more difficult and costly. In sum, given that the installation costs are considered to be prohibitive, whilst the management of such cable networks is more technically challenging, this option is unlikely to be suitable beyond some specific and narrow circumstances.

Some specific quantitative economic feasibility information is available for the UK from the information submitted by the applicant and stakeholders in response to the consultation. This suggests that based on wooden poles forming the main construction material of the overhead power line transmission network (~260,000 km) there are approximately 4.1 million poles, with an associated annual refurbishment cost of £115m (based on 60-year lifespan). An alternative estimate from the applicant suggests annual network costs of £252m. If instead alternative preservatives (with a typically shorter lifespan are used, this would lead to an annual increase in expenditure of around £233m according to one estimate. Again, an alternative estimate according to the applicant is that annual network costs would increase to £755m. Moreover, copper-based preservatives can according to user experience lead to accelerated corrosion of metal fittings leading to premature failure and power outages. The use of poles made from alternative materials such as concrete which are heavier, would require the replacement of installation equipment and machinery at an estimated cost of over £100m. Such poles are said to be 2 – 4 times more expensive to purchase and are also 25% more expensive to install. It is thus estimated that refurbishment cost would double to £230m annually. Moreover, re-routing of isolated lines which could not be reached by heavier installation machinery would cost £20m per annum. It is difficult to ascertain how the different cost estimates on cost relate or differ to one another, since the various estimates are not broken down in terms of their various cost components. Nevertheless, information submitted in the consultation from power distribution stakeholders supports the order of magnitude of costs associated with any move to alternatives.

In the telecommunications sector, the overhead line distribution network consists of around 7 million poles. Openreach alone have around 4.2 million poles (96% wood treated with creosote) and require around 90,000 poles per year for building and maintaining their network. It is estimated that annual refurbishment costs would increase by at least £64m and possibly more. An additional £5m per annum would be required to monitor poles treated with alternative preservatives. Another estimate of costs suggests a figure of around £20 million + additional capital costs, whilst a third estimate from WEI-IEO (2016) suggests that the annual costs of replacing wooden poles would double from £25m to £50m. Unfortunately, it has not been possible to fully scrutinise and verify the calculation of these estimates. Moreover, it is unclear whether those estimates related to capital investments are in present value terms, or whether appropriate discounting and annualisation procedures have been used.

Whilst much of the evidence on chemical wood preservative alternatives submitted by the applicant and stakeholders is not reflective of the latest developments in this domain, a number of users and other stakeholders have identified recently authorised copper oil type preservatives (such as Kopper PP, Tanasote® S40, RVP Repellent and

ScanPole – Pole+) and other protective materials (such as protective sheaths/barrier sleeves) as possible alternatives. Indeed, some users have instigated a programme of testing such wood treatment alternatives, but as reported in the case of railway sleepers, such testing is still ongoing and whilst results are promising, more time is needed to fully conclude on service life capability that would meet the requirements and expectations of the transmission pole sector. Currently such alternatives are said to have not demonstrated service lives above 30 years (40 years under simulation testing), whilst according to one consultee warranties offered in the EU are capped at 25 years.

Furthermore, the market in such alternatives is not yet mature and there is good evidence that current supply capacity constraints (there is no industrial scale capacity in GB) render such alternatives inadequate to meet current demand, particularly given the projected expansion within for example the telecom sector as the UK Broadband rollout takes effect. According to a number of consultees in the 2024 HSE consultation, the process of shifting to copper oil-based treatments is not straightforward and can take up to 5 years and require significant investments of the order of £1.5-6 million. Such alternatives are also said to be around 30-50% more expensive (on a per pole basis), though it is unclear to what extent the comparisons of cost have been made on a like for like basis (see for example the discussion in the railway sleeper section 2.2.1 on this). Estimates from the 2024 HSE consultation suggest the socio-economic impact for the industry to make a transition in 2032 would be of the order of £30m to build industrial scale capacity for alternative wood preservatives to meet GB requirements for the electricity and telecom sectors. There would also be an annual additional cost of £18m p.a. when compared to the cost of creosote. Another estimate from one telecoms operator has suggested additional costs to them alone of around £5 million per year if copper oil treated poles were to be used. HSE has not been able to scrutinise the derivation of these estimates.

The evidence on other protective materials, such as barrier sleeves suggests that these are economically feasible and are in use alongside water-based copper alternatives (which typically have lower service lives) by some utility companies. However, the evidence submitted on these is insufficient to conclude on the performance of these alternatives over the longer time periods required in this use class. Such protective sleeves may be useful in reducing leaching and maximising the effectiveness of preservatives. In this respect they may provide additional risk management protections in environmentally vulnerable contexts.

In summary, although there does appear to be some constrained scope for the use of non-wood alternatives in the transmission poles use class, the arguments against their general use in this sector appear to revolve around concerns over economic feasibility. The situation is more promising with regards to wood preservative alternative, with recent approvals of products with greatly improved service life performance. Some of these are currently undergoing testing with utility companies, but a further period of testing is required before these can be generally adopted pending sufficient supply and cost considerations can be met. HSE accepts that for the moment, in the context of the safety critical nature and strategic economic importance of this use class, there is a lack of solid evidence that suitable alternatives are available in sufficient quantities and with proven service lives for all use conditions currently experienced in GB within this

use class. Therefore, HSE concludes that at least in the short term, for transmission poles there are currently no suitable alternatives to creosote generally available for all applications.

2.2.3 Fencing applications

Creosote treated wood is used extensively in a variety of fencing applications. Although there are numerous examples of alternative preservation treatments and materials being used and accepted in some fencing applications (e.g. some domestic/agricultural fencing which has a service life of 15 years or less), there are, according to the applicant and other stakeholders, a number of fencing applications in which a longer service life is required alongside some other characteristics of creosoted wood, which makes the suitability of alternatives problematic. These include: agricultural fencing in which safety-critical separation of dangerous livestock from the public is needed; highway and industrial fencing where safety-critical exclusion of the public from danger is again needed; and equine fencing where containment and safety of horses is needed alongside the need to prevent 'cribbing' (fence biting). The key function of creosote in these applications is to ensure the preservation of wood over relatively long service lives and variable environmental conditions, thus ensuring confidence that there is no critical failure of the fence as a physical barrier in these safety-critical uses. Creosote treatment of wood in these applications allows for service lives of at least 30 years.

The applicant has undertaken a specially commissioned socioeconomic analysis of this use class, which includes a systematic analysis of alternatives. In total 13 alternatives, ranging from alternative wood preservatives, wood modification techniques, types of wood, and alternative materials to wood, were screened for their suitability as potential alternatives. Seven of the alternatives were subsequently taken forward for more detailed assessment of their technical and economic feasibility.

Regarding those alternatives which involve alternative wood preservative treatments the applicant assesses two copper-based wood preservatives already available on the domestic market. Both of these alternatives suffer from reduced performance in terms of the associated service life of the treated wood, with a reduction by a third of the 30-year service life of creosote treated wood. This reduction whilst related to a technical factor, impacts this use in so far as it increases the lifetime costs to end users and hence ultimately concerns the economic feasibility of the alternatives. The increase in costs taking account of the reduced service life is estimated at 50% and 225% across the two alternatives, with the applicant thus concluding that neither are suitable alternatives. One estimate from an industry stakeholder suggests that ongoing maintenance costs in GB would increase by around £6.25 million per annum if such alternative preservatives are used. Moreover, these costs do not take into account the alternatives inability to prevent cribbing, which would necessitate additional expenditures in the context of equine fencing. However, it should be noted that there is contradictory evidence from some stakeholders suggesting that water-based copper organic preservatives with a desired service life specification of 30 years are available and indeed widely in use.

The applicant further assessed 3 alternative materials to wooden fencing, including concrete, metal and plastic. For all three types of materials, lifetime costs are

considered to be higher than for creosote treated wood fencing, thus making these alternative unsuitable according to the applicant. These (unspecified) higher costs arise due to the apparent higher unit costs of the material in each case, along with higher installation costs, and in the case of concrete and metal, higher transportation costs (due to the higher weight). However, it is unclear how the service life (>25 years) of these materials compares with creosoted wood fencing and whether this has been adequately taken into account in the economic feasibility assessment. Prevention of cribbing is again a problem with all three materials, thus necessitating additional costs for equine fencing.

The final set of alternatives in this use class includes wood modification techniques and alternative (naturally durable hardwood) types of wood. Regarding the use of the latter, these involve higher material costs and possibly installation costs depending on the length of service life (which depends on the quality of hardwood). Cribbing is again a problem, whilst there is also uncertainty as to whether there is availability of the wood in sufficient quantities. The use of alternative modification techniques such as the use of heartwood, incising, heat treatment and acetylation are all considered to be unsuitable primarily for reasons of supply restriction or higher costs.

Once again, more recent evidence from the HSE 2024 consultation is suggestive of more recent alternatives which were not previously considered by the applicant and stakeholders, namely the recently approved copper oil preservatives. Moreover, evidence submitted during the consultation from some timber industry trade bodies suggests that even those alternatives previously considered as inferior to creosote can have their performance improved through appropriate treatment processing, such that service life meets BS8417 15- or 30-year service life specifications. It is unclear, albeit unlikely if previous consultees were alluding to these alternatives when claiming that there were already copper based preservatives with a desired service life performance of 30 years. Irrespective, the claim of comparable service life for copper-based preservatives is still uncertain. Even though the requirements in this respect are lower than for transmission poles for example, further testing is needed to ensure confidence in their use in safety critical fencing contexts. Moreover, as already noted elsewhere, supply capacity constraints apply for the copper oil preservatives and are likely to do so for a least some years to come, whilst up-front costs are also said to be significantly more expensive, raising questions about their economic feasibility at the present time.

To summarise, the applicant’s analysis of alternatives for fencing is on the face of it more systematic and comprehensive than for the other use classes. Nevertheless, it suffers from some of the same issues as noted for the other use classes. There is apparently a lack of confidence amongst some users regarding the service life for wood preservative alternatives, even though there is evidence that water-based copper organic preservatives are widely used for agricultural fencing and copper oil preservatives are increasing their presence on the market. The non-wood material fencing has issues around upfront costs to users, whilst the alternative modification techniques are potentially feasible as niche products but are also unlikely to be able to service any significant demand in this sector. Given again the context of safety-critical fencing applications, HSE finds that despite some misgivings about the recency of supporting evidence, there are likely to be some applications of fencing uses for which it is possible to justify the conclusion that no alternatives can adequately substitute for

creosote treated wooden fencing. In particular, those cases related to safety critical barrier and equine fencing are likely to face issues with suitable alternatives at least in the short term. For other types of agricultural fencing, the evidence on economic infeasibility (on which the case for support rests) is not unequivocal given the contradictory information regarding service life performance and hence on the associated costs.

2.2.4 Wooden poles/stakes/supports for use primarily in the agricultural sector

The GB agriculture sector relies heavily on the use of creosote treated wood in the following tree stake applications: fruit stakes and supports; vineyard stakes; stakes/posts for hop growing; and hail protection stakes. The stakes are used by agricultural produce growers in order to enable production of large volumes of produce. The critical failure of tree stakes can result in significant damage and production losses. Given that the lifetime of an orchard is typically around 25 years, the stakes are expected to operate for at least as long without failure (since this necessitates costly and impractical replacement, in addition to the associated costly production losses). The key function of creosote in these applications is once again to ensure the preservation of wood stakes over the long service life (>25 years) associated with their use in orchards.

As was the case of fencing, the applicant has undertaken a specially commissioned socioeconomic analysis of this use class, in which they perform a systematic analysis of alternatives. A total of 14 alternatives across the same 3 types of alternatives that were considered for fencing are screened in this case, with 7 alternatives being taken forward for further investigation of their technical and economic feasibility.

For those alternatives which involve alternative wood preservative treatments (copper based), the same reduction in service life as for fencing apparently (given the noted contradictory information from other sources) applies, such that whilst the unit purchase, transport and installation costs are comparable to creosote treated wood, the lifetime costs are higher due to the accelerated replacement of the tree stakes. According to one estimate from industry, the use of products treated with alternative preservatives would increase routine maintenance costs by £8 million, though it is unclear how this was derived and whether this is an annual cost or not. Another recent estimate suggests additional costs of £38 million over the lifespan of creosoted poles if creosote was replaced by tanalised material in the GB hop sector alone. One industry association has claimed that across all agricultural uses (fencing and tree stakes) the total additional cost of not having creosote available is of the order of £0.5 billion across the lifespan of previously creosoted materials. Although, it has not been possible to properly scrutinise the derivation of this estimate, on the basis of the information available HSE does not consider this estimate to be a realistic assessment of additional current costs from non-approval in this use.

Alternative materials in the form of concrete, metal and plastic were also assessed in the context of this use class. Both concrete and metal (galvanised steel) stakes are already on the market and are considered to be the most relevant of all of the alternatives. Galvanised steel stakes are extensively used in vineyards since they are suitable for uses which only require short tree stakes. However, they are less suitable

for those application requiring long stakes, due to the added thickness of the metal required, which makes the stakes heavier and consequently more costly to purchase, transport and install. Although concrete stakes are also currently used, they are more expensive to purchase and install. Concrete stakes are also not available at heights above 4.8m and hence are not available for hop and hail protection uses. Moreover, whilst in theory concrete stakes have a long service life, user experience indicates that this is not the case in practice, making them even less economically feasible. Plastic stakes are not considered suitable due to their higher unit costs, though the evidence here is based only on limited information.

Wood modification techniques and alternative (naturally durable hardwood) types of wood suffer the same deficiencies in this use class context as was the case in the fencing use class.

Once again, the applicant's analysis concludes that there are no technically and economically feasible alternatives in this use class. HSE finds that although the analysis is again more systematic than in other use classes, the evidence is not entirely convincing and leaves quite a bit of uncertainty about the unsuitability of the alternatives examined. Again, more recent evidence regarding copper-based alternatives has not been considered, though the issues highlighted previously in terms of price and supply constraints apply to the copper oil alternatives. Creosote treated wood stakes are apparently the market leader and whilst there are other alternatives currently in use in many areas, it is said that these do not enjoy the same confidence amongst users regarding their service life and premature failure. Costs are considered to be higher for the alternatives, though again the evidence is not always straightforward to interpret and verify. Again, HSE accepts that there might be an economic feasibility justification to use creosote treated wooden stakes in some agricultural uses, at least in the short term at least until there is more confidence in the service life of the alternatives and sufficient availability of supply. Overall, HSE concludes that for wooden poles/stakes/supports for use primarily in agriculture, there are likely to some suitable alternatives to creosote available in some applications (i.e. those with service life requirements of up to15 years), though there may be more of an issue for those uses requiring longer service lives, at least in the short term.

### 2.2.5 Wood in marine applications

Wood treated with creosote has been used as a material in marine applications, for example wharfing structures, bridgework and other pilings, as well as other marina installations. No substantive information on alternatives in this use class has been submitted, other than to state that copper organic preservatives are not effective against certain marine organisms (shipworm and gribble), and that none of the suppliers of copper organic preservatives claim effectiveness for seawater uses. HSE notes that no creosote products are currently authorised under GB BPR for treating wood in this use class.

### 2.2.6 Surface treatment of creosote impregnated wood after modifications.

The final use class considered relates to the surface treatment of creosote impregnated wood after modification. Essentially this use relates to the need to re-treat wood in its

final form following any modifications, such as cutting, etc, in order to ensure protection is maintained around the area of modification. Preservatives for this purpose will usually be applied by brush to the wood. Given that the preservative applied must be compatible with the original treatment, then for those use classes for which creosote is authorised, it will be necessary to re-treat the modified wood also with creosote. So long as there are no technically and economically feasible alternatives in the use class for which surface treatment of wood is required, then clearly the same justification could also apply for the use of creosote as a surface treatment in that use class. HSE thus in principle supports the conclusion that there will not be suitable alternatives for surface treatment of creosoted wood following any modification that takes place to the wood used in any use class for which creosote has been authorised.

### *3. Conclusion on technical and economic feasibility of alternatives*

To conclude on the assessment of technical and economic feasibility of alternatives, HSE accepts that whilst there may in principle be suitable and available alternatives to replace the use of creosote in some specific circumstances, these cannot be deemed to be technically and economically feasible in general across all the use classes considered in this report. In particular, there appear to be technical and economic impediments in the case of railway sleepers, transmission poles, and some safety critical fencing. For non-safety critical fencing and tree stakes there is more credible evidence of suitable alternatives, though this is contested, such that there may be availability and confidence issues at least in the short term. In the other cases (marine applications and surface treatment), very little evidence has not been submitted in support of the case.

It should be noted that the evidence submitted on alternatives sometimes lacks detailed and objective technical and economic feasibility evidence but is nevertheless supported by subjective user experience. It is not always easy to fully scrutinise and challenge some of the claims and counter claims made, resulting in some uncertainty regarding the conclusions, particularly in terms of comparable cost and service life performance of alternatives in some uses. Nevertheless, the conclusion that there is a lack of suitable and widely available alternatives for railway sleepers, transmission poles and some fencing uses is considered to be robust. This is based on the safety-critical and strategic economic importance of these applications, as well as the lack of strong evidence demonstrating that alternatives are technically and economically feasible (particularly in terms of supply capacity, cost, service life length and capital expenditures required).

## Part II: Consideration of Disproportionate Impacts (GB BPR Art 5(2)(c)) and Availability of Suitable Alternatives

### *1. Introduction to disproportionate impacts evaluation*

In consideration of whether there are disproportionate negative impacts, no guidance or specific requirements have been developed under the Biocidal Products Regulation 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 UK REACH (EUR 2006/1907). UK REACH, under which a broad range of chemical substances are regulated, has a well-documented approach to

socioeconomic analysis that is relevant and broadly applicable to GB BPR. Although there are some nuanced differences with proportionality assessment under REACH, the disproportionate negative impacts criterion is operationalised here in terms of whether the “benefits of continued use of the active substance disproportionately exceed the risks of continued use of the substance”. The evaluation in this report is thus performed specifically in terms of whether the benefits of continued use (costs of non-renewal) of creosote in certain use classes related to product type 8 (wood preservatives) would disproportionately exceed the risks of their continued use (benefits of non-renewal) across various uses in the following use classes for which an active substance renewal application has been made for uses within GB:

- 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 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)

The report focuses on the following general use areas covered under these specific use classes for which application for renewal in GB is made: 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. Use related to environmental barriers, industrial landscape retaining timbers and cladding for non-residential buildings is not considered since no evidence has been submitted in support of its approval.

The evaluation and conclusions reached are based on the information available to HSE at the time of writing in July 2025. The report is an update of the Disproportionate Impacts Evaluation Report of February 2018, which was itself an updated version of the August 2016 Evaluation Report.

The following information, much of which was submitted to HSE by the applicant in

support of the active substance renewal of creosote has been considered in undertaking this evaluation:

- A 2016 socio-economic analysis of creosoted tree stakes applications. This document presents the findings of a socio-economic study of creosote as a preservative for tree stakes applications.
- A 2016 socio-economic analysis of creosoted fencing applications. This document presents the findings of a socio-economic study of creosote as a preservative for fencing applications.
- A 2013 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 2017 socio-economic analysis of creosote as a preservative for wood poles for power and telecommunication networks.
- Several lifecycle and other technical analyses comparing alternatives
- Information received during various EU and UK consultations during the period 2008 to 2021. These include amongst others the 2019 ECHA consultation on potential candidates for substitution; the 2021 ECHA consultation on derogation to the exclusion criteria; the 2024 HSE consultation on potential candidates for substitution and derogation to the exclusion criteria. The various submissions to the consultations contained information regarding the technical and economic feasibility and availability of possible alternatives to creosote, as well as practical experience from end users of creosote and the alternatives.
- Information on the hazards and risks associated with creosote.

A full list of studies and submission documents can be found in Part III. A summary of the information submitted in the 2024 HSE consultation are published on the HSE website.

## *2. Disproportionate impacts evaluation: Do the costs of not approving creosote for use classes for which an active substance renewal application has been made for uses within GB exceed the benefits (avoided risks) of not approving creosote?*

### *2.1. Background*

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 UK

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.

### *2.2. Assessment of disproportionate impacts; general considerations and approach*

In consideration of whether there would be a disproportionate negative impact on society from not renewing the approval of creosote compared to the risks to human health, animal health or the environment from the approval and continued use of creosote, HSE has undertaken an evaluation of the package of documents submitted by the applicant and which contain a variety of relevant qualitative and quantitative socioeconomic, technical and other evidence, alongside additional information submitted as part of a HSE consultation undertaken in 2024 specifically in consideration of this application for renewal of the approval of creosote.

The documents and consultation submissions contain a variety of information relating to the technical and economic feasibility of alternatives to creosote, in addition to information on the socioeconomic impacts and risks associated with its use. This information can be used to assess the implications of not renewing creosote across the different uses classes applied for. The negative impacts on society of this so-called ‘non-renewal scenario’ will depend on the reactions of manufacturers and users to the non-renewal, and in particular on the availability and suitability of alternatives to creosote. These negative impacts are typically assessed in terms of any additional socio-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 renewing creosote.

For some of the uses within the use classes applied for (agricultural tree stakes, fencing, wood pole uses), the applicant has submitted some formal socioeconomic analysis studies that explicitly assess the ‘non-renewal scenario’ and the associated costs and risks in a quantitative or semi-quantitative manner. These studies are from 2016, such that some of the information on alternatives contained in those reports requires updating. Where necessary HSE has supplemented that evidence with more recent additional information submitted by the applicant or from the consultation conducted by HSE in 2024. However, for the other use class cases, the information from the applicant’s submission and consultation responses 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 approving creosote 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-renewal exceed the avoided risks of non-renewal in the applied for use classes over the relevant analytical timeframe. It should be noted that the analytical timeframe normally relates to the period sufficient to cover the lifecycle of all major impacts associated with

the decision, which may or may not coincide with the time horizon for which use is permitted. Given, that the renewal period may be up to 7 years, 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. The analytical timeframe considered to be relevant in this case is 7 years, in line with the maximum period of renewal available. In the case of the analysis provided for wood pole applications, the period of approval considered in some of the applicant's analysis is 10 years (even though the maximum legally permissible under Article 10(4) of GB BPR is 7 years, albeit further renewable), though it is not explicit to what extent the study actually uses this in assessing relevant impacts. This difference between analytical time period and period for which approval is sought is explicitly recognised in some of the other studies submitted, but it is not clear whether and how it has been taken into account in those studies which provided a fully quantitative or semi-quantitative assessment. Nevertheless, for reasons which will become apparent later, any deficiencies in this respect are unlikely to affect the conclusions of the evaluation.

HSE's evaluation of the evidence submitted seeks to consider impacts occurring to affected stakeholders within GB (though the quantitative analyses provided by the applicant have assessed broader impacts at EU level), with the impacts being defined in terms of a non-renewal scenario in which creosote can no longer be marketed and used in the use classes for which renewal is sought. The non-renewal scenario is explicitly identified and described for the use classes concerning tree stakes, fencing and wood pole applications, whilst it is implicitly assumed but not described for the remaining use classes (see section 2.3).

The non-renewal scenario should ideally seek to establish the least costly (in terms of both direct financial costs and overall economic viability) situation for the manufacturers and users of creosote not being approved for use. Likewise, the non-renewal scenario should establish the avoided risks and associated avoided health and environmental impacts of not being approved for use. The extent that the costs and risks are considered and appropriately assessed is considered in more detail in the sub-sections below.

Overall, the assessments and analyses provided by the applicant vary in quality across the different use classes, with the studies for tree stakes, fencing and (to some extent) wood pole applications conforming best with typical practice for these types of assessments, whilst the picture for the remaining use classes is based on evidence that is often partial, opaque and not presented coherently.

### *2.3. Costs of non-renewal*

The evaluation of the costs of non-renewal is based on evidence submitted by the applicant which differs across the different use classes for which renewal of the approval is sought. In all cases the applicant has submitted information on alternatives in which they assess, to a greater or lesser extent, the economic (and technical)

feasibility of the alternatives.

In the case of the tree stakes and fencing (and to a limited extent wood pole) use classes, specially commissioned studies have been submitted by the applicants that develops cost estimates of the non-renewal scenario. For the remaining use classes, the applicant does not provide a compiled study assessment of costs but submits a variety of individual stakeholder users evidence of increased cost expectations associated with different candidates for substitution.

An evaluation by HSE of the technical and economic feasibility information submitted by the applicant and from the consultation conducted by HSE in 2024 is provided in Part I of this report. This evaluation suggests that although the evidence is not entirely convincing, the applicant's claim that there are no suitable alternatives is to some extent supportable for some of the use classes considered (and thus leading to a differential conclusion across the different uses classes - see Part I for details). A suitable alternative is defined as one which is technically and economically feasible and available in sufficient quantities (see Part I).

Regarding the cost assessment studies submitted by the applicant for tree stakes and fencing, these seek to estimate using standard assessment procedures the financial costs of switching to an alternative preservative or alternative material to wood. The evidence provided indicates that under the non-renewal scenario, the switch to alternative wood preservatives or alternative non-wood 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 applicant's analysis suggests that the costs are of the order of around £41 million and £82 million (both present values - £2016) for tree stakes and fencing respectively over a 25 years period. These figures are EU wide costs rather than GB specific. Assuming a proportionate relationship between these costs and GDP estimates, the GB share would be in the region of around £6.5 million and £13 million (PV over 25 years) respectively (based on the UK GDP being roughly around 16% of EU GDP and assuming that GB GDP is not hugely different to UK GDP). This compares to an estimated annual UK sales revenue of around £2 million for creosoted tree stakes and around £7 million for creosoted fencing (again based on a proportionate relationship between EU sales revenues and GDP estimates), according to sales figures reported in the same studies.

There are a number of uncertainties with the methodological approach and data used (primarily due to the lack of transparency regarding the assumptions used), such that the cost estimates noted above are likely to be rather speculative and cannot necessarily be relied upon as an accurate representation of costs. Moreover, the analysis of alternatives which is used to assess the costs of non-renewal is based on the availability of alternatives at the time the study was conducted in 2016. Since then, a few new wood preservative alternatives have been developed, authorised and are available on the UK and EU market. Although these appear to have improved service lives compared to those considered in the 2016 analysis, they are considered to be more costly than creosote (and the most likely alternatives identified in 2016), are in limited supply and do not yet have a proven track record in terms of their longevity.

These alternatives are discussed in further detail in Part I. It should also be noted that evidence from some timber trade bodies suggests that even those alternatives previously considered as inferior to creosote can have their performance improved through appropriate treatment processing, such that service life meets BS8417 15 or 30 year service life specifications.

Although the cost estimates are thus not entirely reflective of the current position given the availability of some new alternatives and possible improved performance of existing alternatives, the limited availability and higher cost of such alternatives does mean that at least for some time still, users will to some extent have to rely on the alternatives discussed in the 2016 analysis if creosote is not renewed.

Despite the uncertainties in the 2016 analyses, the estimates from those studies can be considered to be illustrative of the additional costs, possibly of the order of magnitude noted above, in the event of non-renewal. At the same time, as indicated in the analysis in Part I and as discussed above, there is evidence that new and existing alternatives with improved performance and comparable cost are becoming increasingly available and in use in agricultural fencing and tree stake uses, though users do perceive these to have limitations in their service life and/or higher costs associated with them.

In the case of the socioeconomic analysis for wood pole applications, the study submitted by applicant sets out the expected behaviours and associated costs of the non-renewal scenario in which creosote is not renewed for use as a treatment for wood poles. The expected behavioural responses and associated impacts are generated using a stakeholder consultation exercise, including discussions and structured questionnaires with relevant industry actors, associations and research bodies.

The analysis contained in the study 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 transparency and a systematic methodological approach, whilst also not calculating an aggregate estimate for the entire supply chain. Nevertheless, the information is sufficient to conclude on the general plausibility of impacts for the sector.

The temporal boundary of the wood pole study 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 parts of the analysis related solely to the UK. Although the analysis seeks to justify a renewal for a period of 10 years, it should be noted that renewal can only be granted for a maximum period of 7 years.

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 coal tar pitch used to manufacture creosote to other markets). HSE has not been able to scrutinise the validity of the impacts on the forest sector since no evidence was presented to substantiate the impact estimates.

According to the wood pole study, the main impacts of a non-renewal 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. The study suggests 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-renewal 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 Part I) suggests that wood poles treated with other preservatives did not at the time of the analysis have the life expectancy typically desired by end users (60 years), such that any move to using alternatives would 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 from the evidence presented in the study 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 of impacts or the extent that they would be transitory and localised.

The other main impacts of non-renewal assessed in the study 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), annual impacts of around £0.5 billion in additional replacement costs are estimated for UK power network operators from the use of such alternatives (compared with current annual network costs of £0.25 billion). A more realistic option to alternative wood preservatives 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 in the UK (approximately double current costs).

Although in the power and telecom cases, there is more transparency regarding the

estimation of costs, the information provided is not sufficient 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' option. Moreover, the study suffers from containing somewhat outdated information on alternatives as noted earlier for fencing and tree stake uses. Once again, new wood preservative alternatives have in the period since 2016 been authorised and are on the market for pole uses. However, given the size of the wood pole market, the issues around supply capacity, increased price/costs noted earlier, as well as the more stringent requirements regarding service life in this use, are considered to be much more of a barrier to their widespread use. As such it is highly likely that very significant cost impacts would still arise if creosote is not approved at least until further supply capacity is established and uncertainties over service life are resolved.

Despite the uncertainties over the nature and magnitude of the different cost elements estimated for the wood poles non-renewal scenario, as well as the lack of more recent information on alternatives, it is clear that some aspects of the sectors responses are highly plausible and would likely imply additional costs either in the form of significant additional operating costs or capital expenditures for the sector as a whole, at least in the near term. Industry responses to the various consultations appear to corroborate this view.

Regarding the remaining use classes (railway sleepers, marine applications and surface treatments), no compiled socioeconomic cost assessment was undertaken, such that only the information on economic and technical feasibility included within the applicant's submission relating to analysis of alternatives, and the HSE 2024 consultation is available for consideration. Although some cost information is provided in the various submissions, for the most part this is not based on any form of systematic and methodologically robust approach to cost assessment (and one in which a robust 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-renewal scenario). The information available does nevertheless indicate that additional costs, albeit of a highly speculative but possibly significant magnitude are likely to be incurred for the railway sleeper use class (see Part I for further justification). In the case of marine applications and surface treatments, there is almost no information on costs,

**In summary, the evaluation of socioeconomic evidence on costs has indicated that there are several uncertainties regarding the assessment and magnitude of costs of non-renewal of creosote across the use classes seeking renewal. The uncertainty is such that most of the estimates of costs are somewhat speculative in their magnitude and cannot be relied upon as being an accurate representation of costs. It should be noted that the uncertainties could be in either direction (i.e., tending to increase or reduce the size of additional costs). Nevertheless, even if the magnitude of costs cannot be assessed with any degree of accuracy or robustness, it is clear from the evidence presented that, in the event of non-renewal of creosote, switching to alternatives will likely incur significant higher costs, particularly in the case of transmission poles and railway sleepers. For fencing and tree stakes, although more systematic study evidence was presented of significant costs, more recent evidence presents a conflicting picture regarding the suitability of alternatives that raises doubts as to the validity of that**

**earlier evidence. Nevertheless, across all uses the evidence suggests that to the extent that there are increased costs, these are likely to be more significant at least in the short term given the lack of supply capacity of alternatives with fully proven and comparable service lives to creosote. In the case of transmission poles, railway sleepers and to some extent fencing, there is an additional constraint to substituting to alternatives due to the potential risks and costs of failure in these safety critical uses if alternatives have unproven longevity (see Part I). Moreover, the lack of supply of alternatives could have dynamic impacts on the price of alternatives in the short run, as well as significant opportunity cost impacts in, for example, the telecoms sector in terms of constraining planned broadband infrastructure investments.**

### *2.4. Benefits (avoided risks) of non-renewal*

In order to assess whether the costs are disproportionate, it is necessary to consider the benefits of not renewing creosote. Given that there are risks to human and animal health and the environment from the use of creosote, the benefits of not renewing creosote derive from the avoidance of those risks in each of the use classes concerned. The evidence on the benefits of avoiding these risks is now considered. We look first at the evidence provided by the applicant, followed by additional evidence on risk from the risk assessment conducted by HSE in view of any deficiencies in the applicant's analysis.

As part of two of the studies discussed earlier, the applicant has submitted a monetary assessment of the health and environmental risks for the tree stakes and fencing use classes, but no such evidence has been provided for the remaining use classes. For tree stakes and fencing the studies attempt a quantitative analysis using 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 in the applicant's studies, the aggregated human health risks and associated monetised impacts from the use in both tree stake and fencing uses are negligible (<£1000). These risks largely relate to exposure of workers involved in the treatment process. Although it has not been possible to monetise the environmental (and indirect human health risks via environment) impacts, the study claims 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.

Although the analysis undertaken by the studies conforms with standard methodological practice for estimating health and environmental impacts, HSE considers the estimates of health impacts to be only partial given the lack of assessment of all environmental and indirect human health risk endpoints (for example residues in food), and therefore will underestimate the overall impacts of creosote use. The claim that such impacts are negligible cannot be substantiated given the finding of unacceptable risk associated with these effects (see later). It is also unclear to what extent those impacts which have been quantified are based on appropriate risk assessment assumptions. In any case, given the lack of a full human and environmental impact assessment across all exposure pathways, this raises significant

uncertainties about the extent of human health and environmental impacts for both tree stake and fencing uses. However, it should also be noted that any benefits to human health and the environment from not renewing creosote could partially offset if alternatives such as concrete or metal stakes and fences are used given the environmental costs associated with their production.

For the use classes covering railway sleepers and transmission poles, no quantitative health and environmental risk impact estimate has been calculated. Whilst some parts of the analysis undertaken for tree stakes and fencing may be applicable to these use classes, once again the partial nature of that analysis does not in any case allow for a comprehensive assessment to be made. It is also unclear if any of this analysis applies to any risks from marine applications and surface treatments.

Overall, HSE's evaluation of the studies and information submitted by the applicant in respect of the avoided risks and impacts of non-renewal of creosote across the various use classes has found that the analysis is lacking in scope, covering only some of the use classes and only worker health exposure pathways. Given the incomplete nature of the applicant's submission in this respect, it has been necessary for HSE to consider the additional evidence from its Competent Authority Report (CAR) assessing the risks to human health and the environment across the relevant exposure scenarios across the various use classes. To the extent that the human health and environmental risk assessments are able to demonstrate acceptable risks for any relevant exposure scenarios, then there will be no socioeconomically meaningful health or environmental impacts associated with those scenarios.

However, as discussed in detail in the main CAR and summarised in section 3 and 4 of the report, the risk assessment undertaken by HSE indicates that there are unacceptable risks across most of the environmental and human health risk exposure scenarios considered across the various use classes seeking approval. The only use scenarios with an acceptable level of risk are the environmental exposure scenarios for railway sleepers and fencing (wood above ground). All other scenarios have an unacceptable level of risk or (as in the case of agricultural stakes for food crops) cannot exclude harmful effects on human health.

Given this finding of unacceptable levels of risk across most exposure scenarios, it is not possible to discount the possibility of human health and environmental impacts and associated monetised risks. The magnitude of these impacts and associated monetised risks will depend on a number of factors including for example, extent of exposure, human and environmental populations affected, type of human effects, environmental assets/ecosystem services affected, geographic location and the temporal and spatial extent of effects, etc.

As already mentioned, the applicant's submitted assessment is partial in its scope across both use classes and across exposure scenarios. The applicant has not submitted any further quantitative or qualitative information that would enable HSE to verify the magnitude and scale of human health and environmental impacts and associated monetised risks across all exposure scenarios. HSE has thus considered the additional information it has from the risk assessment reported in the main CAR. However, risk assessment outputs are typically confined to dimensionless Risk

Characterisation Ratios (RCRs), from which it will not usually be possible to assess the magnitude of the human health and environmental impacts, since this requires dose-response functions and/or epidemiological risk estimates, alongside the information noted in the previous paragraph. As such assessment of impacts for the purposes of socioeconomic analysis based solely on RCR's cannot typically be undertaken. Nevertheless, the RCR is useful in that it indicates how exposures compare to some defined threshold, such as a Derived No Effect Level (DNEL), Derived Minimum Effect Level (DMEL) or Predicted No Effect Concentration (PNEC). The greater is the exceedance of exposure above the threshold then the larger the impacts can be expected to be. Thus, we can look at these ratios to provide some indicative information on the possible scale of impacts. The RCR is the % DMEL (as presented in the CAR) expressed as a fraction in its simplest form. In the case of the RCRs found in the main CAR, the exposures have been found in some instances to be orders of magnitude above the relevant threshold levels for both human health and environmental exposure scenarios. For example, albeit these are based on highly conservative assumptions, some of the largest values include an RCR of up to 173 for one of the scenarios looking at exposure to residues in fruit where tree stakes have been treated with creosote, and oral exposure of toddlers exposed to creosote treated wood has found RCRs of more than 3,500. As such, the risk assessment shows a clear non-tolerable risk of getting cancer. The only exceptions are, as indicated earlier, for the environmental exposure scenarios related to railway sleepers and fencing (wood above ground), for which there is no unacceptable risk.

Despite the evidence on unacceptable risk, it has not been possible to even assess the seriousness of the RCR exceedances in terms of 'scale' of potential population or environment affected, since such information on the size of the population and environment at risk for each use and exposure scenario is not available. Nevertheless, even in the absence of the usual conservative Assessment Factor assumptions used to derive the threshold values to which exposures are compared, the potential for significant adverse impacts on human health and the environment cannot be ruled out. This is because in line with standard regulatory practice in the chemicals domain, given that creosote is a non-threshold carcinogen and PBT, then any exposures will result in a risk and should seek to be minimised.

**In summary, the evaluation of evidence on the human health and environmental impacts of exposures to creosote has indicated that there are significant uncertainties regarding the possible scale and magnitude of impacts and associated monetised risks. Although the applicant has presented some evidence suggesting limited impacts, the assessment conducted was partial and limited to a formal assessment for tree stakes and fencing uses only. Furthermore, the HSE's risk assessment finding of unacceptable risks across most exposure scenarios, alongside the associated margins by which exposures exceed threshold values indicates that significant impacts to human health and the environment cannot be excluded. The magnitude of such impacts cannot be determined on the basis of the evidence submitted by the applicant or from the evidence presented in the main Competent Authority Report. The only exception for which there may be limited impacts is for environmental impacts for railway sleepers and fencing (wood above ground).**

### *2.5. Comparison of costs and benefits of non-renewal*

Given the gaps and uncertainties in evidence highlighted in the previous two sub-sections above, it is not possible to undertake a quantitative comparison of the costs and benefits of non-renewal of creosote, with a view to concluding about whether there are 'disproportionate negative impacts for society' across all uses for which renewal is sought. In light of this HSE has considered whether it may be possible to base any conclusions on a weight of evidence approach using the available quantitative and qualitative information.

Regarding the benefits of non-renewal, HSE concluded that significant impacts to human health and the environment could not be excluded across most use classes, with only environmental impacts for railway sleepers and fencing (wood above ground) being the exception. The evidence available was such that it was not possible to determine what the likely scale or magnitude of impacts might be.

Given this, it is not possible to say what level of costs associated with not renewing the approval of creosote would entail a disproportionate negative impact for society. As discussed in section 2.3 on costs, whilst there are a number of uncertainties with the assessment of costs such that the magnitude of impacts is speculative, there are nevertheless reasonable grounds for concluding that significant additional costs would be incurred across some of the various use classes seeking renewal, especially those having a key national infrastructure function. This is particularly so in the short term given the lack of supply capacity of alternatives, along with their as yet unproven service life. For marine applications and surface treatment uses, almost no evidence on costs has been submitted and hence no conclusions can be made.

Despite the uncertainties in the assessment of costs and benefits and consequently in the evaluation of disproportionate negative impacts for society, HSE consider that although it has not been empirically demonstrated, the scale of costs has a greater potential to be disproportionate for railway sleepers, transmission poles, and some (safety critical) fencing uses, given the use volumes involved, and the service life and safety critical performance requirements. The scale of costs in the case of tree stakes and non-safety critical fencing is considered to be relatively smaller, particularly given the evidence suggesting suitable alternatives are more likely available. At the same time, human health impacts may be of more concern around the use of creosoted tree stakes given the potential for consumer exposure though residues in food. To the extent that this is the case, disproportionate negative impacts are considered to have a lower potential to arise in this use if creosote is not renewed. In the case of marine applications and surface treatment, there is a lack of evidence submitted to enable any assessment to be undertaken in this respect.

## *3. Conclusion on disproportionate impacts*

The socioeconomic material submitted by the applicant in support of this disproportionate impacts assessment contains many uncertainties and is often lacking a systematic analytical approach. The analysis and evidence presented contains numerous gaps and is often difficult to fully scrutinise and confirm, particularly due to a lack of detail and transparency, as well as some contradictory evidence submitted in

the HSE consultation. This has meant that it is difficult to draw definitive conclusions regarding disproportionate impacts for society from not renewing creosote in the use classes under consideration.

Overall, HSE concludes that the applicant has not provided sufficient evidence to support the clear demonstration of disproportionate negative impacts across all uses.

In undertaking its assessment of disproportionate impacts, the HSE has been particularly hindered by the lack of information regarding human health and environmental impacts. The RCRs estimated in the HSE CAR risk assessment are in some cases extremely high, especially for a carcinogen (where we normally assume no threshold), such that ordinarily one might expect a complete ban to be proposed. However, in a socioeconomic context, high RCRs mean very little, because they do not say anything about the size of the excess risk an individual might face, or how many individuals are affected. But this information is crucial to any assessment of disproportionate impacts. For some use classes, there are (imperfect) estimates of the costs of switching to alternative substances/materials, which run into millions of pounds per year. When there is no evidence of the size of the health benefits which might come from switching to those alternatives, it is extremely difficult to argue that the costs of that switch would be proportionate.

As such and given the demonstrated technical and economic feasibility constraints of current alternatives highlighted in Part I, there is reasonable evidence to suggest that not approving the renewal of creosote would have potentially significant disproportionate negative impacts for society when compared to the risks to human health or the environment arising from the use of creosote in the following use classes:

- Transmission poles
- Railway sleepers

Although the evidence on technical and economic feasibility of suitable alternatives is more equivocal, especially given the safety critical nature of uses, there is also reasonable evidence to suggest that not approving the renewal of creosote would potentially have disproportionate negative impacts for society when compared to the risks to human health or the environment arising from the use of creosote in the following use class:

- Fencing (safety critical uses, namely those requiring compliance with BS8417 service factor D)

For the remaining use classes for which evidence has been submitted, some estimates of the costs of switching to alternatives are available, though these appear to be rather small in magnitude. But with no real benefit estimates available, a meaningful conclusion on disproportionate impacts is more difficult to reach. In this respect the applicant has failed to demonstrate their case. Given also the apparent greater, albeit somewhat contested, availability of suitable alternatives, the HSE conclusion is that not approving the renewal of creosote is considered to be unlikely to result in disproportionate negative impacts for society when compared to the risks to human

health or the environment arising from the use of creosote in the following use classes:

- Fencing (non-safety critical uses)
- Tree stakes

It should be noted that there is evidence of industry's intention to transition to suitable alternatives, but they are to some extent currently limited in the ability to do so given supply capacity issues and lack of confidence in proven service life of those alternatives. These issues are particularly constraining for transitioning in those uses with a safety critical performance requirement (transmission poles, sleepers, safety critical fencing). Various users are engaged in a programme of ongoing testing on service life (see Part I) at the present time. The length of time required for testing is linked to the service life requirements needed in the different uses. In this respect the requirements appear to be more difficult to meet for transmission poles, where specifications of 50-60 years are stipulated. The requirements in the other uses are typically of the order of up to 30 years, though longer service lives are often desired. If a renewal of the approval for creosote is granted this would be for a period of time that would ideally allow for the completion of testing to ascertain with confidence the service life performance of the alternatives, particularly for use in those uses with safety critical performance requirements, as well as to enable an increase in the supply of suitable alternatives to meet demand.

Whilst there is evidence that suitable alternatives are more widely available for fencing and tree stake uses and that some progress has been made in shifting to these alternatives, a more limited renewal extension might be warranted even though the case has not been demonstrated, in order to allow for a smoother transition to alternatives, thereby limiting any potential supply disruptions and associated costs.

A conclusion on whether there are disproportionate negative impacts for society for the following use classes has not been attempted given the lack of submitted evidence:

- Marine applications
- Surface treatment
- Environmental barriers
- Industrial landscape retaining timbers
- Cladding for non-residential buildings

### *Part III: Reference Lists of Studies consulted for SEA and Analysis of Alternatives for creosote*

The following information, which was submitted to HSE by the applicant in support of an application for mutual recognition of a national authorisation for biocidal products containing creosote has been considered in undertaking the disproportionate impacts and analysis of alternatives evaluation. Information gathered during a number of previous EU consultations were also made available and considered as part of the

assessment. In addition, a number of position papers and submissions from the UK HSE 2024 consultation (published on the HSE website) were also considered as part of the evaluation exercise.

| Authors | Year | Title |
|---|---|---|
| AquAeTer | 2013 | Life Cycle Assessment Procedures and Findings for Creosote Treated Railroad Ties |
| International Union of Railways (UIC) | 2013 | SUWOS: Sustainable Wooden railway Sleepers |
| [redacted] | 2000 | Inventory and emission factors of creosote, Polycyclic Aromatic hydrocarbons (PAH), and Phenols from Railroad Ties Treated with Creosote |
| [redacted] | 2003 | Emissions of polycyclic aromatic hydrocarbons (PAH) from creosoted railroad ties and their relevance for life cycle assessment (LCA) |
| [redacted] | 2008/2009 | Life cycle assessment (LCA) of railway sleepers. Comparison of railway sleepers made from concrete, steel, beech wood and oak wood |
| [redacted] | 2009 | Background data and assumptions made for an LCA on creosote poles |
| [redacted] (WPA) | 2013 | 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 in the context of application for authorisation of creosote in accordance with the Biocidal Products Directive |

| Authors | Year | Title |
|---|---|---|
| [redacted] | 2013 | Socio Economic Case for the Continued Use of Creosote as a Wood Preservative for Wood Poles V1.4 |
| ChemAdvocacy | 2014 | Evaluation of the technical and economic feasibility of substituting creosote for wooden railway sleepers protection |
| [redacted] | 2014 | If Creosote is Banned by the EU what are the alternatives to Creosote Wood Poles |
| Daw Bytom Sp. z o.o. | 2014 | Analysis of technical and economic consequences in Poland of potential phasing out of creosote (2014) |
| EFTEC | 2016 | SOCIOECONOMIC ANALYSIS (SEA) OF CREOSOTED FENCING<br><br>APPLICATIONS |
| EFTEC | 2016 | SOCIOECONOMIC ANALYSIS (SEA) OF CREOSOTED TREE STAKES<br><br>APPLICATIONS |
| [redacted] (DHV) | 2015 | Fragebogen an alle Kreosotanwender zur Alternativeanalyse: Analysis of Alternatives Germany |
| VHN | 2015 | Position paper VHN - 2015 11 26 |
| [redacted] (DHV) | 2015 | Position_paper_stakes_fencing_DHV_Germany |
| [redacted] (DHV) | 2015 | Position_paper_timber_sleepers_SGH_Germany |

| Authors | Year | Title |
|---|---|---|
| [redacted] (DHV) | 2015 | Position_paper_timber-poles_DHMV_Germany |
| Kusters | 2015 | Position Paper PG Kusters - d.d. 24-11-2015 |
| Schuurman | 2015 | Position Paper Schuurman - d.d. 24-11-2015 |
| van Swaay | 2015 | Position Paper Van Swaay - d.d. 30-11-2015 |
| Jan Arts | 2015 | Scan Jan Arts Omheinigen |
| Marmetschke | 2015 | Positionspapier des impregnierswerkes Marmetschke |
| Norway/Finland | 2015 | Position paper meetings in Norway and Finland with the local stakeholders |
| WEI Brussels | 2016 | Wood Pole SEA |
| WPA | 2016 | UK position paper |
| ChemAdvocacy | 2016 | SEA for transmission poles in France |
| Horse fencing papers Sweden | 2015/2016 | Several documents regarding the use of creosoted wood for horse fencing in Sweden. |
| Finnish Transport Agency | 2016 | Economic and operational consequences of a possible prohibition on the use of creosote on bridges and other engineering structures |
| [redacted] | 2012 | Quality of tree stakes |

| Authors | Year | Title |
|---|---|---|
| Aneproma (Spanish Wood Protection Association) | 2016 | Position paper Spain |
| Foreco | 2016 | Position paper Foreco Netherlands |
| BCP | 2016 | position paper |
| Fedustria | 2016 | position paper |
| Paardenpunt vlaanderen | 2016 | position paper |
| [redacted] | 2016 | position paper WPA (UK situation) |
| WEI Brussels | 2016 | Comparative Life Cycle Assessment of Utility Poles - Final report |
| WEI Brussels | 2016 | Socio economic Analysis (SEA) Of Creosoted Wood Pole Applications |
| 2016 Submission package | 2016 | 2016 - Alternatives to creosote – package.zip |
| 2017 Submission package | 2017 | 2017 - SEA submission by CCE.zip |
| ECHA public consultation on Creosote as a candidate for substitution | 2019 | 2019 - Public consultation.<br><br>Creosote_pt8_comments_received_en_2019.zip |

| Authors | Year | Title |
|---|---|---|
| Oct.-Dec. 2019 | | |
| EU Implementing regulation 1950/2022 renewing the approval of Creosote as an active substance | | CELEX_32022R1950_EN_TXT.pdf |
| UK Key infrastructure essential worker documentation to critical suppliers | 2020 | Scanpole BBH COVID-19 Partner Letter – Openreach.pdf |
| UK Key infrastructure essential worker documentation to critical suppliers | 2020 | Scanpole BBH COVID-19 Partner Letter – WPD.pdf |
| European Commission first reply to request for access to documents for 2021 public consultation. | 2024 | Extended deadline letter - EU Comm.pdf |
| European Commission second reply to request for access to documents for | 2024 | Fair Solution Proposal - EU Comm.pdf |

| Authors | Year | Title |
|---|---|---|
| 2021 public consultation. | | |
| European Commission e-mail correspondence<br><br>regarding fair proposal to request for access to documents for 2021 public consultation. | 2024 | RE [redacted](2024)2140023_Request.pdf |
| WPA Consultation – April 2024. Position from GB Electricity Sector | 2024 | Appendix 1- WPA consultation with GB Electricity Sector.docx |
| Letter to UK MP [redacted] from ISPA UK | 2024 | 070324 - ISPA_Pole Coating_Industry Letter_Final.pdf |
| Carbon Storage Assessment of Wooden Poles in Europe and the UK | 2024 | EU Wood Pole population carbon assessment_CE_110324.docx |
| Wood – Building the bioeconomy (Cei-Bois) | 2019 | WOOD-BUILDING-THE-BIOECONOMY.pdf |
| Treated wood- a sustainable choice | 2019 | TREATED-WOOD-A-sustainable-choice.pdf |

| Authors | Year | Title |
|---|---|---|
| (EWPM/WEI) | | |
| WEI Poles a better choice | 2020 | WEI Poles a better choice.pdf |
| Life Cycle Assessment of Utility Poles (WEI) | 2020 | WEI Utility Poles LCA Report - 7 Feb - Final – Issued.pdf |
| Summary of the UK agricultural fencing market | 2024 | 040424 - Cost to Farmers of no creosote Fencing.pdf |

## Appendix VII: Evaluation of residues in fruit trees and consumer risk assessment

### *A.1 Introduction to assessment of residues in food crops*

Product type 8: Wood preservative

Label recommended uses are for use of creosote products (containing 100% creosote, as a ready to use liquid treatment). It can be used as (use class 4, UC4) where treated posts are used outdoors and embedded in the ground and are in direct contact with the soil.

Creosote is a highly complex mixture of over a hundred distinct organic compounds, including bi- and polycyclic aromatic hydrocarbons (PAHs), phenols, as well as heterocyclic, oxygen-, sulphur- and nitrogen-containing compounds. The mixture is formed by distillation of coal tars, and the precise chemical composition can be influenced by the starting materials and by the process which is high-temperature destructive distillation of bituminous coal to form coke. It consists of hydrocarbons boiling in the range of approximately 200°C-355°C. A main part of the composition, is as polycyclic aromatic hydrocarbons (PAHs). There is a European standard for creosotes (European Standard EN 13991 (CEN 2003)). Only creosotes in line with the provisions in the standard for Grade B or Grade C have been permitted in the market in Europe. Further compositional information, including the nature of composition of Grade B, Grade B composites and Grade C creosotes, is given in Appendix VIII. Please see a further discussion under the definition of residues in section A.2.

Treatment of agricultural tree stakes/supports (fruit, vineyard, and hops) is recommended when a long service life is needed. Treatment is via pressure impregnation (pressure process/vacuum impregnation) at the following treatment rates:

One application cycle per batch

Softwood: 100 to 195 kg per $m^3$

Hardwood: 160 to 210 kg per $m^3$

For wood treatments generally, there is the potential for transfer of residues into food crops, either by way of uptake of residues from the soil, especially if the residues are highly persistent in the soil, or via contact of the wooden posts with the growing crop directly.

The lifespan of the wooden posts is estimated to be around 25 years. The label states that for this professional use (including stakes for tree support), initial treatment and retreatment *in situ* is permitted. When used in the vicinity of fruit trees, the leaching of residues from wooden posts into the soil are expected to be at the highest levels in the first few years. When young fruits are grown in a training (espalier) system no significant harvest of fruits occurs in the first few years (an exception would be annual plants). Additionally, exposures later in the commercial life span of the crop should also be considered.

The applicant has made available three studies to determine the potential for residues of creosote to occur in fruit crops, when creosote has been used in wood treated stakes. No studies have been made available specifically to address residues in grapes (vines) or hops.

One focus of the studies has been to consider the background exposures as PAHs originate from various anthropogenic and natural sources, often associated with combustion processes e.g. vehicle traffic, fossil fuels combustion, forest fires and wood stoves. For example studies have sought to look at residues of PAHs in fruits grown in soil not affected by treated wood stakes to consider the possible residue levels that might occur anyway in fruits, separate to the possibility of being impacted by use of creosote products.

Therefore this assessment provides a form of comparative assessment to compare the residues in fruits arising from potential exposures from use of creosote treated wooden stakes in fruit orchards with background uses.

### *A.2 Definition of residues*

Residue definition for dietary risk assessment:

In order to assess dietary exposure consideration needs to be given to the appropriate definition of residues in order to consider the compounds of interest to dietary risk assessment considering prevalence and toxicological significance.

In the case of creosote, the substance is (at the time of application to the wooden posts) a highly complex mixture.

Please refer to the Appendix VIII which reports the overall chemical composition of creosote, as influenced by the origin of the starting material and by the nature of the distillation process. In the creosote material up to 106 products have been identified (please refer to the Appendix VIII which gives full compositional details of the US and European creosotes). Creosote compositions vary and this is reflected in the compositional details presented in Appendix VIII. A summary of the composition of material that the applicant cited in the planning of their residues work (outlined in the first fruit tree study) Grade B, based on a Grade B composite material, and Grade C (the European creosotes) which are relevant to this evaluation is provided below in Table A.1.

Data are not available in plants or livestock to address the potential for metabolism of creosote residues to occur. However radiolabelled studies that are intended to address metabolic fate would normally focus on a main component that is part of the treated product or which will be consumed by livestock. Since creosote is highly complex, then it might be reasonable for the definition of residues to be based on the chemical composition of the active substance and the toxicological properties of these components. However, there are no specific toxicological data that has been provided and evaluated by HSE on the individual constituents of creosote (as noted by HSE in section 12.2 (Reference values)).

Food monitoring already takes place to address food exposures to some PAHs (from

various sources, please see section A.3 on MRLs). Whilst the constituents listed in Table A.1 comprise only 40-43% of creosote, this covers the main identified components (see Appendix VIII for full compositional details).

**Table A.1 Creosote compositions cited by the applicant in their first fruit tree study taken from the original BPR dossier for Grades B (based on a composite of Grade B materials) and C (single Grade C material) respectively.**

**n.d. denotes 'not detected' (limit of determination was 10 mg/kg = 0.001% w/w)**

| Compound | Creosote Grade B[1] (%w/w) | Creosote Grade C (%w/w) | EFSA (2008) PAH8- see text below | EPA priority 16 PAHs (see text below) | PAH18 (analysed for in the residues studies in this evaluation) |
|---|---|---|---|---|---|
| Naphthalene | [redacted] | [redacted] | | Yes | Yes |
| Acenaphthylene | [redacted] | [redacted] | | Yes | Yes |
| Acenaphthene | [redacted] | [redacted] | | Yes | Yes |
| Fluorene | [redacted] | [redacted] | | Yes | Yes |
| Phenanthrene | [redacted] | [redacted] | | Yes | Yes |
| Anthracene | [redacted] | [redacted] | | Yes | Yes |
| Fluoranthene | [redacted] | [redacted] | | Yes | Yes |
| Pyrene | [redacted] | [redacted] | | Yes | Yes |
| **Benz[a]anthracene** | [redacted] | [redacted] | **Yes** | **Yes** | **Yes** |

[1] Based on a composite of different Grade B materials

| | | | | |
|---|---|---|---|---|
| **Chrysene** | | **Yes** | **Yes** | **Yes** |
| **Benzo[b]fluoranthene** | | **Yes** | **Yes** | **Yes** |
| **Benzo[k]fluoranthene** | | **Yes** | **Yes** | **Yes** |
| **Benzo[a]pyrene** | | **Yes** | **Yes** | **Yes** |
| **Benzo[g,h,i]perylene** | | **Yes** | **Yes** | **Yes** |
| **Indeno[1,2,3-cd]pyrene** | | **Yes** | **Yes** | **Yes** |
| **Dibenz[a,h]anthracene** | | **Yes** | **Yes** | **Yes** |
| 1-Methylnaphthalene | | | | Yes |
| 2-Methylnaphthalene | | | | Yes |
| Sum of above listed constituents | | | | |

The applicant has noted that some PAHs are known to have unfavourable properties relating to both environment and human health, including carcinogenic and mutagenic properties.

In the submitted residues studies (on magnitude of residues), the approach that the applicant has set out, has been to cover the main components of creosote (including acenaphthene, fluorene, phenanthrene, fluoranthene, pyrene, napthphalene, 1-methyl naphthalene and 2-methyl napthphalene) as well as the eight carcinogenic PAHs recommended by EFSA for food control[2]: namely benz[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[g,h,i]perylene. EFSA (2008) referred to these as

2 Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Polycyclic Aromatic Hydrocarbons in Food. The EFSA Journal (2008) 724, 1-114.

the PAH8. In the EFSA Scientific Opinion, it was concluded that the risk characterisation should be based upon these eight substances for which oral carcinogenicity data were available. It was concluded that these eight PAHs ('PAH8' in this assessment), either individually or in a combination, are currently the only possible indicators of the carcinogenic potency of PAHs in food. Two other combinations were used in the EFSA assessment, PAH4: the sum of benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene and PAH2: the sum of benzo[a]pyrene and chrysene. These components that the applicant set out to include in the residues work also cover the '16 EPA priority PAHs' as outlined below. As noted, the composition of creosotes, and the levels of individual constituents, can vary. When comparing amounts in the Appendix VIII for the main components for the various batches tested for composition of individual creosote constituents, the most prevalent components (each > 3% w/w) in Table A.1 (summary table above in this residues section) were also prevalent in the batches presented with the renewal assessment[3]. Therefore this overview of composition (Table A.1) that the application provided (in their assessment of residues) in the first fruit tree study is also considered to be suitable in the assessment of all the three fruit tree studies.

Whilst the applicant for creosote states that the abovementioned components noted to be of special toxicological concern are not the main PAH constituents of Grade B or Grade C creosotes, the residues studies have included all these components to establish their possible presence or non- presence arising from the use of creosoted wood posts. It is noted that of the EFSA PAH8, only two chrysene and benz[a]anthracene (two of the 'EFSA 2008 PAH4') are part of the chemical composition of creosote considered in this evaluation. These are present only in low amounts in the European creosote products at a maximum of 0.17% Benz[a]anthracene and 0.08% chrysene.

The analytical suites in the residues studies have included all the '16 EPA priority PAHs'[4]. Of the hundreds of known PAHs, sixteen have been designated High Priority Pollutants by the US Environmental Protection Agency (EPA); they include: naphthalene (NAP), acenaphthylene (ACY), acenaphthene (ACE), fluorene (FLU), phenanthrene (PHEN), anthracene (ANTH), fluoranthene (FLTH), pyrene (PYR), benzo[a]anthracene (B[a]A), chrysene (CHRY), benzo[b]fluoranthene (B[b]F), benzo[k]fluoranthene (B[k]F), benzo[a]pyrene (B[a]P), benzo[g,h,i]perylene (B[ghi]P), indeno[1,2,3-c,d]pyrene (IND), and dibenz[a,h]anthracene (D[ah]A). These 16 PAHs

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[3] Grade B (based on grade B composites) in table A.1 the seven main components (>3% w/w) matched to six of the main components (>3% w/w) in the tested Grade B batch reported by the applicant submitted in the renewal assessment; Grade C in table A.1 the four main components (>3% w/w) matched to four of the main components (>3% w/w) in the tested Grade C batch reported by the applicant submitted in the renewal assessment.

4 16 US EPA Priority PAHs- as described in [redacted] et al., 2012 "Human Health Risk Assessment of 16 Priority Polycyclic Aromatic Hydrocarbons in Soils of Chattanooga, Tennessee, USA " Water Air Soil Pollut. 2012 Nov 1; 223(9): 5535–5548

are of environmental concern because of their potential toxicity in humans and other organisms and their prevalence and persistence in the environment.

As such, some of the PAHs in creosote are known to have unfavourable properties related to human health, including carcinogenic and mutagenic properties (ATSDR, 1995[5]). Section 4 (Summary of the human health risk assessment) of this evaluation concludes ‘ Since creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded, AELs cannot be derived. A systemic DMEL (Derived Minimal Effect Level) for workers based on its carcinogenic effects has been established ((ECHA (2008): REACH Guidance on information requirements and chemical safety assessment, Chapter R.8). To facilitate a quantitative risk assessment for the consumer, an oral DMEL for the general population has been established by HSE. This is detailed further in part C of this document.’

The DMEL derived (GB) for the indicative consumer risk assessment, therefore is $DMEL_{oral_consumers}$ 0.3 µg/kg bw/day (0.0003 mg/kg bw/day). The derivation of this value by HSE is stated in section 12.2 (Reference values), where it is further explained by HSE that “This is a chronic value. There are no appropriate data to derive an acute DMEL. However, as in theory, it is possible that even one single exposure could lead to genetic damage and eventually to carcinogenicity, this chronic value should also be used when assessing acute exposure scenarios. It should be noted, however, that for acute exposures, the chronic DMEL is an extremely conservative value.“

It is noted that for this evaluation, the DMEL proposed by HSE is for creosote, and is not tailored to specific individual constituents of the material (as noted by HSE in section 12.2 (Reference values)).

*Residue definition for risk assessment:*

None - A formal proposal for the residue definition for dietary risk assessment cannot be proposed.

A residues definition for dietary risk assessment is not being proposed since the residue findings are of concern since it is concluded that creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded (see section 12.2 on Reference values). Furthermore, creosote is a highly complex mixture, and specific toxicity data for individual constituents have not been evaluated (see section 12.2 on Reference values). However, an indicative risk assessment has been performed in this evaluation, to compare residues in fruits (treated sites) compared to background levels (control sites) in order to assess chronic and acute dietary intake estimates. This also enables comparison with previously reported estimates of dietary exposure to PAHs (see section A.6).

HSE has conducted an indicative dietary risk assessment covering the main

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5 Agency for Toxic Substances and Disease Registry (ATSDR, 1995). Toxicological profile for polycyclic aromatic hydrocarbons, retrieved on 26/12/2014 from http://www.atsdr.cdc.gov/toxprofiles/index.asp

components of creosote (see section A.6). This uses a DMEL for the consumer that has been proposed by HSE as relevant to both chronic and acute dietary estimation (though the DMEL is likely to be conservative for the acute exposure assessments ).

The indicative consumer risk assessment has covered the following scenarios :

- Sum PAHs (covering in most cases the 18 PAHs, the 16 EPA list plus 1-methyl naphthalene and 2-methyl naphthalene which have been analysed in all the trials)
- Sum of chrysene and benz[a]anthracene (the two of the 'PAH8' compounds of concern which are present in creosote products in low amounts)
- Phenanthrene (the most prevalent residue in creosote products and in the fruit tree residues study)

Please see the assessment in section A.5 based on the magnitude of residues.

In the overview of residues (comparison of residues in fruits arising from creosote treatment compared to background levels), section A.5.4, a summary of the following is also included.

- PAH18
- PAH8 (EFSA, 2008)
- PAH4 (EFSA, 2008) – see Table A.2 in section A.3 below (MRLs)
- PAHother (n=10, not EFSA8)
- chrysene and benz[a]anthracene
- Fluoranthene
- Phenanthrene
- Pyrene

*Residue definition for compliance and/or enforcement*

None - A formal proposal for the residue definition for compliance and/or monitoring cannot be proposed.

In principle, if needed for monitoring and enforcement purposes, then a residue definition would be needed to consider the component compounds (parent and/or relevant metabolites) which should be monitored based on the evaluation of residues. Also full details of a suitable analytical method for the determination of the components of the residue definition for compliance and/or monitoring in fruit would need to be submitted and evaluated. This would need to include validation for fruits demonstrating acceptability of the method of analysing the components and supporting a suitable

validated LOQ. Please refer to Guidance supporting the BPR "ECHA (BPR) Guidance on information requirements Version 1.0 July 2013" for full requirements covering the needs, such as for confirmatory methods and ILV (interlaboratory validation) data for the primary method.

Section 5.2 of ECHA (BPR) Guidance on information requirements Version 1.0 July 2013 states that analytical methods for monitoring purposes for biocidal products classified toxic/very toxic, toxicologically relevant components must be analysed if human exposure cannot be excluded. The evaluation of the available information methods of analysis were presented in this residues evaluation (see detailed evaluation of studies, section A.5.1, A.5.2 and A.5.3)). Whilst validated methods were used, the detail on the methods of analysis and the supporting validation data submitted were not acceptable to the required standards in section 5.2 of the above mentioned guidance, and as such the data available would not be of the required regulatory standard to enable these to be acceptable monitoring methods.

Please refer to the overview of residues (section A.5.4), which indicates that residues above background levels will be anticipated for some of the components of creosote. Since residues are of concern only an indicative dietary risk assessment has been performed as creosote is a genotoxic carcinogen, see section A.6. Therefore, neither residue definitions for dietary risk assessment or compliance and/or monitoring are being proposed at this time. The indicative dietary risk assessment (section A.6) shows high dietary intakes (exceedances) versus the reference value used for indicative chronic and acute dietary risk assessment.

It should be noted that during the evaluation based on the prevalence of residues, HSE considered that the residue definition for compliance/ monitoring could be:

- Phenanthrene (lead component in creosote products and fruit trials data) and/or
- chrysene and benz[a]anthracene present in creosote or
- EFSA PAH4, which covers these two components of particular toxicological concern (chrysene and benz[a]anthracene), for which some MRLs are already set in some foods (see section A.3 on MRLs)].

However, no specific recommendation is made at this time.

If, in future, residue definitions for risk assessment or for compliance and/or enforcement are further considered, HSE recommend considering the compositions of modern creosotes to address the suitability of any proposed residue definitions, also taking account of this residues assessment.

### *A.3 MRLs for PAHs in food*

For context for this evaluation, the available existing MRLs for PAHs in foods are set out in this section.

There is food legislation which imposes maximum amounts of PAH in food (Assimilated Regulation 835/2011) focussing primarily on processed foods (such as smoked fish and

meat where elevated PAHs could occur due to the production process) and to exclude PAHs from infant formulae, milk and infant foods. Based on the 2008 EFSA Scientific Opinion, the legislation established MRLs for the sum of four substances (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene), and a separate maximum level for benzo(a)pyrene. Whilst some MRLs were set for a small number of plant derived products, e.g. cocoa beans, MRLs were not established for fruits or hops (commodities in consideration for the current evaluation). Not all of these PAH components for which MRLs are already set in foods are present in the creosote products. The components benzo[a]anthracene and chrysene are present in low amounts in creosote.

The MRLs were set in the specified foods on the principle that maximum levels for polycyclic aromatic hydrocarbons must be safe and as low as reasonably achievable (ALARA) and taking onto account contamination background levels and food processing (e.g. concentration of PAHs into fat in the case of cocoa butter). MRLs were not set for all foods at this time. Assimilated Regulation 835/2011 stated that occurrence data on PAH in cereals and vegetables were limited, but the available data indicate that cereals and vegetables contain rather low levels of PAH. It was considered that PAH levels in cereals and vegetables should be further monitored, which could form the basis for a future evaluation of the need for MRLs to be set in wider crops.

The Available Draft Guidance (Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses, published on ECHA website 2022) states “When it can be shown that biocide residues in food do not exceed the threshold level of 0.01 mg/kg food, no MRL setting is required and no dietary risk assessment needs to be performed, unless the a.s. is particularly toxic.” In this case residues are of potential health concern so low level residues are of interest in the assessment.

**Table A.2 The levels at which the MRLs were set (Assimilated Regulation 835/2011) are as follows (some of these MRLs applied from 2013, 2014 or 2015):**

| Commodity | Benzo(a)pyrene µg/kg | Benzo(a)pyrene mg/kg | Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene<br><br>(Lower bound concentrations are calculated on the assumption that all the values of the four substances below the limit of quantification are zero.)<br><br>(These are the PAH4 (EFSA, 2008) components)<br><br>µg/kg | Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene<br><br>(Lower bound concentrations are calculated on the assumption that all the values of the four substances below the limit of quantification are zero.)<br><br>(These are the PAH4 (EFSA, 2008) components)<br><br>mg/kg |
|---|---|---|---|---|
| Oils and fats (excluding cocoa butter and coconut oil) | 2 | 0.002 | 10 | 0.01 |
| Cocoa beans and derived products | 5 | 0.005 | 30 | 0.03 |

| | | | | |
|---|---|---|---|---|
| Coconut oil | 2 | 0.002 | 20 | 0.02 |
| Smoked meat and smoked meat products | 2 | 0.002 | 12 | 0.012 |
| Muscle meat of smoked fish and smoked fishery products), excluding fishery products listed below. | 2 | 0.002 | 12 | 0.012 |
| Smoked sprats; bivalve molluscs (fresh, chilled or frozen) ; heat treated meat and heat treated meat | 5 | 0.005 | 30 | 0.03 |

| | | | | |
|---|---|---|---|---|
| products | | | | |
| Smoked bivalve molluscs | 6 | 0.006 | 35 | 0.035 |
| Processed cereal based foods and baby foods for infants and young children | 1 | 0.001 | 1 | 0.001 |
| Infant formulae and follow-on formulae, including infant milk and follow-on milk | 1 | 0.001 | 1 | 0.001 |
| Dietary foods for special medical purposes intended | 1 | 0.001 | 1 | 0.001 |

| | | | | |
|---|---|---|---|---|
| specifically for infants | | | | |

These MRLs help guide the expectation as to what suitable LOQ values might be for the current regulatory assessment of residues of creosote in fruit crops. ECHA (BPR) Guidance on information requirements Version 1.0 July 2013 ECHA explains that generally an LOQ of 0.01 mg/kg should be met, though in special cases, the LOQ may need to be lower than 0.01 mg/kg (e.g. in infant formulae and follow-on formulae).

In each of the residues studies (see section A.5 on magnitude of residues) LOQs of 0.5 µg/kg or 0.1 µg/kg (for each of the PAH8 components of particular concern, EFSA 2008) were typically reported. Validated methods were used, although concurrent validation confirming the performance of the method and the LOQ at the time of the residues analysis for the samples was not available. These analytical results would give a summed LOQ (for PAH4) of 2 µg/kg (0.002 mg/kg), which is acceptable when considering the above tabulated MRLs and the components of particular concern.

In the fruit tree studies, the LOQs were more variable for the components that the applicant proposes are of 'lesser toxicity' , namely the PAHother (n=10 (PAH18-PAH8), not EFSA PAH8) as summarized in section A.5.4. LOQs in the range of 0.5 to 2.8 µg/kg for each of these 'other' (non PAH8) individual components were reported in the fruit tree study results (section A.5.1, A.5.2 and A.5.3). This range equates to 0.0005 to 0.0028 mg/kg, well below a level of 0.01 mg/kg.

There are no established MRLs for the PAHs anthracene, phenanthrene, fluorene, fluoranthene, pyrene, acenaphthene, and naphthalene which are the ones detected at the highest concentrations in fruit in the residues studies presented in this evaluation (see sections A.5.1, A.5.2, and A.5.3).

### *A.4 Storage stability of residues and uncertainty in the quantitative assessment of residues*

Some limited data are available in this submission on the cold or freezer temperature storage stability of residues. These data were not obtained following a set up as a specific freezer storage stability study but involved analysis of some samples at different times (see description with regard to some samples in Study 3 below). Therefore, these can be used to consider the quantitative analysis of samples when a period of time has elapsed before the samples are re-analysed in the laboratory.

In the course of the residues studies submitted (see section A.5), the facilities explained how they kept samples cool or frozen prior to analysis (fruits, soil and wood). The dates of the analysis reports (in the raw data appendices) indicate that the samples were (especially in Study 1 and 2) analysed without having been stored for excessive periods. Study 3 (section A.5.3) involved analysing some samples at different times.

Study 1 - Analytical report within one month (2014 season samples) or two months (2015 season samples) of sample receipt.

Study 2 - Samples (2019 season) were shipped to the analytical testing facility

(under frozen temperature conditions) within around 2 months and then analysed within a week of receipt at the laboratory.

Study 3 – Fruits were taken July 2020. Laboratory 1 analyses were done in October 2020. Repeat analysis work - Laboratory 2 analyses were done in February 2021 and July 2021. Please see the write up of study 3 (section A.5.3 for an explanation of the reasons for this).

Whilst a specific freezer storage stability study is not available, Study 3 (see section A.5.3) involved (as an 'in part' aspect of the study) the analysis of same fruit samples by different laboratories at different times (with the samples having been kept in the freezer in the intervening timepoints). A more direct comparison could be made by results for a laboratory ('lab 2') for two field sites (one plum and one cherry) where samples were analysed with a 5 month time difference February 2021 and July 2021 by that same laboratory). Some differences in residues were observed, and as such there is some uncertainty in the quantitative data determinations. Please refer to Table A.20 in the evaluation below for study 3. The results for some analytes show an increase in the residue level (between the two different results 5 months apart) and the results for other analytes show a decrease in the residue level (between the two different results 5 months apart). There also seem to be some marked differences between some analyte results for this same lab 2 which could possibly be indicative of some form of storage stability issue, though this is uncertain. For example phenanthrene lab 2 trial site UK1 (plum) samples taken in the field in July 2020, the samples showed residues of 11.8 µg/kg when analysed in February 2021 by lab 2 and results of 5 µg/kg when analysed in July 2021 (5 months later) by lab 2. It is recognised that the results represent fairly low level determinations (e.g. 12 µg/kg represents 0.012 mg/kg) and this could also be a contributing factor to variations in results.

The second laboratory (lab 2) was used because of some uncertainty in the initial results (lab 1) that had arisen for one of the trial sites (UK1) where the results for this particular site had been considerably higher than the results for the other trial sites for this study. Lab 1 had not had the capacity to re-run the samples and these were sent to lab 2 for confirmatory analysis.

However these results do not give confidence on the understanding of the potential for storage stability issues to occur. It is possible that the inter-laboratory and intra-laboratory variations in determinations are being observed due to the determination of the residue levels at low levels. In the overview of residue levels in fruits summarised in section A.5.4, the median (M) and highest residue (HR) values determined are represented, and the data for all labs is presented. Regarding the trial (UK1 study 3), for which the applicant suspected the first (lab 1) result might be an outlier, the high results for UK1 study 3 (lab 1) are presented along the HR as determined by lab 2 for this trial site. HSE has therefore presented and included all of the data, and to show the variations in results obtained. No data has been excluded, as it is difficult to decide what could constitute an outlier.

PAHs are known for being persistent in the environment, so there is not an *a priori* assumption that the residues would be labile, unstable or have degraded in the

residue samples prior to analysis. There could also be some instability of residues reflected in the results that could be coming into play, but this is not certain.

As noted in the evaluation of all the residues studies (see section A.5), whilst validated methods of analysis are used for the determination of residues in the fruits, mainly using laboratories that are accredited for the analysis of the relevant analytes (there are some limited exceptions-see the detailed write up of each of the residues studies), there tended to not be available procedural recovery data that has been generated concurrently to the studies performed. Provision of such procedural recovery data had it been generated, could have given more confidence in the performance of the methods of analysis at the time of analysing the residue samples and to support/justify the reported LOQs relevant to the time of analysis.

## *A.5 Magnitude of residues*

Three residues studies have been submitted for evaluation to consider the potential levels of residues in fruit trees. No data are available for vines (grapes) or hops.

This section is presented as follows; some overall HSE remarks are made in the overview section A.5.4.

Section A.5.1 Study 1 - Residues in apples and pears (seasons 2014 and 2015)

Section A.5.2 Study 2 - Residues in apples (season 2019)

Section A.5.3 Study 3 - Residues in cherries and plums (season 2020)

Section A.5.4 Summary overview of residues levels (including a comparison with background levels)

An indicative consumer risk assessment is undertaken in section A.6.

### *A.5.1 Study 1 - Residues in apples and pears (seasons 2014 and 2015)*

Study title:

“Screening of PAH residues on fruit grown in orchards constructed with creosote-treated stakes” CCE (Creosote Council Europe) (2016).

Annexes to this study provided to HSE in January 2024

And

“Risk assessment on fruit grown in orchards constructed with creosote-treated stakes” CCE (Creosote Council Europe) (version 8, 20 November 2018)

[2018 study report is an updated version of the 2016 report, with additional text on risk assessment]. HSE remarks have been made in an annotated version of the main body of the (2018) pdf version of the report, (also making references to information in the Annexes provided to HSE in January 2024).

GLP: No

Guidance: No guideline was available at the time of conducting the study.

Study test guidelines (on residues) are not available for biocides.

A draft guidance document ArtFood " DRAFT Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses" is now available (ECHA, draft published March 2022), which advises (section 5.7.4) on the need to address potential residues in foods arising from use of wood preservative treatments for wood posts used on supporting in vining plants and training systems for fruit trees.

Summary:

The study involved assessing levels of PAH (polycyclic aromatic hydrocarbon) compounds in fruits (apples or pears) from orchards in years 2014 and 2015 using fully creosoted wooden stakes, together with background concentrations (fruits analysed from control sites) and also with reference to background levels cited from the literature.

Soil in the vicinity of the wood stakes was also assessed together with soil from a roadside sample, in order to compare the soil exposures near the fruit trees with possible anthropogenic 'background' sources.

Further analyses were performed on creosoted wood (from the same sites) to examine the PAH profile in the treated wood compared to the soil and fruit profiles.

Fruits sampled that had been in direct contact with the stakes had much higher residues than fruits without contact. This result is not surprising. The sampling of the fruits in the 'direct contact' set, have not followed the convention of taking a representative sample (from the crop destined for consumption), but instead are targeted to where the highest residues would be found. It is expected that in commercial practice that fruit with visible damage caused by stake contact would be discarded.

The appendices of the report contain much of the analytical data presented in this evaluation as laboratory analytical reports (all for fruit samples and some for soil samples); for soil and fruit sample analysis, although the main PAHs were analysed using validated methods and are covered by the accredited scope of the methods for the laboratories only limited validation data is available (see section on analytical methods). The GC method used for the wood samples (where only some of the reported data seemed available in the analytical reports) was not stated to be covered by laboratory accreditation but the wood results can be regarded as indicative and do not need to be relied upon in this evaluation.

Methods

*Field phase*

There were stakes referred to as 'new' and 'old'. 3-year old creosoted stakes were

considered by the applicant as new (they note that the third year is typically the first year an orchard is commercially harvested). 20 years old stakes is considered to be old. No statements were made about the way in which (method and rates of application) the posts were creosoted or whether the posts were only initially treated or subject also to re-treatment *in situ*. The table below (Table A.3) does indicate the types of creosote (e.g. Grade C (2 trial sites) or a mix of Grade B/Grade C etc (1 trial site)) used for the treatment.

There were six different sites as outlined in Table A.3 below, four (nos 1-4) representing treatment with creosote (two 'new' and 'old'), and two sites (site 5 and 6) representing controls (using untreated concrete poles as support stakes).

**Table A.3 Field orchard site specifications – see notes below the table.**

| Sites | Number of trees between stakes | % in contact with stake | Geometry of site | Creosote grade used | Age of plantation | Soil type | Wood type | Fruit species (variety) | Closeness to roads, traffic |
|---|---|---|---|---|---|---|---|---|---|
| Site 1 | 6 | 0.07% | Individual | Mixture B/C | 3 years | Loam (dry) | Spruce | Apple (Everina) | 150 m from busy road, 6 km from motorway |
| Site 2 | 5 | 0.13% | Individual | C | 20 years | Loam (dry) | Spruce | Apple (Jonagold | 1.3km from secondary road; 10km from nearest motorway |
| Site 3 | 8 | <0.08% | V-stakes | C | 3 years | Clay (moderately sandy, light clay) | Spruce | Pear (Conference) | 3 km from secondary road; 8,25km from nearest motorway; 6km from Antwerp harbor. |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Site 4 | 6-7 | 0.36% | V-stakes | C | 20 years | Clay (heavy clay, medium wet) | Spruce | Pear (Conference) | 1km from secondary road; 4,25km from nearest motorway; <1km from Antwerp harbor. |
| Site 5 | 11 | N/A | V-stakes | N/A | 10 years | Clay | (concrete) | Pear (Conference) | 100m from secondary road; 4,5km from nearest motor-way; 2km from Antwerp harbor. |
| Site 6 | 8 | N/A | Individual | N/A | <5 years | Clay | (concrete) | Pear (Conference) | 20m from secondary road; 6,3km from nearest motorway; 4,4km from Antwerp harbor. |

To note: Geometry and number of trees: affects proximity and concentration of treated posts to the fruit trees. In some commercial practice some individual stakes are used (most expensive set up) where there is one stake next to an individual tree. This would represent a higher proportion of creosoted poles for a given area of fruit trees than in the current study.

% in contact with the stake (counted on 25 trees in each site). Annex XI to the study provides a comment (in relation to German Scenarios) that this is anticipated to be a reasonable worst case estimate. Also that wine growing regions in Germany, vine plants are not expected to have direct contact with the stakes.

Closeness to roads/traffic- likely to contribute to background levels of PAHs.

N/A denotes not available

*Sampling*

Sampling dates and details are given in Table A.4

Samples were kept cool (soil [refrigerated] and fruit [frozen] and were transferred to the analytical laboratory. The analytical reports (Annexes V.1 and V.2) for the fruits, indicate that the samples were analysed within 1 month (2014 samples) or 2 months (2015 samples) of receipt in the laboratory. The analytical reports (Annexes VII.1 and VII.2) for the available raw data for the soils (some of the 2015 data was not included in an analytical report (in an Annex to the main report, whereas some was), indicate that the samples were analysed within 11 days (2014 samples) or 2 months (2015 samples) of receipt in the laboratory. The analytical report for wood (Annex IX.1) is dated 30 March 2015.

Soil: samples were collected at a lateral distance of 25 cm or 5 m (2.5 m for site 2) from the stake and a depth of 40 cm. The depth of 40 cm was considered sufficiently deep to avoid contamination from agricultural operations, and that the stakes were planted deeper than the sampling depth. When sampled at 25 cm, soil was taken from below the row where the fruit samples were picked. A roadside sample was also taken for comparative purposes (background levels). It is not clear whether this sampling was also taken at a depth of 40 cm.

Composite fruit samples were taken and analysed without washing the samples. These comprised 5 pieces of fruit taken randomly from the sampling row in the orchard (for no contact sampling), and five pieces of fruit targeted as fruit that were in direct contact with the wood to comprise the 'contact' composite fruit sample.

Wood samples, comprised one or two wood centrepieces and one core drilling from the treated wood posts from each site.

**Table A.4 Sampling details**

| **Samples** | **Sample campaign 1**<br><br>**(11 August 2014 to 18 August 2014)** | **Sample campaign 2**<br><br>**(4 March 2015)** | **Sample campaign 3**<br><br>**(2015)** |
|---|---|---|---|
| Soil 25cm from the stakes | Yes (5 soil samples per site) | | |
| Soil 5m (or 2.5 m- site 2) from the stakes | | Yes (4 soil samples per site)<br><br>(additionally one soil sample was also taken from the | |

| | | | |
|---|---|---|---|
| | | roadside at each of the 'treated' sites) | |
| Fruit random (composite of 5 pieces of fruit)<br><br>Not contact | Yes (sites 1 to 5) | | Yes (sites 1,2,4 and 6) |
| Fruit contact (composite of 5 pieces of fruit) | Yes (sites 1 to 5) | | |
| Wood | | Yes | |

*Analytical methods*

Information on the validated methods used, the accreditation status and scope of the participating laboratory are provided in table A.5. Only limited validation parameters are provided. Despite this the limits of detection/quantitation provided were low. In fruits, for most of the PAH analytes (including the EFSA PAH8) the highest reported limit of detection/quantitation, was 0.5 µg/kg (0.0005 mg/kg). For other PAHs with a higher reported limits of detection/quantitation (various across analytes and sites), these were still well below a level of 0.002 mg/kg (in fruits). The reported limit of detection/quantitation for soil were typically 0.02 mg/kg dw (see table A.5 for further details).

When considering dietary risk assessment in fruits, the data provided in soil and wood provide supplementary information.

**Table A.5 Overview of analytical methods and accreditation status/scope and validation parameters provided**

| Component analysed | Analytical Method | Reference and Overview of method | GLP | Analytes determined | ISO 17025 certification of laboratory? | Scope of accreditation and associated remarks | Concurrent method validation provided, such as procedural recoveries | Validation parameters of the method | Form of analytical data |
|---|---|---|---|---|---|---|---|---|---|
| Soil | GC-HRMS | Provided in Dutch (Annex VI) (basic information in English).<br><br>Official methods (CMA, 2014, in Annex VI, method is provided in Dutch, no validation data provided, aside from recoveries | No | 16 EPA priority PAHs and 1- and 2-methylnaphthalene<br><br>Soil samples were analysed individually and then afterwards a 'site average' across samples campaigns 1 and 2 was calculated (where <limits of detection/quantification results were assumed | Yes<br><br>BELAC (Belgium) accreditation for the 16 EPA priority PAHs.<br><br>Annex III.2 provides details of the BELAC accreditation | 16 EPA priority PAHs | Generally no (uncertain whether the validation data presented for 1- and 2-methylnaphthalene in the next column could (possibly) be concurrent to the analysis of the samples).<br><br>The | No data on validation provided, aside from recovery data for 1- and 2-methylnapthalene. (recoveries in the range of 100 to 105% for each analyte when spiked at 0.02 mg/kg, 0.1 mg/kg and 1 mg/kg, following 'matrix addition').<br><br>Example chromatograms | Analytical reports provided covering some of the soil data only. (Annex VII.1 and VII.2) Statement of results (2014 and 2015 data).<br><br>The analytical reports only covered |

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| | | for 1- and 2-methylnaphthalene)<br><br>extraction with acetone/hexane and analysing with GC-MS with quantitation achieved by internal standardisation using deuterated standard equivalents which were added prior to extraction<br><br>analysis on a dry weight basis.<br><br>It also | | to be at half the limit). | (Annex III.2 provides details of the BELAC accreditation (GC-MS) | | analytical reports for the samples do not contain the validation data (but this might be usual convention to report validation data separately). | in Annex VI.2 (method for analysis of 16 EPA Priority PAHs)<br><br>The results refer to detection/quantification limits (of 0.02 mg/kg dw) aside from benzo[k] fluoranthene where 0.01 mg/kg was reported for some site results. 0.04 mg/kg was the stated as the detection/quantification limits for each of 1- and 2-methylnaphthalene. | some of the presented data.<br><br>The data for soil in the vicinity of the stakes (2015) were not available in the analytical reports.<br><br>For 2015, roadside samples the data presented in the main report on 1- and 2-methylnaphthalene were not available in the analytical |

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| | | gives an alternative quantitatio n method (Annex VI.2) but does not say what was done in the study | | | | | | | Annexes. |
| Wood | GC-FID | The results (report IX.1) were stated to be for method WI 317 020.<br><br>The method details provided were as follows:<br><br>Analysed in accordanc e with EN | No | 16 EPA priority PAHs and 1- and 2-methylnaphthal ene<br><br>(also benzo(e) pyrene) | Not stated | Not stated | No | LOQs and supporting validation data were not provided. Results appear to be reported above a detection limit of 0.001%.<br><br>(In the description of the method in Annex VIII it is stated that repeatability and reproducibility | Annex IX.1 is a certificate of analysis for GC results for wood samples- only some of the presented results are in this Annex.<br><br>(two out of four of the samples for |

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| | | 12490.<br><br>The wood was analysed according to EN 12490. The standard describes a method for determination of retention of creosote in treated wood. Cut-wood samples were weighed and extracted in a Soxhlet apparatus using toluene as solvent. | | | | | | are to be determined; however, no data on repeatability of reproducibility have been presented) | which data are presented in the main body of the report it seems) |

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| | | A - Wood was extracted using toluene and analysed by GC-FID analysis. Reference: D095E – European standard CEN/TC 317 WG 2<br><br>Coal tar based oils and coal tar pitch<br><br>Determination of the boiling range by gas chromatography with FID. | | | | | | | |

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| | | (method details given in Annex VIII)<br><br>Elution from the separation column in the order of their boiling points. Co-chromatography to a reference a standard<br><br>mixture of polycyclic aromatic compounds.<br><br>B - Additionally retention of creosote was | | | | | | | |

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| | | determined according to EN 12490 (according to dry wood mass). Defined wood cuts were taken in accordance with EN 351-2. After extraction using toluene, the water content of the sample was determined. The wood sample was dried and the dry wood mass determined | | | | | | | |

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| Fruit | GC-HRMS | Provided, basic details only.<br><br>clean up on a silica/alumina column after saponification, extraction and analysis with GC-HMRS, and quantitation according to internal standard method using deuterated standard equivalent | No | 16 EPA priority PAHs and 1- and 2-methylnaphthalene | Yes<br><br>BELAC (Belgium) accreditation for the trace analysis of numerous pollutants in food including PAHs. Annex III.1 provides details of the BELAC accreditation (GC-HRMS test method | 'the EFSA 2008 PAH8'<br><br>And<br><br>Fluoranthene<br><br>And<br><br>Pyrene (the EFSA PAH8 include benzo(a) anthracene; chrysene; benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a] pyrene, | See the validation data outlined in the next column.<br><br>The analytical reports for the samples do not contain the validation data (but this might be usual convention to report validation data separately).<br><br>Also, please see HSE evaluation write up of the 2022 | The LOQs were stated to be 0.5 µg/kg (2014 sampling) or 0.1 µg/kg (2015 sampling), except for naphthalene, 1- and 2-methylnaphthalene, acenaphthene, acenaphthylene and anthracene, for which the LOQ varied depending on substance and sampling site.<br><br>(Annex IV provided data for reproducibility data and measurement uncertainty, see table A.6 below) | Analytical reports provided. (Annex V.1 and V.2) Statement of results (2014 and 2015 data) |

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| | | s which were added prior to extraction<br><br>analysis on a fresh weight (wet weight) basis. | | | code MIM-OR-017) | benzo[g,h,i]perylene, indeno[1,2,3-cd]pyrene, and dibenzo[a,h]anthracene )<br><br>The report stated that although other relevant PAHs were not officially covered under the certified scope, their analysis had internally been validated | study (2020 cherry/plum samples) as this includes some validation data for this method by VITO (dated 30 August 2016) | Also, please see HSE evaluation write up of the 2022 study (2020 cherry/plum samples) as this includes some validation data for this method by VITO (dated 30 August 2016) | |

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| | | | | | | by the very same method, and were therefore considered to be of similar reliability. | | | |

Note: Of the hundreds of known PAHs, sixteen have been designated High Priority Pollutants by the Environmental Protection Agency (EPA); they include: naphthalene (NAP), acenaphthylene (ACY), acenaphthene (ACE), fluorene (FLU), phenanthrene (PHEN), anthracene (ANTH), fluoranthene (FLTH), pyrene (PYR), benzo[a]anthracene (B[a]A), chrysene (CHRY), benzo[b]fluoranthene (B[b]F), benzo[k]fluoranthene (B[k]F), benzo[a]pyrene (B[a]P), benzo[g,h,i]perylene (B[ghi]P), indeno[1,2,3-c,d]pyrene (IND), and dibenz[a,h]anthracene (D[ah]A). These 16 PAHs are of environmental concern because of their potential toxicity in humans and other organisms and their prevalence and persistence in the environment. As advised in Water Air Soil Pollut. 2012 Nov 1; 223(9): 5535–5548

**Table A.6 Method validation data for determining PAH in foodstuffs (method MIM-OR-17).**

Reproducibility (%RSD), % Measurement uncertainty and % bias reported for determination of PAHs in food using method MIM-OR-17. Further information on the methods of determining these parameters, the units (e.g. ds is not known) or the specific foodstuff on which these determination are based was not given. The report for this residues study describes these validation parameters so it assumed that the samples might have been run concurrently to the analysis work reported in this study, although this is not clear.

HSE remark: The LOQs cited for these methods in the results were 0.1 µg/kg or 0.5 µg/kg

Note: Since the report was in Dutch, ds thought to mean on a dry matter basis (ds- droge stof)

| Substance | Concentration (ng/g ds) (µ g/kg ds) | Bias (%) | Reproducibility (%RSD) | Measurement uncertainty (%) |
|---|---|---|---|---|
| Fluoranthene | 38.7 | -11 | 5.5 | 22 |
| Pyrene | 78.9 | -16 | 4.6 | 25 |
| Benzo(a)anthracene | 20.34 | -19 | 11.1 | 42 |
| Chrysene | 49 | -23 | 7.6 | 38 |
| Benzo(b)fluoranthene | 15.6 | 20 | 3.2 | 26 |

| | | | | |
|---|---|---|---|---|
| Benzo(k)fluoranthene | 4 | 20 | 8.3 | 37 |
| Benzo(a)pyrene | 8.35 | -11 | 6.6 | 24 |
| Indeno(1,2,3,c,d)pyr | 4.84 | -13 | 7.1 | 27 |
| Dibenzo(a,h)anthrac | 1.41 | 6 | 3.4 | 12 |
| Benzo(g,h,i)pyrelene | 9.53 | -20 | 8.7 | 37 |

Also, please see section A.5.3 (2020 cherry/plum samples) as this includes some validation data for this method by VITO (dated 30 August 2016).

Results

*Fruits:* Residue levels in fruits are provided in Table A.7. The results are expressed in µg/kg (as fresh weight).

Regarding the EFSA PAH8:

The levels of benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, benzo[g,h,i]perylene, indeno[1,2,3-cd]pyrene, and dibenzo[a,h]anthracene measured in fruit were <0.5 µg/kg for in 2014 and <0.1 µg/kg in 2015 in all fruits at all sites. The non-detection of these components is expected since these components are not present in the creosote products that we anticipate were used in the treatment of the wooden posts in this study (the creosotes under current assessment, see Table A.1).

Only two of the 'EFSA PAH8' were found at determinable levels, two components in the group EFSA termed PAH4. These are benzo[a]anthracene and chrysene, which are present in low amounts in creosote, but they were only determined in fruits that had had direct contact with the wooden stakes. Chrysene levels and Benz[a]anthracene levels in fruit were <0.5 µg/kg in 2014 and <0.1 µg/kg in 2015 when fruit was grown without contact with the stakes.

Fruit in contact with the stakes: Benz[a]anthracene was only found in the fruits from one site (site 3) that were in contact with the stakes (at 0.79 µg/kg). Chrysene levels were above the LOQs in fruits grown in contact with the stakes (site 2: 2.7 µg/kg, Site 3: 6 µg/kg, site 4: 2.4 µg/kg). Thus, the highest determined level of chrysene observed in fruit which had been in contact with the stakes equates to 0.006 mg/kg.

Regarding other PAHs:

The PAHs with highest levels in fruits when fruits were grown without contact with the stakes were phenanthrene (up to 110 µg/kg, 0.11 mg/kg), fluoranthene (up to 50 µg/kg, 0.05 mg/kg), pyrene (up to 24 µg/kg, 0.024 mg/kg) and fluorene (up to 10 µg/kg, 0.01 mg/kg) followed by naphthalene and acenaphthene at levels around 1 µg/kg.

Direct contact of the fruits with the creosoted poles led to significantly higher levels of PAHs, generally (with some variation for particular PAHs) an order of magnitude times higher than the PAH levels compared with fruits without contact.

For the 'contact' fruits, the highest total (sum of PAH18) levels (site 3) were: 2.1 mg/kg

For the 'contact' fruits, the lowest total (sum of PAH18) levels (site 4) were: 0.23 mg/kg

For the 'contact' fruits, the total highest of sum of chrysene and benz(a)anthracene (the only of the PAH8 present in the creosotes under assessment) levels (site 3) were: 0.0068 mg/kg

For the 'non-contact' fruits, the highest total (sum of PAH18) levels (site 1) were: 0.141 mg/kg

For the 'non-contact' fruits, the lowest total (sum of PAH18) levels (site 2) were: 0.029 mg/kg

For the ‘non-contact’ fruits, the sum of chrysene and benz(a)anthracene (the only of the PAH8 present in the creosote under assessment) across all sites were non-determinable using suitable low levels of detection/quantitation.

**Table A.7: Results of the PAH analysis of fruits (results in µg/kg):**

| Compound | Site 1 Loam – new No contact 2014 | Site 1 Loam – new No contact 2015 | Site 1 Loam – new Contact 2014 | Site 2 Loam – old No contact 2014 | Site 2 Loam – old No contact 2015 | Site 2 Loam – old Contact 2014 | Site 3 Clay – new No contact 2014 | Site 3 Clay – new Contact 2014 | Site 4 Clay – old No contact 2014 | Site 4 Clay – old No contact 2015 | Site 4 Clay – old Contact 2014 | Site 5 Reference No contact 2014 | Site 5 Reference No contact 2015 | Literature Garden soil, Apples ([redacted] et al., 2002) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Naphthalene | **0.6** | **0.36** | **4.7** | **1.6** | **0.41** | **1.8** | **1.3** | **2.3** | <0.8 | **0.62** | **1.8** | <0.94 | **0.54** | N/A |
| Acenaphthylene | <1.3 | <0.1 | <1.5 | <1.0 | <0.1 | <1.3 | <1.2 | **1.3** | <0.9 | <0.1 | <0.85 | <1.1 | <0.1 | N/A |
| Acenaphthene | **1.3** | **0.32** | **34** | <0.69 | **0.4** | **34** | <0.61 | **15** | **0.69** | <0.1 | <0.79 | <0.5 | <0.1 | 0.26 – 1.62 (0.54) |
| Fluorene | **10** | **1.9** | **150** | **1.9** | **1.7** | **78** | **0.93** | **74** | **2.9** | **0.21** | **3.4** | **0.51** | **0.17** | 0.21 – 2.26 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | (0.62) |
| Phenanthrene | **110** | **20** | **780** | **15** | **13** | **570** | **13** | **740** | **48** | **1.8** | **70** | **3.9** | **1.2** | 1.92 – 8.01 (3.33) |
| Anthracene | <0.5 | **0.33** | **7.1** | <0.51 | **0.24** | **4.6** | <0.55 | **5.9** | <0.73 | <0.1 | **0.52** | <0.5 | <0.1 | 0.09 – 0.78 (0.22) |
| Fluoranthene | **13** | **4.3** | **350** | **4.5** | **3.3** | **470** | **11** | **680** | **50** | **1.1** | **110** | **4.4** | **0.47** | 0.40 – 0.85 (0.59) |
| Pyrene | **4.3** | **1.2** | **130** | **1.2** | **0.65** | **200** | **4.6** | **540** | **24** | **0.42** | **33** | **1.7** | **0.25** | 0.15 – 0.25 (0.21) |
| Benz[a]anthracene | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | **0.79** | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | 0.09 – 0.20 (0.14) |
| Chrysene | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | **2.7** | <0.5 | **6** | <0.5 | <0.1 | **2.4** | <0.5 | <0.1 | 0.58 – 1.04 (0.74) |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Benzo[b]fluoranthene | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | 0.05 – 0.10 (0.07) |
| Benzo[k]fluoranthene | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | 0.02 – 0.04 (0.03) |
| Benzo[a]pyrene | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | 0.04 – 0.09 (0.06) |
| Benzo[g,h,i]perylene | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | 0.05 – 0.08 (0.06) |
| Indeno[1,2,3-cd]pyrene | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | 0.02 – 0.04 (0.03) |
| Dibenz[a,h]anthracene | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.5 | <0.5 | <0.1 | <0.5 | <0.5 | <0.1 | n.d. – 0.03 (0.01) |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1-Methylnaphthalene | <1.4 | **0.16** | **9** | <1.4 | **0.21** | **10** | <1.0 | **1.1** | <0.90 | **0.12** | <1.2 | <1.0 | **0.13** | N/A |
| 2-Methylnaphthalene | **1.6** | **0.37** | **19** | <3.0 | **0.45** | **19** | <2.8 | **2.5** | <2.4 | **0.38** | **1.6** | <2.7 | **0.41** | N/A |
| Sum of PAH | **141** | | **1485** | **29** | | **1392** | **33** | **2069** | **128** | | **225** | | | |

Where positive/determinable residues of individual PAHs were observed, the highest reported levels were as follows (in mg/kg). Emboldened values for chrysene and benz(a)anthracene represent the constituents are that also included by EFSA in the list of EFSA PAH8.

Note: Highest background levels reported in the respective control crops below are those reported as either analysed at site 5 or 6 (pears) or reported in the literature (for apples) , according to [redacted] *et al.,* 2002.

| **Compound** | **Wood treated sites 'contact fruits' (highest residue level in fruits)** | **Wood treated sites 'non-contact fruits' (highest residue level in fruits)** | **Highest background residue levels (control crops)** |
|---|---|---|---|
| Phenanthrene | 0.78 | 0.11 | 0.0080 |
| Pyrene | 0.54 | 0.024 | 0.0017 |
| Fluoranthene | 0.35 | 0.05 | 0.0044 |
| Fluorene | 0.15 | 0.01 | 0.0023 |
| Acenaphthene | 0.034 | 0.0013 | 0.0016 |
| 2-methylnaphthalene | 0.019 | 0.0016 | 0.0027 |
| 1-methylnaphthalene | 0.01 | 0.00021 | 0.00013 |
| Anthracene | 0.0071 | 0.00033 | 0.00078 |
| **Chrysene** | **0.006** | Not detected (<0.0005) | 0.00104 |
| **Benz(a)anthracene** | **0.00079** | Not detected (<0.0005) | 0.00020 |
| Naphthalene | 0.0047 | 0.0016 | 0.00054 |
| Acenaphthylene | 0.0013 | Not detected (<0.0015) | <0.00011 |

When considering the comparison of residues in the 'non-contact' fruit with background levels, it seems to be only phenanthrene, pyrene, fluoranthene, and fluorene that have levels which seem to be somewhat above the highest reported background levels. This could suggest that there is low level uptake of these constituents into above ground fruits, either from the soil (surrounding the posts), or relating to upper plant transfer of residues and some fruit affected by the trees having been in contact with wood posts. However, presence of other constituents analysed in the non-contact fruits could relate to the possible background levels of these components that are determined anyhow in low levels in fruits (as reported in the literature).

*Soil:* Results of soil analyses, 25 cm from impregnated stakes and 40 cm depth are

presented in Table A.8. Residues in soil of different PAHs varied. The levels of the following substances were below the detection/quantification limit of <0.02 mg/kg dw or <0.04 mg/kg dw (1-methylnaphthalene and 2-methylnaphthalene) at all the sites: naphthalene, acenaphthylene, acenaphthene, fluorene, anthracene, dibenz[a,h]anthracene, 1-methylnaphthalene and 2-methylnaphthalene. Residues of the other substances in levels above the detection/quantification limit (0.02 mg/kgdw) were not found at Site 2 (Loamy (loam, dry) soil with stakes installed 20 years ago (old) or Site 5 (reference (control) site). Higher levels of most substances were found in soil from site 3 (clay-new) than in soil from Site 1 (loam – new) and also in soil from site 4 (clay-old) compared to site 2 (loam-old). The most abundant substances found in soil were fluoranthene and pyrene (up to 0.09 and 0.06 mg/kg respectively, dw basis).

The presence of benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, benzo[g,h,i]perylene, and indeno[1,2,3-cd]pyrene are unlikely to originate from the creosote posts due to their absence in the chemical composition of the creosotes being considered in the current assessment. These are likely to be from the natural/anthropogenic background source. However, chrysene and benz(a)anthracene (up to 0.034 and 0.014 mg/kg respectively, dw basis) could be present in the soils due to the presence of the creosoted wood stakes.

**Table A.8. Soil samples taken in 2014. Soil analyses average results in mg/kg (dw basis, average results are from 5 determinations), 25 cm from impregnated stakes and at 40 cm depth (note: individual results at <limits of detection, were assumed to be at half the limit of detection). Substances with all results below the detection/quantification limits are not included in this table.**

| Compound | Site 1 Loam - new | Site 2 Loam - old | Site 3 Clay - new | Site 4 Clay - old | Site 5, Reference (control) site |
|---|---|---|---|---|---|
| Phenanthrene | 0.0154 | <0.02 | 0.0303 | 0.0145 | <0.02 |
| Fluoranthene | 0.0376 | <0.02 | 0.0853 | 0.0729 | 0.0091 |
| Pyrene | 0.0314 | <0.02 | 0.0579 | 0.0477 | <0.02 |
| Benz [a]anthracene | 0.0123 | <0.02 | 0.0138 | <0.02 | <0.02 |
| Chrysene | 0.0225 | <0.02 | 0.0344 | 0.0291 | <0.02 |
| Benzo[b]fluoran thene | 0.0196 | <0.02 | 0.0299 | 0.0161 | <0.02 |
| Benzo[k]fluoran thene | 0.0077 | <0.02 | 0.0097 | <0.01 | <0.01 |
| Benzo[a]pyrene | 0.0127 | <0.02 | 0.0146 | <0.02 | <0.02 |

| | | | | | |
|---|---|---|---|---|---|
| Benzo[g,h,i]perylene | 0.0115 | <0.02 | 0.0140 | <0.02 | <0.02 |
| Indeno[1,2,3-cd]pyrene | 0.0117 | <0.02 | 0.0138 | <0.02 | <0.02 |

Table A.9 shows the values for the substances that were found as measurable residues in samples 5m from the stakes and Table A.10 roadside samples for each of the sites. Results from soil analyses (expressed in mg/kg dw basis), 5 m from impregnated stakes (2.5 m for site 2) and 40 cm depth and roadside showed that residues in soil of different PAHs varied and several substances (naphthalene, acenaphthylene, acenaphthene, fluorene, anthracene, dibenz[a,h]anthracene, 1-methylnaphthalene and 2-methylnaphthalene) were below the detection/quantification limit of <0.02 mg/kg (dw) or <0.04 mg/kg (dw) (1-methylnaphthalene and 2-methylnaphthalene).

Residues of the other substances above the detection/quantification limit (<0.02 mg/kg dw) were not found at Site 2.

In terms of comparison to the roadside samples (average residues), levels of all analytes found were possibly at higher levels (not by a marked amount) in the roadside samples (Table A.10) compared to the orchard soil samples (Table A.9) (when the orchard soil was sampled 5m (or 2.5m for site 2) from the wooden stakes).

**Table A.9. Soil Samples taken in 2015. Soil analyses average results in mg/kg (dw basis, average results are from 5 determinations), soil orchard samples 5 m from impregnated stakes (or 2.5 m for site 2). (note: individual results at <limits of detection, were assumed to be at half the limit of detection). Substances with all results below the detection/quantification limits are not included in this table. These data were not reported in an analytical report (in an Annex to the report, in the way that other soil results were reported).**

| Compound | Site 1 Loam - new | Site 2 Loam - old | Site 3 Clay - new | Site 4 Clay - old |
|---|---|---|---|---|
| Phenanthrene | <0.02 | <0.02 | 0.0197 | <0.02 |
| Fluoranthene | 0.0132 | <0.02 | 0.0378 | 0.0176 |
| Pyrene | 0.0126 | <0.02 | 0.0312 | 0.0200 |
| Benz[a]anthracene | <0.02 | <0.02 | 0.0174 | <0.02 |
| Chrysene | 0.0134 | <0.02 | 0.0242 | 0.0165 |

| | | | | |
|---|---|---|---|---|
| Benzo[b]fluoranthene | 0.0126 | <0.02 | 0.0209 | 0.0156 |
| Benzo[k]fluoranthene | <0.02 | <0.01 | 0.0105 | <0.01 |
| Benzo[a]pyrene | <0.02 | <0.02 | 0.0189 | <0.02 |
| Benzo[g,h,i]perylene | <0.02 | <0.02 | 0.0176 | <0.02 |
| Indeno[1,2,3-cd] pyrene | <0.02 | <0.02 | 0.0179 | <0.02 |

**Table A.10. Soil samples taken in 2015. Soil analyses average results in mg/kg (dw basis, highest results are from 5 determinations, or average residue from 5 determinations), residue levels found in the roadside sample for each site. Substances with all results below the detection/quantification limits are not included in this table. (note: individual results at <limits of detection, were assumed to be at half the limit of detection, when the average of the 5 results was calculated)**

| Compound | Site 1 roadside sample (highest residue, n=5) | Site 1 roadside sample (average residue, n=5) | Site 2 roadside sample (highest residue, n=5) | Site 2 roadside sample (average residue, n=5) | Site 3 roadside sample (highest residue) | Site 3 roadside sample (average Residue, n=5) | Site 4 roadside (highest residue, n=5) | Site 4 roadside (average residue, n=5) |
|---|---|---|---|---|---|---|---|---|
| Phenanthrene | <0.02 | <0.02 | <0.02 | <0.02 | 0.0637 | 0.0284 | 0.0217 | 0.0124 |
| Fluoranthene | 0.0397 | 0.0185 | <0.02 | <0.02 | 0.212 | 0.0726 | 0.0439 | 0.0228 |
| Pyrene | 0.0344 | 0.0170 | <0.02 | <0.02 | 0.159 | 0.0567 | 0.0378 | 0.0236 |
| Benz[a]anthracene | <0.02 | <0.02 | <0.02 | <0.02 | 0.0771 | 0.0293 | 0.0227 | 0.0126 |
| Chrysene | 0.0315 | 0.0170 | <0.02 | <0.02 | 0.115 | 0.0423 | 0.0383 | 0.0208 |
| Benzo[b]fluoranthene | 0.0291 | 0.0159 | <0.02 | <0.02 | 0.0963 | 0.0359 | 0.0315 | 0.0188 |
| Benzo[k]fluoranthene | 0.0145 | 0.0069 | <0.01 | <0.01 | 0.0482 | 0.0180 | 0.0158 | 0.0112 |
| Benzo[a]pyrene | 0.0194 | 0.0116 | <0.02 | <0.02 | 0.0826 | 0.0317 | 0.0242 | 0.0129 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Benzo[g,h,i]perylene | <0.02 | <0.02 | <0.02 | <0.02 | 0.0662 | 0.0273 | 0.0217 | 0.0124 |
| Indeno[1,2,3-cd] pyrene | <0.02 | <0.02 | <0.02 | <0.02 | 0.0717 | 0.0286 | 0.0212 | 0.0123 |

Conclusions from soil analyses:

It was shown that clay soil in general contained higher PAH residue levels than loam soil. Fluoranthrene and pyrene were found at levels in the range of 0.05 to 0.1 mg/kg (dry weight basis) in the clay soil samples sampled at 25 cm from the fruit stakes, whereas in the 5 m samplings these residues were found in the range of 0.02 mg/kg to 0.04 mg/kg. Therefore, there seems to be a limited degree of contamination of the soil from residues which have leached from the treated wooden posts. Therefore, the low level of residues in the fruits sampled in the non-contact fruit samples could have arisen as low-level uptake from the soil. However, the precise source of these non-contact low level residues is not clear (whether anthropogenic sources contribute and whether there is above ground transfer from other parts of the trees that might have come into contact with the stakes). It is difficult to draw conclusions on how these low-level residues in the non-contact fruit have arisen.

The content of PAHs in soil from the roadside was possibly higher (not by a marked amount) than the residues found in the orchard soils, when orchard soils were sampled at a distance of 5 or 2.5 m from the wooden stakes.

This indicates that PAHs originate in these soils from natural/anthropogenic sources, e.g. soot deposition from cars/tractors passing by.

Further demonstrating anthropogenic sources, the report summarized data from the literature ([redacted] *et al.*, 2008) which measured background concentrations in UK and Norwegian soils. The PAH ranges in the soil were in the same range as those found in the sampled orchard soils.

The applicant noted the absence of lower molecular weight PAHs in soils (naphthalene, 1-methylnapththalene, 2-methylnapththalene, acenaphthene, acenaphthylene, fluorene, anthracene and dibenz(a,h)anthracene). It is noted in the published literature that these types can degrade in soils more rapidly than the higher molecular weight PAHs[6] (ATSDR, 1995).

6 Agency for Toxic Substances and Disease Registry (ATSDR, 1995). Toxicological profile for polycyclic aromatic hydrocarbons, retrieved on 26/12/2014 from http://www.atsdr.cdc.gov/toxprofiles/index.asp

*Wood:* Wood analysis results are presented in Table A.11. The PAHs with the highest levels in wood were phenanthrene, fluoranthene and pyrene with levels at up to 2.3 %. These PAHs are also found in soil and fruit at higher levels. The analysis of PAHs in wood confirms that residues of most of the EFSA PAH8 are not found in the treated wood samples (of the EFSA PAH8, only benz(a)anthracene and chrysene are present in the creosote products). Chrysene was determined in the wood samples at up to 0.048%.

**Table A.11: Wood analysis results (2015) in %**

| Compound | Site 1 Loam -new (wood treated with creosote Grade B/C) | Site 2 Loam-old (wood treated with creosote Grade C) | Site 3 Clay -new (wood treated with creosote Grade C) | Site 4 Clay -old (wood treated with creosote Grade C) |
|---|---|---|---|---|
| Naphthalene | 0.037 | 0.052 | 0.004 | 0.014 |
| Acenaphthylene | 0.009 | 0.003 | 0.001 | 0.007 |
| Acenaphthene | 0.319 | 0.224 | 0.080 | 0.130 |
| Fluorene | 0.385 | 0.217 | 0.141 | 0.191 |
| Benzo[a]pyrene | Not detected | Not detected | Not detected | Not detected |
| Phenanthrene | 2.267 | 0.916 | 0.839 | 1.271 |

| | | | | |
|---|---|---|---|---|
| Anthracene | 0.136 | 0.111 | 0.055 | 0.090 |
| Fluoranthene | 1.958 | 0.579 | 0.543 | 0.989 |
| Pyrene | 1.160 | 0.300 | 0.296 | 0.536 |
| Benz[a]anthracene | 0.007 | 0.005 | 0.002 | 0.022 |
| Chrysene | 0.008 | 0.007 | 0.003 | 0.048 |
| Benzo[b+k]fluoranthene | Not detected | Not detected | Not detected | 0.001 |
| Benzo[a]pyrene | Not detected | Not detected | Not detected | Not detected |
| Benzo[e]pyrene | Not detected | Not detected | Not detected | Not detected |
| Benzo[g,h,i]perylene | Not detected | Not detected | Not detected | Not detected |
| Indeno[1,2,3-cd]pyrene | Not detected | Not detected | Not detected | Not detected |

| | | | | |
|---|---|---|---|---|
| Dibenz[a,h]anthracene | Not detected | Not detected | Not detected | Not detected |
| 1-Methylnaphthalene | 0.132 | 0.145 | 0.006 | 0.066 |
| 2-Methylnaphthalene | 0.073 | 0.073 | 0.004 | 0.046 |
| Sum of above GC volatiles | 6.5 | 2.4 | 2.0 | 3.4 |
| Total GC volatiles | 12.4 | - | 3.5 | - |

The wood results show absence of the EFSA PAH8 compounds aside from low levels of chrysene and Benz[a]anthracene which is as expected (based on the composition of the creosotes – Table A.1). The results do not seem to reflect a stark difference in the levels of naphthalene, 1-methyl naphthalene, and 2-methyl naphthalene noting that Table A.1 (on composition of the creosotes) shows that these components are present in higher amounts in creosote Grade B compared to creosote Grade C. These wood results do reflect that the main components in creosote products were found in these wood samples in the highest amounts, namely phenanthrene, fluoranthene and pyrene.

Conclusions:

The study showed that fruits in direct contact with the creosoted poles had significantly higher PAH levels, generally (with some variation for particular PAHs) an order of magnitude times higher than the PAH levels compared with fruits without pole contact.

It was shown that the highest residues of the PAHs found in fruit are phenanthrene, fluoranthene and pyrene which were also present in the highest levels in wood from stakes, and are the components present in highest amounts in the creosote products.

Although not fully clear-cut (especially as there were only two 'new' and two 'old' sampling sites considered in this study with different soil types), using old stakes tended to result in lower residues in fruit/soil than derived from the use of the new stakes. This indicates a possible concern for the residues that could arise in the proximity of the newer stakes (even before the 3 year timepoint if any of the fruits from such plants were to be commercially harvested for consumption). Please see section A.5.4 where the results across all the studies (studies 1 to 3) have been considered with age of creosoted wood stakes in mind.

Comparing the content of PAHs in soil from the roadside samples and the amount found in soil where creosote impregnated stakes are used shows that the levels are similar but possibly higher in soil from the roadside samples indicating that the soil exposures of PAHs often derive from 'natural'/anthropogenic background levels, e.g. soot deposition from cars/tractors passing. Some PAHs found at the roadside, i.e. benzo[b+k]fluoranthene, benzo[a]pyrene, benzo[g,h,i]perylene, indeno[1,2,3-cd]pyrene were not found in fruit, and do not appear to be related to use of creosote. For the components which are thought to be derived from creosote use (including phenanthrene, fluoranthene and pyrene), the PAH levels in soil at 25 cm from the stakes tended to be higher than in the soil at 5 m from the stakes, which indicate that the impregnated stakes cause an increased level of PAHs in soil in the vicinity. The difference in residues between the 5 m and 25 cm sampling from the wood posts were not very stark and within an order of magnitude. The levels of uptake into fruit, are low. It is difficult to know the precise source of the low level of residues in the 'non-contact fruit' whether the residues are occurring as a result of uptake from the soil in the areas around the base of the treated posts, or whether there is above ground transfer of residues arising from parts of the tree (fruit/wood) that might come into direct contact with the posts.

*A.5.2 Study 2 - Residues in apples (season 2019)*

Study title:

“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] 2020). Study number AUK-087. HSE remarks have been made in an annotated pdf version of the report.

GLP: field report to GLP - GLP compliance certificate for environmental fate test type (exception selection of field trial sites and farmer interviews); analytical work not to GLP.

A supplementary summary of the results was also provided in the pdf documents titled “Arcardis_AUK-087_Tables 1-3_AnalyticResults”, “Arcardis_AUK-087_Table 4_ResultsComparison” and “Arcadis_AUK-087_Table B_Compartimental PAH profiles”. These provided an amendment to some of the results tables presented in the GLP report. This represented a small number of amendments (names of analytes/alignment of results to correct analyte names) for the soil and fruit tabulated results.

Guidance:

No guideline was available at the time of conducting the study. Study test guidelines (on residues) are not available for biocides.

A draft guidance document ArtFood “DRAFT Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses” is now available (ECHA, draft published March 2022), which advises (section 5.7.4) on the need to address potential residues in foods arising from use of wood preservative treatments for wood posts used on supporting in vining plants and training systems for fruit trees.

The following pesticide regulatory guidelines were used where relevant (such as sampling aspects): OECD guidelines and guidance documents as listed in Commission Communication 2013/C 95/01and SANCO 7525/VI/95 - rev.10.3 (June, 2017).

Summary:

The study involved assessing levels of eighteen PAH (polycyclic aromatic hydrocarbon) compounds in apples from eight orchards/trial sites with use of fully creosoted wooden stakes across the UK and other parts of Northern Europe (Belgium , BE and Poland, PL) in 2019, together with background concentrations (analysed from two further apple orchard sites as controls). Treatment (dates stakes installed) and site history information was obtained from farmer interviews.

Soil taken (up to 25 cm soil depth) from the vicinity of the staked fruit trees were sampled and analysed, as well as soil from the control sites. Specific details were not given on the proximity of soil samples taken in relation to the wood posts in the ground. Further analyses were performed on creosoted wood (from the same sites)

to examine the PAH profile in the treated wood compared to the soil and fruit profiles.

The appendices of the report contain all the analytical data presented in this evaluation as laboratory analytical reports. For soil and fruit, although for most analytes covered (see section on analytical methods), accredited methods have been used, there are no data on concurrent validation demonstrating performance of the method on the occasions of the analyses. The GC method used for the wood samples was not stated to be covered by laboratory accreditation but the wood results can be regarded as indicative and do not need to be relied upon in this evaluation.

Following a 'randomised' sampling approach (not targeted to potential hotspots of contamination, see section on sampling), it can be seen that use of creosote-treated wooden stakes in apple orchards increases the presence of PAH residues in the fruit of the types that are found in the creosote products (and supported by the determination of residues in the wood samples).

The data suggest that there are low level residues of persistent PAH chemicals in all the soils, covering soil presence of PAHs beyond the types that are found in the creosote products, indicating anthropogenic sources beyond the use of creosote. Although precise information on the proximity of the soils taken compared to the wood stakes was not reported, it is observed that the soil residues in the 'treated' site soils are broadly of the same level and nature of the soil residues in the control sites.

It is possible that the elevated residues in crops are due to above ground transfer of residues from trees potentially touching the wood stakes to the fruits, in combination with possibly low level of uptake from the soil into the plants. It is difficult to know the precise way of residues occurring in the crops. The fruits sampled were considered not to have been in direct contact with the wood stakes (representing what is anticipated to be commercial practice). Even in these 'non-contact' fruit there were raised levels of PAHs (compared to the control sites, no creosote used), most notably of the types which are most prevalent in creosote products. There are some uncertainties in the data, but the data are acceptable to determine anticipated residue levels in 'treated crops'. The most prevalent substance in the fruits was phenanthrene, which comprised a large amount of the overall PAH level in 7 out of the treated 8 sites. The total PAH levels (PAH18) in the 'untreated' control sites (2) were 8 and 2 µg/kg, and the range of sum PAH18 for the other (eight) 'treated' sites were 20 to 99 µg/kg (average 70 µg/kg).

Methods

*Field phase*

The selected orchard sites (UK, BE and PL) and samplings were stated to be representative of commercial practice in the use of creosote-treated support wooden stakes in fruit cultivation. Please see the table A.12 which provides further details on the trial sites. The UK sites were located in Kent (various sites) as well as Herefordshire. The two field sites in Belgium were in separately located sites. The

samples of fruit were taken as a fairly randomised sample (see further details in the section on sampling) and were not biased towards apples or included apples that had come into direct contact with the wooden stakes. There were eight sites with creosote treated stakes and two further (UK) control sites (no creosote treated stakes).

The apple orchards sampled were of varying age and the age of the orchard reflected the time over which the creosote posts had been used (on the treated sites). The newest sites reflected 3, 4 and 5 years and the oldest orchard reflected 22 years of exposure. No statements were made about the way in which the posts were creosoted (no details provided on method and dose of application or product details (type/grade of creosote used) or whether the posts were only initially treated or subject also to re-treatment *in situ*. As this is an EU study, then it is anticipated that the creosote used will have been Grade B, Grade C or a mixture Grade B/C.

The characteristics of the sites are as outlined in Table A.12. Details were not provided on soil types, apple varieties or wood type (for the creosote stakes).

**Table A.12 Apple orchard site specifications (information from farmer interviews) – see notes below the table.**

| Sites | Country/trial site code | Control or creosote used | Grade of creosote used | Date orchard planted | Years of use of creosote stakes | Irrigation (When used, tended to be above ground trickle irrigation or drip irrigation) | Number of trees between stakes |
|---|---|---|---|---|---|---|---|
| Site 1 | UK<br>AUK-087-UK1 | Control | Control | 2015 | N/A | Yes | N/A |
| Site 2 | UK<br>AUK-087-UK2 | Creosoted wooden stakes used | Not stated | 1997 | 22 | Yes | No information |
| Site 3 | UK<br>AUK-087-UK3 | Creosoted wooden stakes used | Not stated | 2012 | 7 | Yes | Creosote-staked trees approximately every seven trees, with intervening trees staked with |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | | bamboo. |
| Site 4 | UK<br><br>AUK-087-UK4 | Creosoted wooden stakes used | Not stated | 2015 | 4 | Yes | Large diameter creosote-staked<br><br>trees approximately every 13 trees,<br><br>with smaller diameter creosote stakes supporting intervening trees. |
| Site 5 | UK<br><br>AUK-087-UK5 | Creosoted wooden stakes used | Not stated | Nov 2014 | 5 | No | No information |
| Site 6 | UK<br><br>AUK-087-UK6 | Control | Control | April 2019 | N/A | Yes | N/A |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Site 7 | UK<br>AUK-087-UK7 | Creosoted wooden stakes used | Not stated | 2010 | 9 | No | No information |
| Site 8 | Belgium<br>AUK-087-BE1 | Creosoted wooden stakes used | Not stated | 2010 | 9 | No | No information |
| Site 9 | Belgium<br>AUK-087-BE2 | Creosoted wooden stakes used | Not stated | 2009 | 10 | No | No information |
| Site 10 | Poland<br>AUK-087-PL1 | Creosoted wooden stakes used | Not stated | 2016 | 3 | Infrequent | No information |

Note: the creosote treated stakes were installed at the same time as the orchard unless stated otherwise. The site information also provided details of agronomic activities such as pruning

*Sampling*

Fruit, soil and wood samples were kept cool immediately after sampling and were stored frozen when they reached field study facility before shipment to the analytical laboratory in a frozen state. Samples of fruit and soil were shipped to the analytical testing facility (under frozen temperature conditions) within around 2 months and then analysed within a week of receipt at the laboratory. No mention is given to washing of samples, so it is assumed that all samples were not washed prior to analysis. Wood samples were analysed in a similar timeframe.

Soil: samples of approximately 1 kg were collected concurrently to the fruit sample dates (between 17 and 24 September 2019 across all the sites) at a shallow depth of up to 25 cm depth in the vicinity of each sampled tree using a hand trowel. Depth varied according to soil conditions (25 cm depth was typical). Bagged soil samples were shaken to obtain a thoroughly mixed sample. Prior to shipment to the analytical laboratory a soil sample (250 g) obtained from the base of each tree was combined with the soil from the other of the four trees sampled for that site to obtain an overall composite sample for the site. For the control site, AUK-087-UK6, only a single soil sample was collected.

Apples: Composite fruit samples were taken (between 17 and 24 September 2019 across all the sites) at crop maturity. At each site, samples were taken from four fruit bearing trees taken at random within the orchard. As such proximity of the apples to the stakes was not part of the selection process and the distances were not recorded. The aim was to obtain an at harvest sample that was representative of commercial practice in terms of a harvested ‘bulk lot’ from which the sample was obtained and was not targeted to obtain contamination hot-spots. From each tree sampled, a composite sample was taken comprising 16 pieces of fruit (four pieces from each approximate quarter of the tree were taken). Each sample was divided into 2 parts (each comprising 8 pieces of fruit). Just prior to shipment to the analytical laboratory a composite sample was made taking half the contents of the bagged samples (4 fruits) and placing this together with a similar sample taken from each of the four fruit bearing trees contributing to the sampling from each site, As such the final composite sample sent to the analytical facility comprised 16 fruits, four apples from each of four trees. The pesticide guidelines for field trial sampling (OECD, 509) indicates that a sample for pesticide analysis should comprise 12 apples from several places on 4 individual trees (and that if this produces a sample weight of less than 2 kg, more fruit should be taken to yield a 2 kg sample). As such the sampling approach followed is in line with this guideline approach.

At site AUK-087-UK6, the crop had not reached maturity and a single composite sample was obtained from numerous trees. This is one of the control sites. A single soil sample was also taken from this site.

Wood samples were taken from the creosoted wood stakes (8 trial sites) in place for each of the trees from which fruit samples (so 4 per trial site). No wood samples were taken at the control sites (no creosote used). Wood samples were obtained between 24 September 2019 and 11 November 2019 using a hand drill, comprising 2-3 wooden cores, approx. 2 cm diameter. Prior to shipment to the analytical

laboratory a single composite wood sample was formed for each trial site (13, 19 or 20 November). A single wood core from each of the original samples was used so that four wood cores made up the composite sample per trial site which was then analysed for residues.

*Proximity of stakes to fruit trees:* In the overview to the study, the applicant reported that the results reflected measured concentrations of PAHs in fruit, which had not been in contact directly with the support stake. The site details provided, only give limited details of frequency of stakes or geometries.

*Distance of soil and wood samples to fruit trees:* Depth of soil samples taken is stated above. Distance of the soil sample taken to the position of the creosote stake(s) in the ground was not stated in the report. It was however stated that wood samples were taken from creosote stakes "in place for each of the trees from which fruit were taken (four per site)" so all the fruit trees sampled had stakes nearby. However more specific information on site specific distances and stake geometries are not stated.

*Analytical methods*

The analysis of fruit, soil and wood was conducted at different analytical facilities.

Soil, fruit and wood samples were analysed for 18 PAH, which included the 16 EPA-priority PAH and 1- and 2-methylnaphthalene.

The information available on details of the analytical methods used and the validation criteria/whether accredited method are presented in Table A.13 below.

Fruit and soil samples were analysed 21 and 25/27 November 2019 (and PL soil sample 2 December 2019) respectively; samples were received in the laboratory typically up top a week prior to analysis. The samples for soil and fruit were taken concurrently between the 17 and 24 September 2019. Wood samples – analytical report date 4 December 2019 (within 1 to 2.5 months of sampling).

**Table A.13 Overview of analytical methods and accreditation status/scope and validation parameters provided**

| Component analysed | Analytical method | Reference and overview of method | GLP | Analytes determined | ISO 17025 certification of laboratory? | Scope of accreditation and associated remarks | Concurrent method validation provided, such as procedural recoveries | Validation parameters of the method | Form of analytical data |
|---|---|---|---|---|---|---|---|---|---|
| Soil | GC-HRMS | Details not provided. However, this seems to be the same method used for in the write up for the 2014/2015 apple and pear study.<br><br>Results sheets in analytical reports (in Dutch) states CMA/3/B for the analysis of the 16 EPA PAHs (Appendix 2) | No | 16 EPA priority PAHs and 1- and 2-methylnaphthalene<br><br>A single sample result per soil/site, covering all analytes | Yes<br><br>BELAC (Belgium) accreditation for the 16 EPA priority PAHs.<br><br>The report provides a link to the laboratories list of test methods accredited (BELAC cert no 052-TEST), including | 16 EPA priority PAHs | None - The analytical report for the samples does not contain validation data | None presented - The LOQs in the results were stated to be around 0.03 to 0.04 mg/kg ds (dry matter) and 0.02 mg/kg ds (dry matter) for 1-methylnapththalene and 2-methylnapththalene | Analytical reports (4) provided covering soil data. (Appendix 2)<br><br>Analytical results for 1-methylnapththalene and 2-methylnapththalene, also included in the report (but not within scope |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | analysis and results expressed on a dry weight basis. | | | this method for the 16 EPA PAHs in soil. | | | | of the accredited methods) |
| Wood | GC-FID | Analysed in accordance with EN 12490 and the resulting extracts were analysed using GC (see the write up for the 2014/2015 residues apple/pear study).<br><br>Certificate of analysis states WI 317 020 (as per write up for the 2014/2015 residues apple/pear study) | No | 16 EPA priority PAHs and 1- and 2-methylnaphthalene<br><br>(also benzo(e) pyrene) | Not stated | Not stated | No | LOQs and supporting validation data were not provided. Results appear to be reported above a detection limit of 0.001%.<br><br>(In the description of the method in Annex VIII it is stated that repeatability and reproducibility are to be determined; however, no data on repeatability of | Appendix 1 of the report includes the certificate of analysis (results) for GC results for the wood samples for each site |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | reproducibility have been presented) | |
| Fruit | GC-HRMS | Details not provided. However, this is the method used in the write up for the 2014/2015 apple and pear study.<br><br>Results sheets in analytical report states GC-MS/MS MIM-OR-017 (Appendix 3) | No | 16 EPA priority PAHs and 1- and 2-methylnaphthalene | Yes<br><br>BELAC (Belgium) accreditation for the trace analysis of numerous pollutants in food including PAHs. | 'the EFSA 2008 PAH8'<br><br>And<br><br>Fluoranthene<br><br>And<br><br>Pyrene<br><br>(EFSA PAH8 include benzo(a) anthracene; chrysene; benzo[b]fluoranthene, benzo[k]fluoranthene, | None - The analytical report for the samples does not contain validation data.<br><br>However, see HSE evaluation write up of the 2022 study (2020 cherry/plum samples) as this includes some validation data for this method by VITO (dated 30 August 2016) | None presented - The LOQs in the results were stated to be 0.5 µg/kg (or 0.5, 0.6, 0.7 or 0.8 µg/kg for naphthalene).<br><br>However, see HSE evaluation write up of the 2022 study (2020 cherry/plum samples) as this includes some validation data for this method by VITO (dated 30 August 2016) | Analytical reports provided. (Appendix 3 to the report) Statement of results (2019 trials data) |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | benzo[a]pyrene, benzo[g,h,i]perylene, indeno[1,2,3-cd]pyrene, and dibenzo[a,h]anthracene)<br><br>The report gives the results for the other relevant PAHs (not officially covered under the certified scope) as GC-MS/MS 'indicative result'.<br><br>Lab is | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | VITO which is the same laboratory as in the 2018 apple pear study report (2014 and 2015 analyses). In the 2018 report (2014/2015 analyses), it was explained that for these extra components, their analysis had internally been validated | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | by the very same method, and were therefore considered to be of similar reliability. | | | |

Note: of the hundreds of known PAHs, sixteen have been designated High Priority Pollutants by the Environmental Protection Agency (EPA); they include: naphthalene (NAP), acenaphthylene (ACY), acenaphthene (ACE), fluorene (FLU), phenanthrene (PHEN), anthracene (ANTH), fluoranthene (FLTH), pyrene (PYR), benzo[a]anthracene (B[a]A), chrysene (CHRY), benzo[b]fluoranthene (B[b]F), benzo[k]fluoranthene (B[k]F), benzo[a]pyrene (B[a]P), benzo[g,h,i]perylene (B[ghi]P), indeno[1,2,3-c,d]pyrene (IND), and dibenz[a,h]anthracene (D[ah]A). These 16 PAHs are of environmental concern because of their potential toxicity in humans and other organisms and their prevalence and persistence in the environment. As advised in Water Air Soil Pollut. 2012 Nov 1; 223(9): 5535–5548

Results

Residue levels in fruits, soil and wood are provided in Table A14, Table A.15, and Tables A.16.

**Table A.14 Residues in fruits. Results are expressed in µg/kg (as fresh weight). Sample date is given alongside the site. AUK-087-UK1-FT-c and AUK-087-UK6-FT-c represent control sites – no creosoted wood stakes. Sum PAH4 relates to sum of benzo(a)anthracene, chrysene, benzo(b)fluoranthene and benzo(a)pyrene.**

| Compound | AUK-087-BE1-FT-c 19/09/2019 | AUK-087-BE2-FT-c 19/09/2019 | AUK-087-PL1-FT-c 24/09/2019 | AUK-087-UK2-FT-c 17/09/2019 | AUK-087-UK3-FT-c 18/09/2019 | AUK-087-UK4-FT-c 18 - 19/09/2019 | AUK-087-UK5-FT-c 19/09/2019 | AUK-087-UK7-FT-c 23/09/2019 | AUK-087-UK1-FT-c 17/09/2019 | AUK-087-UK6-FT-c 18/09/2019 |
|---|---|---|---|---|---|---|---|---|---|---|
| Naphthalene | <0.7 | <0.7 | **16** | <0.6 | <0.5 | <0.5 | <0.6 | <0.8 | <0.6 | <0.5 |
| 1-Methylnaphthalene | <0.5 | <0.5 | **11** | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| 2-Methylnaphthalene | <0.5 | <0.5 | **31** | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Acenaphthylene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |

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|---|---|---|---|---|---|---|---|---|---|---|
| Acenaphthene | **0.64** | **0.77** | **6.5** | <0.5 | <0.5 | <0.5 | **1.2** | **0.54** | <0.5 | <0.5 |
| Fluorene | **2.8** | **2.3** | **3.4** | **0.79** | **1.4** | **2.5** | **6.9** | **2.5** | <0.5 | <0.5 |
| Phenanthrene | **59** | **50** | **4.7** | **15** | **36** | **69** | **81** | **57** | **6.6** | **1.8** |
| Anthracene | **0.67** | <0.5 | <0.5 | <0.5 | <0.5 | **0.55** | **0.71** | <0.5 | <0.5 | <0.5 |
| Fluoranthene | **19** | **14** | <0.5 | **3.6** | **7.7** | **10** | **7.4** | **14** | **1.2** | <0.5 |
| Pyrene | **4.5** | **2.2** | <0.5 | **0.61** | **1.5** | **1.9** | **1.3** | **2.6** | <0.5 | <0.5 |
| Benzo[a]anthracene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Chrysene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Benzo[b]fluoranthene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |

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|---|---|---|---|---|---|---|---|---|---|---|
| Benzo[k]fluoranthene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Benzo[a]pyrene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Indeno[1,2,3-cd]pyrene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Dibenzo[ah]anthracene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Benzo[ghi]perylene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Sum PAH4 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | <2 |
| Sum PAH | **87** | **69** | **73** | **20** | **47** | **84** | **99** | **77** | **8** | **2** |

**Table A.15 Residues in soil. Results are in are expressed in mg/kg (as dry weight). Sample date is given alongside the site. AUK-087-UK1-SL-c and AUK-087-UK6-SL-01 represent control sites – no creosoted wood stakes.**

| **Compound** | **AUK-087-BE1-SL-c 19/09/2019** | **AUK-087-BE2-SL-c 19/09/2019** | **AUK-087-PL1-SL-c 24/09/2019** | **AUK-087-UK2-SL-c 17/09/2019** | **AUK-087-UK3-SL-c 18/09/2019** | **AUK-087-UK4-SL-c 18 – 19/09/2019** | **AUK-087-UK5-SL-c 19/09/2019** | **AUK-087-UK7-SL-c 23/09/2019** | **AUK-087-UK1-SL-c 17/09/2019** | **AUK-087-UK6-SL-01 18/09/2019** |
|---|---|---|---|---|---|---|---|---|---|---|
| Naphthalene | <0.0312 | <0.0322 | <0.0363 | <0.0338 | <0.0350 | <0.0376 | <0.0348 | <0.0372 | <0.0360 | <0.0348 |
| 1-Methylnaphthalene | <0.02 | <0.02 | <0.02 | <0.02 | <0.02 | <0.02 | <0.02 | <0.02 | <0.02 | <0.02 |
| 2-Methylnaphthalene | <0.02 | <0.02 | **0.022** | <0.02 | <0.02 | <0.02 | <0.02 | <0.02 | <0.02 | <0.02 |
| Acenaphthylene | <0.0312 | <0.0322 | <0.0363 | <0.0338 | <0.0350 | <0.0376 | <0.0348 | <0.0372 | <0.0360 | <0.0348 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Acenaphthene | <0.0312 | <0.0322 | <0.0363 | <0.0338 | <0.0350 | <0.0376 | <0.0348 | <0.0372 | <0.0360 | <0.0348 |
| Fluorene | <0.0312 | <0.0322 | <0.0363 | <0.0338 | <0.0350 | <0.0376 | <0.0348 | <0.0372 | <0.0360 | <0.0348 |
| Phenanthrene | <0.0312 | **0.066** | **0.0445** | **0.196** | **0.191** | <0.0376 | **0.208** | **0.0773** | **0.125** | **0.116** |
| Anthracene | <0.0312 | <0.0322 | <0.0363 | **0.0431** | <0.0350 | <0.0376 | <0.0348 | <0.0372 | <0.0360 | <0.0349 |
| Fluoranthene | **0.0539** | **0.109** | **0.237** | **0.483** | **0.435** | **0.148** | **0.606** | **0.224** | **0.249** | **0.22** |
| Pyrene | **0.0406** | **0.0877** | **0.221** | **0.424** | **0.356** | **0.142** | **0.536** | **0.169** | **0.214** | **0.206** |
| Benzo[a]anthracene | <0.0312 | **0.0539** | **0.129** | **0.221** | **0.145** | <0.0376 | **0.213** | **0.081** | **0.137** | **0.095** |
| Chrysene | **0.0359** | **0.0652** | **0.155** | **0.26** | **0.235** | **0.0564** | **0.299** | **0.128** | **0.172** | **0.123** |
| Benzo[b]fluoranthene | **0.0394** | **0.0644** | **0.142** | **0.25** | **0.252** | <0.0400 | **0.299** | **0.13** | **0.173** | **0.127** |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Benzo[k]fluoranthene | **0.0197** | **0.0322** | **0.0708** | **0.125** | **0.126** | **0.02** | **0.15** | **0.0652** | **0.0866** | **0.0636** |
| Benzo[a]pyrene | <0.0312 | **0.0515** | **0.155** | **0.229** | **0.191** | **0.0395** | **0.273** | **0.102** | **0.167** | **0.11** |
| Indeno[1,2,3-cd]pyrene | <0.0312 | **0.0442** | **0.127** | **0.16** | **0.172** | <0.0376 | **0.247** | **0.0838** | **0.145** | **0.0915** |
| Dibenzo[ah]anthracene | <0.0312 | <0.0322 | <0.0363 | **0.0372** | **0.0367** | <0.0376 | **0.0522** | <0.0372 | **0.036** | <0.0349 |
| Benzo[ghi]perylene | <0.0312 | **0.0394** | **0.125** | **0.161** | **0.161** | <0.0376 | **0.226** | **0.0875** | **0.136** | **0.0959** |
| Sum 16 PAH | **0.189** | **0.614** | **1.41** | **2.59** | **2.3** | **0.406** | **3.11** | **1.15** | **1.64** | **1.25** |

**Table A.16 Residues in wood for each of the sites with creosoted wood stakes. Site, sample date and year the stake was installed (as per farmer interviews) is given. Results expressed in % (w/w); as such results can be multiplied by 10,000 to give mg/kg results. [0.0081% represents 81 mg/kg and 0.578% represents 5780 mg/kg].**

| Compound | AUK-087-BE1-WD-c<br>01/10/2019<br>2010 | AUK-087-BE2-WD-c<br>01/10/2019<br>2009 | AUK-087-PL1-WD-c<br>24/09/2019<br>2016 | AUK-087-UK2-WD-c<br>29/10/2019<br>1997 | AUK-087-UK3-WD-c<br>30/10/2019<br>2012 | AUK-087-UK4-WD-c<br>31/10/2019<br>2015 | AUK-087-UK5-WD-c<br>01/11/2019<br>2014 | AUK-087-UK7-WD-c<br>11/11/2019<br>2010 |
|---|---|---|---|---|---|---|---|---|
| Naphthalene | **0.0081** | **0.0016** | **0.0108** | <0.001 | **0.0031** | <0.001 | **0.0015** | **0.0026** |
| 1-Methylnaphthalene | **0.0439** | **0.0042** | **0.0496** | <0.001 | **0.0036** | <0.001 | <0.001 | **0.0187** |
| 2-Methylnaphthalene | **0.0242** | **0.0032** | **0.0247** | <0.001 | **0.0022** | <0.001 | <0.001 | **0.0178** |
| Acenaphthylene | **0.0022** | **0.0003** | **0.0041** | **0.0033** | **0.0011** | <0.001 | **0.0016** | **0.0016** |
| Acenaphthene | **0.0713** | **0.0102** | **0.0581** | **0.0495** | **0.0309** | <0.001 | **0.0439** | **0.0555** |
| Fluorene | **0.0953** | **0.0113** | **0.0413** | **0.1189** | **0.1015** | **0.0291** | **0.2146** | **0.086** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Phenanthrene | **0.578** | **0.0828** | **0.1018** | **0.7177** | **0.6858** | **0.2721** | **0.12346** | **0.5437** |
| Anthracene | **0.0276** | **0.0043** | **0.0128** | **0.0618** | **0.0447** | **0.0128** | **0.0963** | **0.0204** |
| Fluoranthene | **0.4675** | **0.0853** | **0.0171** | **0.454** | **0.4918** | **0.202** | **0.568** | **0.3496** |
| Pyrene | **0.2556** | **0.0436** | **0.0067** | **0.2277** | **0.2742** | **0.0953** | **0.2714** | **0.1602** |
| Benzo[a]anthracene | **0.0023** | **0.0007** | **0.003** | **0.0087** | **0.0015** | **0.0002** | **0.0045** | **0.0035** |
| Chrysene | **0.0018** | **0.0027** | **0.0007** | **0.0126** | **0.001** | **0.0014** | **0.0039** | **0.0038** |
| Benzo[b+k]fluoranthene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | **0.0044** | <0.001 | <0.001 |
| Benzo[e]fluoranthene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Benzo[a]pyrene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Indeno[1,2,3-cd]pyrene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Dibenzo[h]anthracene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Benzo[ghi]perylene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Total | **1.5778** | **0.2499** | **0.3308** | **1.6543** | **1.6415** | **0.6137** | **2.4403** | **1.2633** |

*Fruit*

The results in fruit show that none of the eight carcinogenic PAHs recommended by EFSA for food control, EFSA, Scientific Opinion 2008 were found in any of the apples (above 0.5 µg/kg): namely benz[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[g,h,i]perylene.

In the control sites, the only positive residues found were phenanthrene (up to 6.6 µg/kg) and fluoranthene (up to 1.2 µg/kg).

Residues of PAHs (but not including the 'EFSA PAH8') were found at determinable levels in the fruits from the 'treated' sites (use of creosoted wood stakes in the orchards). The highest residues found were of phenanthrene (up to 81 µg/kg) and fluoranthene (up to 19 µg/kg):

The applicant stated that the findings of PAHs in fruits from 'treated sites' typically comprised the mid-range PAHs including phenanthrene (HR of 81 µg/kg =0.081 mg/kg), fluoranthene (HR of 19 µg/kg =0.019 mg/kg), fluorene (HR of 6.9 µg/kg =0.0069 mg/kg, acenaphthene (HR of 6.5 µg/kg =0.0065 mg/kg), pyrene (HR of 4.5 µg/kg =0.0045 mg/kg) and anthracene (HR of 0.71 µg/kg =0.00071 mg/kg). As the main component found in the treated fruits, phenanthrene comprised 70-80% of the PAH residue determined.

The applicant reported the sum of PAHs in fruits determined for each site, see Table A.14. The levels of sum PAH in the 'untreated' control sites (2) were 8 and 2 µg/kg, and the range of sum PAH for the other (eight) 'treated' sites were 20 to 99 µg/kg (average 70 µg/kg). Therefore, use of creosoted wood stakes does increase the residues in fruits compared to background levels, even when fruits directly in contact with the fruit stakes have not been sampled. If fruits that had been in contact with the wood stakes had been sampled then the residues would be expected to be higher (as indicated in study 1).

As the information on the treatment (product, application rate) of the creosoted wood stakes is not available, it is difficult to comment on whether the compounds found reflects the types/grades of creosote used. However, information on the nature of components which the wood stakes expose the fruit trees to, can be obtained from the wood analyses.

Levels found in the fruit tend to match the patterns of PAHs determined in the individual wood samples. For example, phenanthrene and fluoranthene were found at relatively lower levels in the fruits taken from the Polish orchard site, and the wood sample results for these components was on the lower end level results reported for this site, compared to the other sites. This (PL) was the only site that naphthalene, 1-methyl naphthalene, and 2-methyl naphthalene were found in the fruits (at 16, 11 and 31 µg/kg respectively) and the wood analysis showed that these components were at highest levels in these wood samples. These were the most recently treated creosote stakes (3 years; stakes installed in 2016).

The precise means of how the residues arose in the fruits (non-contact) is not known, whether from low level uptake via the soil, or, in the main, by upper plant part tree contact with wood stakes and transference of the residues into the fruit (which has not come into contact with the wood stakes).

On occasion, a relatively high residue in fruit accompanied both a residue finding in the soil and wood sampled:

e.g. site UK5 phenanthrene 81 µg/kg in fruit, 0.21 mg/kg dw in soil, and 0.123% in wood

On occasion, a relatively high finding in fruit accompanied a wood finding but less so a determined level in soil:

e.g. site BE1 phenanthrene 59 µg/kg in fruit, < LOQ of 0.0312 mg/kg dw in soil, and 0.578% in wood

*Wood:*

In terms of the 'EFSA PAH8' only low levels (in % w/w) were determined in the wood samples:

benz[a]anthracene up to 0.0087%

chrysene up to 0.0126%

benzo[b]fluoranthene and benzo[k]fluoranthene up to 0.0044%

benzo[a]pyrene – none found (<0.001%)

indeno[1,2,3-cd]pyrene - none found (<0.001%)

dibenzo[a,h]anthracene - none found (<0.001%)

benzo[g,h,i]perylene - none found (<0.001%)

Of the above components, it is only benz[a]anthracene and chrysene which are present in low amounts in the European creosotes.

The highest amounts (%) in wood of the other (non 'EFSA PAH8') components in which residues were found in wood are: phenanthrene (0.718), fluoranthrene (0.568), pyrene (0.27), fluorene (0.215), anthracene (0.0963), acenaphthene (0.071), 1-methyl naphthalene (0.050), 2-methyl naphthalene (0.025), naphthalene (0.011), and acenaphthylene (0.0041).

Therefore, the applicant concluded that the PAHs in the wood mainly comprised the mid- to -light range molecular mass PAHs, with little or none of the heavier range PAHs.

Some of the wood results show presence of naphthalene, 1-methyl naphthalene, and 2-methyl naphthalene suggesting that possibly Grade B (or a mixture Grade B/C) had been used in some of the sites (e.g. highest levels of these in the trial site in Poland, PL). Conversely, some sites showed absence of these components (naphthalene, 1-methyl naphthalene, and 2-methyl naphthalene) e.g. site UK2 and UK4, so creosote Grade C might have been used at these sites, when taking account of the composition of the various creosotes (Table A.1).

However, the report does not give details of the form of creosote used at each site.

*Soil:*

Given that details of the distance of soil taken from the wood stakes is not specifically reported, it is difficult to draw too many conclusions from the soil results, though it is clear that soil was taken in the vicinity of the fruit trees/stakes (see above description of sampling details). Whilst there are variations in the data, the results are broadly comparable in terms of residue levels reported for the 'treated site' soils and the control site soils. This can be seen by the comparison of sum PAH16 reported by the applicant (as per Table A.15) for each of the soils. The range of sum PAH16 in soils for the eight 'treated' sites is 0.4 to 3.1 mg/kg dw, with an average of 1.5 mg/kg dw. The results for sum PAH16 for the two control sites (no creosoted wood stakes) was 1.6 and 1.3 mg/kg dw respectively.

This data is evidence that background levels of PAH do exist in soils and that soil residues observed in the treated sites were similar in nature and amount to these background soil exposures.

As residues are generally higher in the (non-contact) fruits in the treated sites compared to the non-treated sites (no creosote stakes), it could be possible that above ground transfer of residues (from wood touching the trees) in fruit trees occurs (possibly in addition to only low uptake of residues from the soil).

*A.5.3 Study 3 - Residues in cherries and plums (season 2020)*

Study title:

"Magnitude of the Residue Determination of Polycyclic Aromatic Hydrocarbons (PAH) Following the use of Creosote Treated Wooden Stakes on Stone Fruit Trees in the United Kingdom" ([redacted] 2022). Study number AUK-090. HSE remarks have been made in an annotated pdf version of the report.

GLP: field report to GLP - GLP compliance certificate for environmental fate test type (exception selection of field trial sites and farmer interviews); analytical work not to GLP.

Guidance:

No guideline was available at the time of conducting the study. Study test guidelines (on residues) are not available for biocides.

A draft guidance document ArtFood " DRAFT Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses" is now available (date March 2022), which advises (section 5.7.4) on the need to address potential residues in foods arising from use of wood preservative treatments for wood posts used on supporting in vining plants and training systems for fruit trees.

The following pesticide regulatory guidelines were used where relevant (such as sampling aspects): OECD guidelines and guidance documents as listed in Commission Communication 2013/C 95/01and SANCO 7525/VI/95 - rev.10.3 (June, 2017).

Summary:

The study involved assessing levels of eighteen PAH (polycyclic aromatic hydrocarbon) compounds in stone fruits from six cherry and one plum orchard/trial sites with use of fully creosoted wooden stakes across the UK in 2020. Treatment and site history information was obtained from farmer interviews. There were also further sites as controls, in order to determine background concentrations (analysed from two different control sites- one cherry and one plum). These were chosen to be in the vicinity of the test sites to minimise variances in background PAHs present.

Soil taken (15 to 40 cm depth) from the vicinity of the staked fruit trees were sampled and analysed, as well as soil from the control sites. Specific details were not given on the proximity of soil samples taken in relation to the wood posts in the ground. Further analyses were performed on creosoted wood (from the same sites) to examine the PAH profile in the treated wood compared to the soil and fruit profiles.

The appendices of the report contain all the analytical data presented in this evaluation as laboratory analytical reports. For soil and fruit, although for most analytes covered (see section on analytical methods), accredited methods have been used, there are no data on concurrent validation to support performance of the method on the occasions of the analyses. The GC method used for the wood samples was not stated as being covered by laboratory accreditation but the wood results can be regarded as indicative and do not need to be relied upon in this evaluation.

For this study, two different laboratories were used for the analysis of fruit samples. The reason for this is that for the initial analysis there was a result (site UK1) that had a markedly higher residue than the other sites and it was questioned whether this could be an outlier. The initial laboratory (lab 1) could not re-run the samples, so all (back up) samples for the sites were sent to lab 2 for analysis. The data for lab 1 and lab 2 are both presented in this evaluation in tables A.19, A.20, and A.21. It is difficult to conclude on outlier data and so all data from this study (combined with the other fruit tree studies) were taken forward into HSE's risk assessment. The UK1 site is the only ('treated' site) that is plum; the other 'treated' sites in study 3 are cherry, so it is very difficult to consider whether the lab1 results for site UK1 do represent an outlier.

Following a 'randomised' sampling approach (not targeted to potential hotspots of

contamination, see section on sampling), it can be seen that use of creosote-treated wooden stakes in plum and cherry orchards can increase the presence of PAH residues in the fruit of the types that are found in the creosote products (and supported by the determination of residues in the wood samples). Residues of some PAH components can be raised in the non-contact fruits (compared to the controls) but not in a consistent fashion.

The data suggest that there are low level residues of persistent PAH chemicals in all the soils, covering soil presence of PAHs beyond the types that are found in the creosote products, indicating anthropogenic sources beyond the use of creosote. Although precise information on the proximity of the soils taken compared to the wood stakes was not reported, it is observed that the soil residues in the 'treated' site soils are broadly of the same nature of the soil residues in the control sites. The residues in the 'treated soils' are somewhat raised compared to the control sample soil residues, but not very markedly so.

It is possible that elevated residues observed in crops are due to above ground transfer of residues from trees potentially touching the wood stakes to the fruits, in combination with possibly low level of uptake from the soil into the plants. It is difficult to know the precise way of residues occurring in the crops. The fruits sampled were considered not to have been in direct contact with the wood stakes (representing what is anticipated to be commercial practice). Even in these 'non-contact' fruit there were some raised levels of some PAHs (compared to the control sites, no creosote used), most notably of the types which are most prevalent in creosote products. In this particular study (different compared to the other studies) phenanthrene, a main component, seemed to be present at the same amounts in control sites compared to the treated sites for lab 2 determinations but with raised levels of phenanthrene in two sites for the lab 1 determinations.

There are some uncertainties in the data, but the data are acceptable to determine anticipated residue levels in 'treated crops'. The most prevalent substance in the fruits were phenanthrene, pyrene, fluorene, acenaphthene, fluoranthene and 2-methyl naphthalene. The total PAH levels (PAH18) in the 'untreated' control sites (2) were 22 (30 lab 1) µg/kg and 10 µg/kg, and the range of sum PAH18 for the other (seven) 'treated' sites were lab 1- 10 to 271 µg/kg (average 65 µg/kg) and lab 2- 15 to 32 µg/kg (average 22 µg/kg).

Methods

*Field phase*

The selected UK orchard sites and samplings were considered to be representative of commercial practice in the use of creosote-treated support wooden stakes in fruit cultivation. Please see table A.17 which provides further details on the trial sites. The UK sites were located in Kent (various sites) as well as Herefordshire (trial AUK-090-UK9). The samples of fruit were taken as a fairly randomised sample (see further details in the section on sampling) and were not biased towards cherries or plums that had come into direct contact with the wooden stakes. There were seven sites with creosote treated stakes (6 cherry + 1 plum) and two further (UK) control sites (no creosote treated stakes (1 cherry + 1 plum).

The orchards sampled were of varying age and the age of the orchard usually reflected the time over which the creosoted posts had been used (on the treated sites). The only exception to this was the newest site reflecting 3 years, and in this case the creosoted posts had been in the ground for 5 years, installed two years before the planting of the new orchard in 2017. This site (9) was selected to represent a newly planted but producing orchard. The oldest orchard reflected 14 years of exposure. No statements were made about the way in which the posts were creosoted (no details on method of application/dose and product details (type/grade of creosote used) or whether the posts were only initially treated or subject also to re-treatment *in situ*.

The aim of having orchards/creosoted stakes of varying age was to determine whether potential contamination of fruits would vary depending on the age of the orchards. Control sites (one plum and one cherry) were selected to be in close proximity to the test sites to minimise variance in potential background PAH load from external sources, such as nearly roads or industrial exposure. The applicant pointed to an Environment Agency report (2021) which states that PAH are ubiquitous in soils in the UK, as a result of both natural and industrial sources[7] (Environment Agency, 2021).

The characteristics of the sites are as outlined in Table A.17. Details were not provided on soil types, crop varieties or wood type (for the creosote stakes). Details on geometry of stakes (V stakes or individual stakes etc) or frequency of stakes amongst the trees were not provided. The wood stakes sampled for this study were approximately 10 cm diameter by 2m height.

7 Environment Agency, 2021, Polycyclic Aromatic Hydrocarbons (PAHs): Challenges for the Environment, HMSO. https://www.gov.uk/government/publications/polycyclic-aromatic-hydrocarbonspahs-challenges-for-the-water-environment

**Table A.17 Orchard site specifications (information from farmer interviews) – see notes below the table.**

| Sites | Trial site code | Crop | Control or creosote used | Grade of creosote used | Date orchard planted | Years of use of creosote stakes | UK location |
|---|---|---|---|---|---|---|---|
| Site 1 | AUK-090-UK1 | Plum | Creosoted wooden stakes used | Not stated | 2006 | 14 | Kent |
| Site 2 | AUK-090-UK2 | Cherry | Creosoted wooden stakes used | Not stated | 2006 | 14 | Kent |
| Site 3 | AUK-090-UK3 | Cherry | Creosoted wooden stakes used | Not stated | 2011 | 9 | Kent |
| Site 4 | AUK-090-UK4 | Cherry | Creosoted wooden stakes used | Not stated | 2011 | 9 | Kent |
| Site 5 | AUK-090-UK5 | Cherry | Creosoted wooden stakes used | Not stated | 2011 | 9 | Kent |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Site 6 | AUK-090-UK6 | Cherry | Creosoted wooden stakes used | Not stated | 2011 | 9 | Kent |
| Site 7 | AUK-090-UK7 | Plum | CONTROL | CONTROL | 2019 | N/A | Kent |
| Site 8 | AUK-090-UK8 | Cherry | CONTROL | CONTROL | 2008 | N/A | Kent |
| Site 9 | AUK-090-UK9 | Cherry | Creosoted wooden stakes used | Not stated | 2017 | 3 (5) | Herefordshire |

Notes: the creosote treated stakes were installed at the same time as the orchard unless stated otherwise. Drip irrigation was used at all sites. Although (site 9) the orchard was installed in 2017, the creosote treated stakes were installed in 2015 prior to the orchard being replanted in 2017. Site 9 was selected as a site which was newly planted, yet producing orchard. This site was planted 3 years before sampling, with the creosote-treated stakes being in the ground from two years prior.

No information was provided on the number of trees between the creosoted stakes or other features related to geometry.

*Sampling*

Fruit, soil and wood samples were kept cool immediately after sampling and were stored frozen when they reached field study facility before shipment to the analytical laboratory in a frozen state.

Due to an issue with the analytical testing that was undertaking the crop residue analysis a further set of fruit samples (available as a backup option from the freezer as described in the study) was shipped to a second analytical testing facility (under frozen temperature conditions).

Samples of fruit (initial samples analysed by VITO, lab 1) and soil were shipped to the analytical testing facility (under frozen temperature conditions) and analysed within around 2.5 months. The second laboratory analysing the samples (BIEC) analysed UK1 and UK2 (first analyses) at around 7 months after sampling. BIEC also analysed the fruits (all samples) at around 1 year after sampling. No mention is given to washing of samples, so it is assumed that all samples were not washed prior to analysis. Wood samples were analysed after a period of 6-7 months post sampling.

Further information to support an understanding of the storage stability of the residues between sampling and analysis was not available. Due to an analytical issue with lab 1, a whole new set of samples from each site which formed the later shipment were analysed (by lab 2). The lab 2 data were a retained freezer sample for each site, where the sample was obtained at the same time as the initial sample. All the data were presented in the study report, and none of the trial results have been excluded from the data analysis of residues reported in section A.5.4. Please refer to section A.4 which discusses the issue of storage stability of residues in samples, and associated analytical uncertainties. There could be some instability of residues reflected in the results, but this is not certain.

Soil: samples of approximately 1 kg were collected concurrently to the fruit sample dates at a shallow depth of between 15 and 40 cm (typically around 25 cm only due to hard ground) depth in the vicinity of each sampled tree using a hand trowel. Depth varied according to soil conditions. Distance of the soil sample taken to the position of the creosote stake(s) in the ground was not stated. It was however stated that wood samples were taken from creosote stakes “in place for each of the trees from which fruit were taken (four per site)” so all the fruit trees sampled had stakes nearby. Bagged soil samples were shaken to obtain a thoroughly mixed sample. Prior to shipment to the analytical laboratory a soil sample (250 g) obtained from the base of each tree was combined with the soil from the other of the four trees sampled for that site to obtain an overall composite sample for the site.

Plums/cherries: Composite fruit samples were taken (between 20 and 27 July 2020 across all the sites) at crop maturity. Samples were taken from four fruit bearing trees taken at random within the orchard. As such proximity of the plums or cherry trees to the stakes was not part of the selection process and the distances were not recorded. The aim was to obtain an at harvest sample that was representative of commercial practice in terms of a harvested ‘bulk lot’ from which the sample was

obtained and was not targeted to obtain contamination hot-spots. The report stated that no pieces of fruit were discarded based on discolouration or visual differences, and that further, due to the nature of the trees, none of the fruit was grown in direct contact with the stakes.

From each tree samples, a composite sample was taken comprising a minimum of 16 pieces of fruit (four pieces from each approximate quarter of the tree were taken). Each sample was divided into 2 parts (each comprising 8 pieces of fruit). Just prior to shipment to the analytical laboratory a composite sample was made taking half the contents of the bagged samples (4 fruits) and placing this together with a similar sample taken from each of the four fruit bearing trees contributing to the sampling from each site, As such the final composite sample sent to the analytical facility comprised 16 fruits, four fruits from each of four trees. The pesticide guidelines for field trial sampling (OECD, 509) indicates that a sample for pesticide analysis for plums should comprise 12 fruits from several places on 4 individual trees (and that if this produces a sample weight of less than 2 kg, more fruit should be taken to yield a 2 kg sample). As such the sampling approach for plums followed is in line with this guideline approach. For small stone fruit, such as cherries, OECD 509 recommends that 1 kg should be taken from several places on the trees. A total of 16 cherries is likely to be a small sample size in weight, well below 1 kg (1 cherry might weight between 4 and 20 g depending on its size). The sampling approach for cherries led to a low weight of sample (not recorded in the study).

Wood samples from the creosoted wood stakes (7 trial sites) in place for each of the trees from which fruit samples were taken (4 per trial site). No wood samples were taken at the control sites (no creosote used). Wood samples were obtained between 20 and 27 July 2020 using a hand drill, comprising 2-3 wooden cores, approx. 2 cm diameter taken from different points on each of the support stakes and an approximately 15 cm long section was removed from the top of the stake using a saw. Prior to shipment to the analytical laboratory a single composite wood sample was formed for each trial site. A single wood core from each of the original (core) samples was used as well as one of the long sections so that four wood cores and one section made up the composite sample per trial site which was then analysed for residues.

*Proximity of stakes to fruit trees:* In the overview to the study, the applicant reported that the results reflected measured concentrations of PAHs in fruit, which had not been in contact directly with the support stake.

*Distance of soil and wood samples to fruit trees:* Depth of soil samples taken is stated above. Distance of the soil sample taken to the position of the creosote stake(s) in the ground was not stated in the report. It was however stated that wood samples were taken from creosote stakes “in place for each of the trees from which fruit were taken (four per site)” so all the fruit trees sampled had stakes nearby. However more specific information on site specific distances and stake geometries are not stated.

*Analytical methods*

The analysis of fruit, soil and wood was conducted at different analytical facilities.

During the laboratory analysis (original laboratory, VITO – lab 1), a possible outlier was obtained for the sample from AUK-090-UK1 (a plum orchard study site), showing detections an order of magnitude higher (sum PAH concentration of 270.9 µg/kg) than those measured in the other site samples. When contacted to arrange for the reanalysis of this sample to confirm the results, the laboratory indicated they could not complete this further work. Samples for the possible outlier (UK1) and another sample (UK2) were instead sent to a second laboratory (BIEC, lab 2) and showed results (for UK1 and UK2) in the same order of magnitude as one another.

As such, a full set of new composite samples taken from the freezer from the field facility were sent to lab 2. The results of the second set of samples analysed as undertaken by the second laboratory showed the detections measured at site AUK-090-UK1 to be the same order of magnitude as those measured at the other test sites, whilst the results obtained from the remaining eight sites were broadly in line with the results from lab 1 (with still some variance). In addition, lab 2 undertook a duplicate analysis for AUK-090- UK1, which showed similar results. As such, the initial lab 1 result for site AUK-090-UK1 is considered by the applicant to be erroneous. There are some variations in results presented for some limited samples analysed both in February 2021 and July 2021 by lab 2 (see Table A.20). It is difficult to decide if the results for lab 1 for site UK1 are an outlier. This sample is a treated plum sample, whereas all the other treated results across the other treated sites were for cherries. All results for lab 1 and lab 2 were provided in the report and are provided in this evaluation.

Fruits analysis by lab 2 were stated to have been undertaken by GC-MS following the method described by [redacted] et al., 1997[8]. The laboratory is certified by the German Society for Fat Science (Deutsche Gesellschaft für Fettwissenschaft e.V. (DGF)). The analytical report, for the full repeat analysis work using test method PAH - 0397, includes signed test reports by lab 2 for each sample. These data include a larger number of PAH substances. The laboratory (lab 2) did not explain how the LOQs were derived or provide validation data for analysis in fruits. They provided a certificate of participation in Proficiency Tests dated 2020 in which analysis of PAH contaminants were included.

Some method validation data were made available only by lab 1 (VITO) to support their analytical work. See a summary below the overview of methods table below. This was not carried out concurrently to the analyses done for the samples in this report (the validation work was reported on 30 August 2016). As some variation in residue results has been observed, HSE would prefer the data to be supported by

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8 [redacted] 1997, Atmospheric Emission of Polycyclic Aromatic Hydrocarbons in Sampling Areas of the German Environmental Specimen Bank. Method for the Precise Measurement of Gaseous and Particle-Associated Polycyclic Aromatic Hydrocarbons in the Sub-Nanogram Range Using Deuterated Internal Standards, Chemosphere, Vol. 34.

method validation and procedural validation data for the determination by each of the laboratories to support the determination of the PAH residues in the fruits. The proficiency test participation certificate for laboratory 2 covers the chemical analysis of PAH contaminants.

Soil, fruit and wood samples were analysed for 18 PAH, which included the 16 EPA-priority PAH and 1- and 2-methylnaphthalene (aside from soil which did not include analysis of 1- and 2-methylnaphthalene).

Soil analysis was stated to have been undertaken by GC-HRMS based on methods CMA_3_B version 13.01.2020 and CMA_2_II_A.1 version 13.01.2020 (http://www.emis.vito.be) with the laboratory ISO 17025 certified as well as holding BELAC accreditation (Belgian scheme) for the 16 US PAH.

Wood was analysed by GC-FID (flame ionization detection).

In terms of analytical report, this was by way of provision of certificates of analysis were provided for wood, soil (in Dutch) and fruits. Full details of the analytical methods were not provided in this study report. A brief overview of the GC-MS soil method (in Dutch) was provided, but without a translation into English.

Wood: The certificates of analyses included an analytical results for each wood sample. This indicates that the method of analysis is same (GC-FID) as that described in Study 1 (section A.5.1). The tabular overview results in the report represented an LOQ of 0.001% for wood.

Soil: The certificates of analyses included an analytical results for each soil sample. The tabular overview results in the report represented an LOQ of <0.032 to <0.037 mg/kg (dry matter basis) for the 16 PAH components (please see tables of results for full details).

Fruit: The certificates of analyses included an analytical results for each fruit sample. Lab 2 reported results with a very low LOQ (e.g. <0.019, <0.042 and <0.011 µg/kg ) for the 'EFSA PAH8' substances . The results for lab 2 reported very low level positive detections of the 'EFSA PAH8' compounds at levels that were all below 0.5 µg/kg, which was the LOQ for lab 1.

A summary of the information available on details of the analytical methods used and the validation criteria/whether accredited method are presented in Table A.18 below.

Samples were kept frozen prior to analysis, and samples were kept frozen during shipment. Fruit samples were taken July 2020. Laboratory 1 analyses were done in October 2020. Repeat analysis work - Laboratory 2 analyses were done in February 2021 and July 2021. Please refer to section A.4 which discusses storage stability of residues.

**Table A.18 Overview of analytical methods and accreditation status/scope and validation parameters provided**

| Component analysed | Analytical method | Reference and overview of method | GLP | Analytes determined | ISO 17025 certification of laboratory? | Scope of accreditation and associated remarks | Concurrent method validation provided, such as procedural recoveries | Validation parameters of the method | Form of analytical data |
|---|---|---|---|---|---|---|---|---|---|
| Soil | GC-HRMS | Details not provided.<br><br>This is same method (CMA/3/B) used for in the write up for the 2014/2015 apple and pear study and 2019 apple study. | No | 16 EPA priority PAHs<br><br>A single sample result per soil/site, covering all analytes<br><br>(not including 1-methylnapth | Yes<br><br>BELAC (Belgium) accreditation for the 16 EPA priority PAHs.<br><br>The report provides a link to the laboratories list of test methods accredited (BELAC cert no 052- | 16 EPA priority PAHs | None - The analytical report for the samples does not contain validation data | None presented - The LOQs in the results were stated to be around 0.03 to 0.04 mg/kg ds (dry matter) | Analytical report provided covering soil data. (Appendix 4) |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Results sheets in analytical reports (in Dutch) states CMA/3/B for the analysis of the 16 EPA PAHs (Appendix 4) analysis and results expressed on a dry weight basis. | | thalene and 2- 1-methylnapth thalene as extra to the 16 EPA PAHs). | TEST), including this method for the 16 EPA PAHs in soil. | | | | |
| Wood | GC-FID | Certificate of analysis states code WI 317 020 (as per write up for the | No | 16 EPA priority PAHs and 1- and 2-methylnapht halene | Not stated | Not stated | No | LOQs and supporting validation data were not provided. Results appear to | Appendix 3 of the report includes the certificate of analysis (results) |

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|---|---|---|---|---|---|---|---|---|---|
| | | 2014/2015 residues apple/pear study) and code CEN TC 317 and code WG2<br><br>Methodology assumed to be the same as for the earlier residues studies (2018 and 2020 reports):<br><br>Analysed in accordance with EN 12490 and the resulting extracts | | (also benzo(e ) pyrene) | | | | be reported above a detection limit of 0.001%. | for GC results for the wood samples for each site |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | were analysed using GC (see the write up for the 2014/2015 residues apple/pear study). | | | | | | | |
| Fruit | VITO (lab 1)<br><br>GC-MS/MS | Any further details of the method analysis if given (in Dutch) are brief.<br><br>Results sheets in analytical report states GC-MS/MS MIM-OR-017 | No | 16 EPA priority PAHs and 1- and 2-methylnaphthalene (and triphenylene, benzo(j) fluoranthene, and benzo (e ) pyrene | Yes<br><br>BELAC (Belgium) accreditation for the trace analysis of numerous pollutants in food including PAHs. | 'the EFSA 2008 PAH8'<br><br>And<br><br>Fluoranthene<br><br>And<br><br>Pyrene<br><br>(the EFSA PAH8 include benzo(a)anthracene; chrysene; benzo[b]fluoranthene, | The analytical report for the samples does contain validation data; although they don't seem to have been generated concurrently to the analyses in this report. | See below the table for validation data presented in the validation report (dated 30/08/2016). This indicates rationale for reporting to 0.5 µg/kg. | Analytical reports provided. (Appendix 1 to the report) Statement of results (2020 trials data) |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | (Appendix 1). This is the same method of analysis used in the earlier apple/pear study (2014 and 2015) and apple study (2019). | | | | benzo[k]fluoranthene, benzo[a]pyrene, benzo[g,h,i]perylene, indeno[1,2,3-cd]pyrene, and dibenzo[a,h]anthracene )<br><br>The report gives the results for the other relevant PAHs (not officially covered under the certified scope) as GC-MS/MS 'indicative result'.<br><br>Lab is VITO which is the | The validation report was stated to have been drawn up on 30/08/2016. | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | same laboratory as in the 2018 apple pear study report (2014 and 2015 analyses) and the 2020 apple study (2019 analyses). In the 2018 report (2014/2015 analyses), it was explained that for these extra components, their analysis had internally been validated by the very same method, and were therefore considered to | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | be of similar reliability. | | | |
| Fruit | BIEC (lab2)<br><br>GC-MS | Test method PAH – 0397 (includes EPA PAH)<br><br>(Appendix 2)<br><br>Instrument No L1MSD<br><br>Reported as following the method described by [redacted] et al., 1997. (reference provided) | No | 16 EPA priority PAHs and 1- and 2-methylnaphthalene (and triphenylene, benzo(j) fluoranthene, benzo (e ) pyrene, perylene, anthanthrene, coronene, cyclopenta[cd]pyrene, benzo[b]naphtho[2,1-d]thiophene, benzo[ghi]fluoranthene, benzo[c]phenanthrene) | Yes<br><br>The laboratory is certified by the German Society for Fat Science (DFG) | Scope not stated, assumed covering the analytes reported in the signed analytical report. | None - The analytical report for the samples does not contain validation data. | None presented - The LOQs in the results were various stated to be:<br><br>< 1 .068 µg/kg for naphthalene<br><br><0.279 µg/kg for acenaphthylene, and <0.02 µg/kg or <0.03 µg/kg for a number of PAHs.<br><br>(LOQs were not stated | Analytical reports provided. (Appendix 2 to the report) Statement of results (2019 trials data) |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | where only positive results were stated in the analytical report). | |

Note: Of the hundreds of known PAHs, sixteen have been designated High Priority Pollutants by the Environmental Protection Agency (EPA); they include: naphthalene (NAP), acenaphthylene (ACY), acenaphthene (ACE), fluorene (FLU), phenanthrene (PHEN), anthracene (ANTH), fluoranthene (FLTH), pyrene (PYR), benzo[a]anthracene (B[a]A), chrysene (CHRY), benzo[b]fluoranthene (B[b]F), benzo[k]fluoranthene (B[k]F), benzo[a]pyrene (B[a]P), benzo[g,h,i]perylene (B[ghi]P), indeno[1,2,3-c,d]pyrene (IND), and dibenz[a,h]anthracene (D[ah]A). These 16 PAHs are of environmental concern because of their potential toxicity in humans and other organisms and their prevalence and persistence in the environment. As advised in Water Air Soil Pollut. 2012 November 1; 223(9): 5535–5548

VITO lab 1. Summary of validation report dated 30 August 2016. Not concurrent validation data, but 'initial' validation prior to analysis of the samples reported on here. The data suggest that the PAHs reported here can be successfully analysed in fruits.

| **Validation parameter** | **Results/comment** |
|---|---|
| Linearity | Linear range was stated to be established 0.5 µg/kg to 20 µg/kg for most components. Results not given |
| LOQ | The LOQ was proposed by lab 1 (VITO) as being at least 6 times above the signal to noise ratio based on the sensitivity of the lowest point on the (solvent) linearity series. The LOQ for GC-MS/MS was 0.11 µg/kg at most (across the different analytes) and it was concluded that this was low enough to report to 0.5 µg/kg |
| Repeatability | Results were presented in overview form (%RSD) for duplicate analysis of 4 fruit samples, multiple analysis of a fortified apple fruit sample (2.5 µg/kg), multiple analysis of a certified reference standard, and for multiple analysis of a pasta sample. Results were acceptable %RSD≤10 |
| Recovery (accuracy) | This included the fortification of an apple sample with individual PAH amounts of 2.5 µg/kg and levels were determined by standard addition). Recoveries were in the range of 83 to 117 % (for GC-MS/MS) and 92-104 % (for GC-HRMS). |

Results

Residue levels in fruits, soil and wood are provided in Table A.19 (fruits lab 1), Table A.20 (fruits lab 2), Table A.21 (a comparison of some fruits data for lab 1 and lab 2), Table A.22 (soil) and Tables A.23 (wood).

**Table A.19 Residues in fruits as determined by lab 1. Site and sample date given. AUK-090-UK7-FT-01-c and AUK-090-UK8-FT-c represent control sites – no creosoted wood stakes. Analysed in October 2020**

| Compound | AUK-090-UK1-FT-01-c 20/07/2020 | AUK-090-UK2-FT-01-c 20/07/2020 | AUK-090-UK3-FT-01-c 21/07/2020 | AUK-090-UK4-FT-01-c 21/07/2020 | AUK-090-UK5-FT-01-c 22/07/2020 | AUK-090-UK6-FT-01-c 22/07/2020 | AUK-090-UK7-FT-01-c 23/07/2020 | AUK-090-UK8-FT-c 23/07/2020 | AUK-090-UK9-FT-c 27/07/2020 |
|---|---|---|---|---|---|---|---|---|---|
| Naphthalene | **4.94** | <0.8 | **2.21** | **0.879** | **1.48** | **0.69** | **0.573** | <0.6 | **1.52** |
| 1-Methylnaphthalene | **6.63** | <0.5 | **0.547** | **1.98** | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| 2-Methylnaphthalene | **12** | <0.6 | **2.26** | **4.07** | **1.31** | <0.9 | **0.582** | <0.6 | **0.909** |
| Acenaphthylene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Acenaphthene | **37.4** | **0.885** | **0.993** | **10.9** | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Fluorene | **56.6** | **4.72** | **0.954** | **7.31** | <0.5 | <0.5 | <0.5 | <0.5 | **0.841** |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Phenanthrene | **138** | **49.2** | **5.25** | **10.4** | **4.13** | **4.09** | **13.5** | **6.02** | **13.1** |
| Anthracene | **3.95** | **2.48** | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Fluoranthene | **8.9** | **7.71** | **4.1** | **4.48** | **2.89** | **3.8** | **12.1** | **3.52** | **12.5** |
| Pyrene | **2.48** | **2.17** | **1.35** | **1.48** | **0.706** | **1.74** | **3.03** | **1.44** | **4.77** |
| Benzo[a]anthracene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Triphenylene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Chrysene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Benzo[b]fluoranthene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Benzo[k]fluoranthene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Benzo[j]fluoranthene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Benzo[e]pyrene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Benzo[a]pyrene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Indeno[1,2,3-cd]pyrene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Dibenzo[a,h]anthracene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Benzo[ghi]perylene | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 | <0.5 |
| Sum 18 PAH | **270.90** | **67.17** | **17.66** | **41.50** | **10.52** | **10.32** | **29.79** | **10.98** | **33.64** |

**Table A.20 Residues in fruits as determined by lab 2. Site and sample date given. AUK-090-UK1-FT-01-c3 is represented by duplicate analysis, denoted -I and -II for labs internal QC. AUK-090-UK7-FT-01-c3 and AUK-090-UK8-FT-c3 represent control sites – no creosoted wood stakes. Results are expressed in µg/kg (as fresh weight). Samples designated c3 were analysed in July 2021. Samples designated c2 by lab 2 (see table A.21 below) were analysed in February 2021.**

| Compound | AUK-090-UK1-FT-01-c3-I<br><br>20/07/2020 | AUK-090-UK1-FT-01-c3-II<br><br>20/07/2020 | AUK-090-UK2-FT-01-c3<br><br>20/07/2020 | AUK-090-UK3-FT-01-c3<br><br>21/07/2020 | AUK-090-UK4-FT-01-c3<br><br>21/07/2020 | AUK-090-UK5-FT-01-c3<br><br>22/07/2020 | AUK-090-UK6-FT-01-c3<br><br>22/07/2020 | AUK-090-UK7-FT-01-c3<br><br>23/07/2020 | AUK-090-UK8-FT-c3<br><br>23/07/2020 | AUK-090-UK9-FT-c3<br><br>27/07/2020 |
|---|---|---|---|---|---|---|---|---|---|---|
| Naphthalene | **1.771** | **1.821** | **1.743** | **1.656** | **2.201** | **2.146** | **1.781** | <1.068 | <1.068 | **2.157** |
| 1-Methylnaphthalene | **1.450** | **1.470** | **2.747** | **2.899** | **1.295** | **1.666** | **0.913** | **0.469** | **0.854** | **0.343** |
| 2-Methylnaphthalene | **1.878** | **1.939** | **1.974** | **0.983** | **1.251** | **2.892** | **1.945** | **0.514** | **0.294** | **0.708** |
| Acenaphthylene | <0.279 | <0.279 | <0.279 | <0.279 | <0.279 | <0.279 | <0.279 | <0.279 | <0.279 | <0.279 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Acenaphthene | **1.130** | **1.175** | **4.604** | **0.778** | **0.439** | **0.665** | **0.511** | **0.412** | **0.184** | **0.184** |
| Fluorene | **1.261** | **1.288** | **4.401** | **1.552** | **0.922** | **0.708** | **0.606** | **0.585** | **0.445** | **0.504** |
| Phenanthrene | **4.901** | **5.030** | **7.139** | **7.223** | **6.382** | **3.905** | **4.544** | **9.194** | **4.032** | **7.433** |
| Anthracene | **0.100** | **0.104** | **0.381** | **0.344** | **0.175** | **0.089** | **0.132** | **0.156** | **0.092** | **0.167** |
| Fluoranthene | **2.604** | **2.530** | **5.460** | **1.895** | **3.322** | **2.365** | **4.594** | **8.276** | **2.078** | **6.463** |
| Pyrene | **0.923** | **0.837** | **2.007** | **0.679** | **1.253** | **0.689** | **2.101** | **2.621** | **0.957** | **2.895** |
| Benzo[a]anthracene | <0.029 | <0.029 | **0.100** | **0.029** | **0.030** | <0.029 | **0.129** | <0.029 | **0.044** | <0.029 |
| Triphenylene | **0.037** | **0.037** | **0.083** | **0.030** | **0.032** | **0.028** | **0.122** | **0.042** | **0.044** | **0.023** |
| Chrysene | **0.093** | **0.080** | **0.214** | **0.073** | **0.083** | **0.060** | **0.313** | **0.066** | **0.109** | **0.056** |
| Benzo[b]fluoranthe | **0.039** | **0.037** | **0.146** | **0.043** | **0.033** | **0.031** | **0.210** | **0.026** | **0.085** | <0.006 |

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|---|---|---|---|---|---|---|---|---|---|---|
| ne | | | | | | | | | | |
| Benzo[k]fluoranthene | **0.019** | **0.015** | **0.095** | **0.025** | **0.022** | <0.006 | **0.131** | **0.015** | **0.054** | <0.006 |
| Benzo[j]fluoranthene | **0.032** | **0.029** | **0.091** | **0.026** | **0.024** | **0.020** | **0.143** | **0.021** | **0.053** | <0.006 |
| Benzo[e]pyrene | **0.043** | **0.036** | **0.167** | **0.048** | **0.039** | **0.039** | **0.229** | **0.027** | **0.110** | <0.024 |
| Benzo[a]pyrene | <0.042 | <0.042 | **0.087** | <0.042 | <0.042 | <0.042 | **0.133** | <0.042 | **0.053** | <0.042 |
| Indeno[1,2,3-cd]pyrene | **0.029** | <0.027 | **0.104** | **0.031** | <0.027 | <0.027 | **0.167** | <0.027 | **0.071** | <0.027 |
| Dibenzo[a,h]anthracene | <0.011 | <0.011 | <0.011 | <0.011 | <0.011 | <0.011 | **0.024** | <0.011 | <0.011 | <0.011 |
| Benzo[ghi]perylene | **0.023** | **0.020** | **0.078** | **0.023** | **0.021** | **0.021** | **0.125** | <0.019 | **0.057** | <0.019 |
| Sum 18 PAH | **16.333** | **16.448** | **31.621** | **18.337** | **17.524** | **15.324** | **18.853** | **22.424** | **9.616** | **20.933** |

**Table A.21 A comparison of residues in fruits for site UK1 and UK2 analysed by lab 1 and lab 2. Analytical results for fruit samples in µg/kg.**

Sample date 20 July 2020 (for both UK1 and UK2); Samples designated c were analysed by Lab 1 (VITO) in Oct 2020; Samples designated c2 were analysed by Lab 2 (BIEC) in February 2021; Samples designated c3 were analysed by Lab 2 (BIEC) in July 2021. The samples were sent to lab 2 after it was proposed in the study report, that the result for site UK1 seemed to be an outlier result that required further investigating (as results were an order of magnitude higher (sum PAH concentration) than those measured in the other samples. The original lab (VITO, lab 1) did not have capacity to complete any re-analysis of sample. The duplicate UK-090-UK1-FT-01-c3 result**, denoted -II,** for UK1 was conducted as confirmatory work, which indicated the results as those obtained for the other c3 UK1 analysis, denoted -I. Sample c were taken from the 'a' subsamples taken at each location. Sample c2 and samples c3 were taken from the 'b' subsamples taken at each location (i.e. back up 'retained' subsamples).

Bold represents marked increase; italics represents marked decrease. (Percentage in brackets denotes a + or – add on or lesser amount) when comparing to the analysis by the same laboratory (lab 2) 5 months earlier). [Uncertainty in data]

| **Compounds** | **Site UK1 (plum)**<br><br>**Sample code: AUK-090-UK1-FT-01-c** | **Site UK1 (plum)**<br><br>**Sample code: AUK-090-UK1-FT-01-c2** | **Site UK1 (plum)**<br><br>**Sample code: AUK-090-UK1-FT-01-c3-I** | **Site UK1 (plum)**<br><br>**Sample code: AUK-090-UK1-FT-01-c3-II** | **Site UK2 (cherry)**<br><br>**Sample code: AUK-090-UK1-FT-01-c** | **Site UK2 (cherry)**<br><br>**Sample code: AUK-090-UK2-FT-01-c2** | **Site UK2 (cherry)**<br><br>**Sample code: AUK-090-UK2-FT-01-c3** |
|---|---|---|---|---|---|---|---|
| Napththalene | 4.94 | 1.301 | **1.771** | **1.821 (+40%)** | <0.8 | <1.068 | **1.743 (> + 63%)** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1-methylnapththalene | 6.63 | 0.519 | **1.450** | **1.470 (+183%)** | <0.5 | 0.349 | **2.747 (+ 687%)** |
| 2-methylnaphthalene | 12 | 0.855 | **1.878** | **1.939 (+127%)** | <0.6 | 0.645 | **1.974 (+ 206%)** |
| Acenaphthylene | <0.5 | <0.279 | <0.279 | <0.279 | <0.5 | <0.279 | <0.279 |
| Acenaphthene | 37.4 | 4.385 | *1.130* | *1.175 (-73%)* | 0.885 | 1.180 | **4.604 (+ 290%)** |
| Fluorene | 56.6 | 3.449 | *1.261* | *1.288 (-62%)* | 4.72 | 1.668 | **4.401 (+ 164%)** |
| Phenanthrene | 138 | 11.760 | *4.901* | *5.030 (-57%)* | 49.2 | 9.385 | *7.139 (- 24%)* |
| Anthracene | 3.95 | 0.270 | *0.100* | *0.104 (-61%)* | 2.48 | 0.402 | 0.381 |
| Fluoranthene | 8.9 | 2.299 | 2.606 | 2.530 | 7.71 | 4.820 | **5.460 (+13%)** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Pyrene | 2.48 | 0.751 | 0.923 | 0.837 | 2.17 | 1.707 | **2.007 (+18%)** |
| Benaz[a]anthracene | <0.5 | <0.029 | <0.029 | <0.029 | <0.5 | 0.128 | *0.100 (-22%)* |
| Triphenylene | <0.5 | 0.039 | 0.037 | 0.037 | <0.5 | 0.089 | 0.083 |
| Chrysene | <0.5 | 0.072 | 0.093 | 0.080 | <0.5 | 0.229 | 0.214 |
| Benzo[b]fluoranthene | <0.5 | 0.047 | 0.039 | 0.037 | <0.5 | 0.195 | *0.146 (-25%)* |
| Benzo[k]fluoranthene | <0.5 | 0.022 | 0.019 | 0.015 | <0.5 | 0.096 | 0.095 |
| Benzo[j]fluoranthene | <0.5 | 0.028 | 0.032 | 0.029 | <0.5 | 0.111 | *0.091 (-18%)* |
| Benzo[e]pyrene | <0.5 | 0.038 | 0.043 | 0.036 | <0.5 | 0.209 | *0.167 (-20%)* |
| Benzo[a]pyrene | <0.5 | <0.042 | <0.042 | <0.042 | <0.5 | 0.156 | *0.087 (-44%)* |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Indeno[1,2,3-cd]pyrene | <0.5 | 0.031 | 0.029 | <0.027 | <0.5 | 0.144 | *0.104 (-28%)* |
| Dibenz[a,h]anthracene | <0.5 | <0.011 | <0.011 | <0.011 | <0.5 | 0.024 | <0.011 |
| Benzo[ghi]perylene | <0.5 | 0.023 | 0.023 | 0.020 | <0.5 | 0.113 | *0.078 (-31%)* |
| Sum PAH | 270.90 | 25.889 | 16.33 | 16.448 | 67.17 | 21.650 | 31.621 |

**Table A.22 Residues in soil. Site and sample date given. AUK-090-UK7-SL-01-c and AUK-090-UK8-SL-01-c represents the control sites – no creosoted wood stakes. Results are in are expressed in mg/kg (as dry weight).**

| **Compound** | **AUK-090-UK1-SL-01-c 20/07/2020** | **AUK-090-UK2-SL-01-c 20/07/2020** | **AUK-090-UK3-SL-01-c 21/07/2020** | **AUK-090-UK4-SL-01-c 21/07/2020** | **AUK-090-UK5-SL-01-c 22/07/2020** | **AUK-090-UK6-SL-01-c 22/07/2020** | **AUK-090-UK7-SL-01-c 23/07/2020** | **AUK-090-UK8-SL-01-c 23/07/2020** | **AUK-090-UK9-SL-01-c 27/07/2020** |
|---|---|---|---|---|---|---|---|---|---|
| Naphthalene | <0.0338 | <0.0338 | <0.0352 | <0.0371 | <0.0370 | <0.0350 | <0.0372 | <0.0323 | <0.0343 |
| Acenaphthylene | <0.0338 | <0.0338 | <0.0352 | <0.0371 | <0.0370 | <0.0350 | <0.0372 | <0.0323 | <0.0343 |
| Acenaphthene | <0.0338 | <0.0338 | <0.0352 | <0.0371 | <0.0370 | <0.0350 | <0.0372 | <0.0323 | <0.0343 |
| Fluorene | <0.0338 | <0.0338 | <0.0352 | <0.0371 | <0.0370 | <0.0350 | <0.0372 | <0.0323 | <0.0343 |
| Phenanthrene | **0.24** | **0.142** | **0.0651** | **0.105** | **0.0629** | **0.209** | <0.0372 | **0.0403** | **0.067** |
| Anthracene | <0.0338 | **0.0541** | <0.0352 | **0.0612** | <0.0370 | **0.0437** | <0.0372 | <0.0323 | <0.0343 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Fluoranthene | **0.886** | **0.763** | **0.189** | **0.349** | **0.164** | **0.603** | **0.112** | **0.108** | **0.148** |
| Pyrene | **0.51** | **0.71** | **0.15** | **0.262** | **0.117** | **0.5** | **0.0929** | **0.0935** | **0.0807** |
| Benzo[a]anthracene | **0.107** | **0.5** | **0.0818** | **0.197** | **0.0592** | **0.268** | **0.0557** | **0.0508** | <0.0343 |
| Chrysene | **0.143** | **0.534** | **0.104** | **0.213** | **0.085** | **0.306** | **0.0706** | **0.0669** | <0.0343 |
| Benzo[b]fluoranthene | **0.138** | **0.577** | **0.0972** | **0.172** | **0.0767** | **0.26** | **0.0706** | **0.0633** | <0.0343 |
| Benzo[k]fluoranthene | **0.0692** | **0.289** | **0.0486** | **0.086** | **0.0384** | **0.13** | **0.0353** | **0.0317** | <0.0172 |
| Benzo[e]pyrene | **0.132** | **0.621** | **0.0871** | **0.162** | **0.0813** | **0.3** | **0.0594** | **0.0629** | <0.0343 |
| Indeno[1,2,3-cd]pyrene | **0.116** | **0.481** | **0.066** | **0.115** | **0.073** | **0.225** | **0.0483** | **0.0573** | <0.0343 |
| Dibenzo[a,h]anthracene | <0.0338 | **0.0984** | <0.0352 | <0.0371 | <0.0370 | **0.0472** | <0.0372 | <0.0323 | <0.0343 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Benzo[ghi]perylene | **0.111** | **0.468** | **0.0633** | **0.103** | **0.073** | **0.22** | **0.0474** | **0.0548** | <0.0343 |
| Sum 16 PAH | **2.45** | **5.24** | **0.953** | **1.83** | **0.83** | **3.11** | **0.593** | **0.63** | **0.295** |

**Table A.23 Residues in wood for each of the sites with creosoted wood stakes. Site, sample date and year the stake was installed (as per farmer interviews) is given. Results are in are expressed in % (w/w).**

| **Compound** | **AUK-090-UK1-WD-c**<br>**20/07/2020**<br>**2006** | **AUK-090-UK2-WD-c**<br>**20/07/2020**<br>**2006** | **AUK-090-UK3-WD-c**<br>**21/07/2020**<br>**2011** | **AUK-090-UK4-WD-c**<br>**21/07/2020**<br>**2011** | **AUK-090-UK5-WD-c**<br>**22/07/2020**<br>**2011** | **AUK-090-UK6-WD-c**<br>**22/07/2020**<br>**2011** | **AUK-090-UK9-WD-c**<br>**27/07/2020**<br>**2011** |
|---|---|---|---|---|---|---|---|
| Naphthalene | <0.001 | <0.001 | **0.0022** | **0.0011** | **0.0027** | **0.0034** | **0.0106** |
| 1-methylnaphthalene | <0.001 | <0.001 | **0.0078** | **0.0068** | **0.0146** | **0.0169** | **0.0197** |
| 2-methylnaphthalene | <0.001 | <0.001 | **0.0103** | **0.0095** | **0.0182** | **0.0217** | **0.0339** |
| Acenaphthylene | **0.0005** | **0.0015** | **0.0016** | **0.0019** | **0.0013** | **0.0018** | **0.0023** |
| Acenaphthene | **0.0315** | **0.1522** | **0.0704** | **0.1001** | **0.1046** | **0.1066** | **0.2088** |
| Fluorene | **0.064** | **0.2391** | **0.1207** | **0.1448** | **0.1396** | **0.1291** | **0.2405** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Phenanthrene | **0.7045** | **1.0363** | **0.8054** | **0.8241** | **0.8084** | **0.7537** | **1.4786** |
| Anthracene | **0.0501** | **0.1204** | **0.0645** | **0.0777** | **0.055** | **0.0496** | **0.0936** |
| Fluoranthene | **0.6411** | **0.8312** | **0.4229** | **0.3985** | **0.3193** | **0.3184** | **0.9822** |
| Pyrene | **0.3455** | **0.4447** | **0.257** | **0.1982** | **0.1495** | **0.1475** | **0.5453** |
| Benzo[a]anthracene | <0.001 | **0.0108** | **0.0025** | <0.001 | <0.001 | <0.001 | **0.0215** |
| Chrysene | <0.001 | **0.0144** | **0.0125** | <0.001 | <0.001 | <0.001 | **0.0165** |
| Benzo[b+k]fluoranthene | <0.001 | **0.0063** | <0.001 | <0.001 | <0.001 | <0.001 | **0.0051** |
| Benzo[e]pyrene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Benzo[a]pyrene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Indeno[1,2,3-cd]pyrene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Dibenzo[a,h]anthracene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Benzo[ghi]perylene | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Sum 18 PAH | **1.8372** | **2.8568** | **1.7778** | **1.7627** | **1.6132** | **1.5487** | **3.6586** |

*Fruit*

The results in fruit (non-contact) show that none of the eight carcinogenic PAHs 'EFSA PAH8' recommended by EFSA for food control, EFSA, Scientific Opinion 2008 were found in any of the apples (above 0.5 µg/kg): namely benz[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[g,h,i]perylene.

The main residues found at determinable residues in the non-contact fruits were the residues of PAHs (but not including the 'EFSA PAH8') which were found at determinable levels. However, in this particular study, on occasions similar residues were also found in the control sites. E.g. the highest residues observed of phenanthrene determined by lab 2 was a control site (a level of 9.2 µg/kg). Acenaphthylene was not found in either lab 1 or lab 2 results.

In this study, phenanthrene was one of the main residues found, but not the sole main residue. Whilst there is variation in results across trial sites, fluoranthene and pyrene were also commonly found at appreciable levels by both labs. The following range of residues were obtained in treated sites (non-contact fruits) compared to the control sites. Full details are available in Tables A.19, A.20, and A.21. The below comparisons show how residues of some components can be raised in the non-contact fruits (compared to the controls) but not in a consistent fashion.

| **Compounds** | **Non-contact fruits**<br><br>**Lab 1 = treated sites**<br><br>**(UK1 result (plum, applicant suggests outlier) in brackets)** | **Non-contact fruits**<br><br>**Lab 2 treated sites** | **Lab 1 control sites** | **Lab 2 control sites** |
|---|---|---|---|---|
| Naphthalene | <LOQ to 2.2 µg/kg<br><br>(5.0) | 1.7 to 2.2 µg/kg | <LOQ, 0.6 µg/kg | <LOQ |
| 1-methyl naphthalene | <LOQ to 2.0 µg/kg | 0.3 to 2.7 µg/kg | <LOQ | 0.5, 0.9 µg/kg |

| | | | | |
|---|---|---|---|---|
| | (6.6) | | | |
| 2- methyl naphthalene | <LOQ to 4.1 µg/kg<br>(12) | 0.7 to 2.9 µg/kg | <LOQ, 0.6 µg/kg | 0.3, 0.5 µg/kg |
| Acenaphthene | <LOQ to 10.9 µg/kg<br>(37) | 0.2 to 4.6 µg/kg | <LOQ | 0.2, 0.4 µg/kg |
| Fluorene | <LOQ to 7.3 µg/kg<br>(57) | 0.5 to 4.4 µg/kg | <LOQ | 0.4, 0.6 µg/kg |
| Phenanthrene | 4.1 to 49 µg/kg<br>(138) | 3.9 to 7.4 µg/kg | 6.0, 13.5 µg/kg | 4.0, 9.2 µg/kg |
| Anthracene | <LOQ to 2.2 µg/kg<br>(4) | 0.09 to 0.4 µg/kg | <LOQ | 0.09, 0.16 µg/kg |
| Fluoranthene | 2.9 to 12.5 µg/kg<br>(9) | 1.9 to 6.5 µg/kg | 3.5, 12.1 µg/kg | 2.1, 8.3 µg/kg |

| | | | | |
|---|---|---|---|---|
| Pyrene | 0.7 to 4.8 µg/kg<br>(2.5) | 0.7 to 2.9 µg/kg | 1.4, 3.0 µg/kg | 1.0, 2.6 µg/kg |

Since one control site is plums and one is cherry and for the treated site UK1 is plums, with the remainder of the treated sites being cherries, with the uncertainty regarding the analysis of samples for site UK1, HSE has not sought to draw any conclusions regarding level of residues for plums versus cherries.

As the information on the treatment (product, application rate) of the creosoted wood stakes is not available, it is difficult to comment on whether the compounds found reflects the types/grades of creosote used. However, information on the nature of components which the wood stakes exposes the fruit trees to, can be obtained from the wood analyses.

Whilst levels found in the fruit, do tentatively/occasionally tend to match the patterns of (non-EFSA PAHs) in the wood samples, the comparisons cannot always be directly made. For example, naphthalene, 1-methyl naphthalene, and 2-methyl naphthalene were found in non-contact fruits (lab 2) fruits for UK1 and UK2 in the range of 1 to 3 µg/kg whilst these components were not found in either the corresponding wood or soil samples. Acenaphthene and fluorene tended to not be found in soil, and were found in wood, and were found in non-contact fruits. Phenanthrene, fluoranthene and pyrene were found in soils and wood, as well as non-contact fruits.

The levels found for non-contact fruits in this study (plum and cherry) were combined with the results from the other studies (study 1 and 2, covering apples and pears) to derive median and highest residues for consumer risk assessment (see section A.5.4 (overview of residues) and section A.6 (consumer risk assessment).

*Wood:*

In terms of the ‘EFSA PAH8’ only low levels (in % w/w) were determined in the wood samples:

benz[a]anthracene up to 0.021%

chrysene up to 0.017%

benzo[b]fluoranthene and benzo[k]fluoranthene up to 0.0063%

benzo[a]pyrene – none found (<0.001%)

indeno[1,2,3-cd]pyrene - none found (<0.001%)

dibenzo[a,h]anthracene - none found (<0.001%)

benzo[g,h,i]perylene - none found (<0.001%)

Of the above components, it is only benz[a]anthracene and chrysene which are present in low amounts in the European creosotes.

The highest amounts (%) in wood of the other (non 'EFSA PAH8') components in which residues were found in wood are: phenanthrene (1.48), fluoranthrene (0.98), pyrene (0.55), fluorene (0.24), anthracene (0.12), acenaphthene (0.21), 1-methyl naphthalene (0.020), 2-methyl naphthalene (0.034), naphthalene (0.011), and acenaphthylene (0.0023).

Therefore, the applicant concluded that the PAHs in the wood mainly comprised the mid- to -light range molecular mass PAHs, with little or none of the heavier range PAHs.

Some of the wood results show presence of naphthalene, 1-methyl naphthalene, and 2-methyl naphthalene suggesting that possibly Grade B (or a mixture Grade B/C) had been used in some of the sites (e.g. sites UK3, UK4, UK5, UK6 and UK9). Conversely, some sites showed absence of these components (naphthalene, 1-methyl naphthalene, and 2-methyl naphthalene ) e.g. site UK1 and UK2, so creosote Grade C might have been used at these sites, when taking account of the composition of the various creosotes (Table A.1).

However, the report does not give details of the form of creosote used at each site.

*Soil:*

Given that details of the distance of soil taken from the wood stakes is not specifically reported, it is difficult to draw too many conclusions from the soil results, though it is clear that soil was taken in the vicinity of the fruit trees/stakes (see above description of sampling details). Whilst there are variations in the data, the results are broadly comparable (within a same order of magnitude), especially in terms of the nature of the residues for the 'treated site' soils and the control site soils (see table A.22 where low determinable residues of the EFSA PAH8 substances are observed). The broad comparability of the soil data are evident from a comparison of sum PAH16 reported by the applicant (as per Table A.22) for each of the soils. The range of sum PAH16 in soils for the seven 'treated' sites is 0.295 to 5.24 mg/kg dw, with an average of 2.1 mg/kg dw. The results for sum PAH16 for the two control sites (no creosoted wood stakes) was 0.59 and 0.63 mg/kg dw respectively. Although higher residues are seen in the soil data for the treated sites (compared to the control sites), the soil residues are not markedly higher.

It is difficult to know whether the raised levels of residues observed in (non-contact) fruits for the treated sites versus the control sites is due to some low level uptake of residues from the soil, or mainly based on above ground transfer of residues in above ground parts of the trees (some which might be in contact with the wooden

stakes) to the fruits.

*A.5.4* Summary overview of residues levels (including a comparison with background levels)

HSE remarks (across all the studies):

It is uncertain how well the studies represents a reasonable worst case representation of the intended use patterns for authorisation. Densities of crop, frequency of posts and geometries of the fruits stake were not well explained across all the studies. Various geometries of stakes were used in the studies, but the specific geometries and proximity of posts (and frequency of posts to orchard trees) was not always reported. Whilst the data are representative of commercial orchards, it does not seem that (a more expensive but possible commercial set up) of one creosote stake per orchard tree, has been represented in the trials, which would represent a worst case. There has not been any explanation by the applicant as to which of the trials might represent a reasonable worst case (in terms of density of the stakes planted) and there are no statements concerning the application treatments of creosote made to the wooden stakes (products, dose (application rate) and mode of treatment, whether wood posts were treated with creosote once or re-treated *in situ*). It can only be assumed that the maximum label recommended rates might have been used. Two of the studies did not indicate the specific grades of creosote that have been used in these studies. Inferences can be taken from the wood analyses. The data on residues on wood showed that the types of PAHs present in the wood could vary, and this is likely to be based on the different types of creosote uses: Grade B, Grade C or mixture of Grade B/C. Where it is stated which Grades were represented in the fruit tree studies, the Grade C was used, aside for one trial where a Grade B/C mixture was used. All these aspects are additional quantitative uncertainties in the assessment of the residue levels and in considering how well the studies reflect a representative worst case assessment of the uses of creosote.

Whilst validated methods have been used, and the LOQs provided in the summary results are presented, the studies tend not to be supported by procedural validation data. See HSE's evaluations of each of the studies (sections A.5.1, A.5.2, and A.5.3) which outline uncertainties on the analytical data determinations as the performance of the method on the day of analysis has not been verified.

The determinations have included 18 PAHs covering a number of the main components in creosote as well as the 'EFSA PAH 8' substances which are the eight carcinogenic PAHs 'EFSA PAH8' recommended by EFSA for food control, EFSA, Scientific Opinion 2008. Only two of these, chrysene and benz(a)anthracene, were present at low levels in the EU creosote types used for treatment of the wooden stakes in these studies. It is noted that creosote is a highly complex mixture (>100 components) and not all can reasonably be included in these residues studies. The 18 PAHs studied seems to be a good representative selection (considering the confidential data on constituents of EU creosotes) whilst also covering the EFSA PAH8 of particular toxicological concern.

The data from the three fruit studies has been used to present an overview of the residues in controls, contact fruit and non-contact fruit. Generally residues are at

raised levels in non-contact fruit as well as contact fruit compared to the residues for control sites.

The data show that both relatively new (3 years old) and old creosote stakes (up to 22 years) can be a source of residues in fruits, even those fruits that were sampled that were not in direct contact with the treated wood stakes (non-contact fruits). The data perhaps suggest that newer stakes are producing higher residues in fruits, but this is not consistently shown.

Overall the studies considered treated sites for plum (1), pear (2), cherry (6) and apple (10). An interspecies comparison has not been made by HSE due a number of other variables in the studies (soil type, age of stakes, stake geometries and frequency of stakes). However it is noted that different size crops were well represented across the trials (e.g. apples versus cherry).

Data on soil determinations of PAHs suggest that residues in the soil could lead to low level uptake of creosote constituents into the plants, but this is not always clearly the case. The soil residues findings included wider PAHs not present in creosote products, indicating that there are anthropogenic residues in the soil (separate to the creosote products being the source of these residues). Only study 1 outlined the distances from the wooden stakes that the soil samples were specifically taken. In studies 2 and 3 soil samples were taken from the vicinity of the wooden stakes.

Residues in fruits could be derived from direct contact with fruits (study 1) or in non-contact fruits (studies 1, 2 and 3), either from above ground transfer of residues from parts of the tree that have touched the stakes to the non-contact fruit that have been sampled, or by way of some low level uptake from soils where creosote constituents might have leached from the posts into the surrounding soil.

In the indicative consumer risk assessment (see section A.6), the chronic and acute exposures exceed the consumer DMEL derived by HSE and therefore harmful effects on human health cannot be excluded. Furthermore, the residues are of concern since creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded (see section A.6).

The studies have considered fruit trees (stone and pome fruits). There are no studies available for hops or grape (vines). This residues evaluation concludes that creosote treatment uses for wooden stakes for all crops for food is not an acceptable use. The data available for fruit trees (as per point 9 above) indicate that harmful effects on health cannot be excluded.

There are no risk mitigation measures that are evidenced by provision of residues data and are practical or feasible, which would reduce the residues to acceptable levels. Non-contact fruit residues found results in dietary intakes (in the indicative consumer risk assessment) that are above the consumer DMEL and it is concluded that creosote is a genotoxic carcinogen (see section A.6). As such the risk is unacceptable. Measures that could reduce residues might involve only part treating the creosote stakes (even so this would not be practical in terms of creosote treatment), use of barrier sleeves or sheaths to reduce contact with the fruits or fruit trees, ensuring planting of the fruit trees further away from the wood stakes or having geometries and frequency of wood stakes that would reduce contact with the fruit trees. However, even so, there is no way of knowing whether or how much these

measures could reduce residues to minimal levels. Residues data has not been provided to address these possible risk mitigation measures. The current residues evaluation has stated that the precise source of residues in 'non-contact fruits' (those considered in the residues studies not have had physical contact with the wood stakes) is not clear. The data are suggestive that both anthropogenic background and creosote sourced soil sources of PAHs AND above ground transfer of creosote residues from other parts of the trees that might have come into contact with the creosoted stakes could contribute. Therefore, it is difficult to draw conclusions on precisely how these residues in the non-contact fruit have arisen. As such it is not possible, to apportion levels of exposures in fruit due to soil uptake versus from translocation of residues from parts of the trees that might have had contact with the stakes. Therefore, without further data addressing risk mitigation measures, it is not possible to quantify the effect that using protective sheaths or barrier sleeves might afford, although there could be an appreciable reduction in exposures from the use of such risk mitigation measures (barrier sleeves or sheaths around creosoted wood stakes) which has not yet been quantified. An uncertainty of the current studies is that fruit that could possibly be taken from very young fruit trees (e.g. < 3 years of orchard age) could contain even higher residues than seen in the current study. The applicant considered that when young fruits are grown in a training (espalier) system no significant harvest of fruits occurs in the first few years. In terms of high end residues, HSE considers that it is not possible to be confident that all of the fruit that has been in possible contact with the stakes does not go into human consumption. Such fruit are likely to have 'hot spots' of residues, which can be of potential concern especially for acute consumer exposures. Use of barrier sleeves or sheaths from initial planting/growth next to creosote stakes would mitigate the possibility of any contact fruits that could contain very high residue levels entering the food consumption supply chain.

Therefore this section on overview of residue results provides a comparison of results across field trial samples in order to aid a consideration of the indicative consumer risk assessment (see section A.6). As noted previously, due to some quantitative uncertainty in the data, all results in fruits determined across studies 1 to 3 are included in this summary.

The approaches to deriving data for this summary overview are as follows:

Values were set to the LOQ levels to sum the residues (i.e. residues at <LOQ were assumed to be at the LOQ).

Some LOQs were reported as <0.5 µg/kg (e.g. 0.1 µg/kg) and variously across different years (e.g. across different seasons of study even in one residues study). For these components the LOQ was standardised as 0.5 µg/kg.

Some LOQs were reported at higher values than 0.5 µg/kg (and at various levels for different trials sites). Validation data were not supplied to support the (various) level of the LOQs proposed. For these values the level contributing to the sum of residues was set to the level of the reported LOQ in that trial (where the LOQ was > 0.5 µg/kg).

Residue levels for each trial were summed or included in the below overview of residues as follows:

Note, in this evaluation, as per the applicants studies, residues were summed across the different constituents, without making any adjustment for molecular weight expression (so not sum PAH18 expressed as phenanthrene (for example)).

| | |
|---|---|
| **PAH18:** | The EPA priority 16 PAHs plus 1-methyl naphthalene and 2 methyl naphthalene<br><br>EPA priority 16= naphthalene (NAP), acenaphthylene (ACY), acenaphthene (ACE), fluorene (FLU), phenanthrene (PHEN), anthracene (ANTH), fluoranthene (FLTH), pyrene (PYR), benzo[a]anthracene (B[a]A), chrysene (CHRY), benzo[b]fluoranthene (B[b]F), benzo[k]fluoranthene (B[k]F), benzo[a]pyrene (B[a]P), benzo[g,h,i]perylene (B[ghi]P), indeno[1,2,3-c,d]pyrene (IND), and dibenz[a,h]anthracene (D[ah]A). |
| **PAH8:** | The sum of benz[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[g,h,i]perylene (EFSA, 2008) |
| **PAH4:** | the sum of benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene. (EFSA, 2008) – see Table A.2 (MRLs) in section A.3 |
| **PAHother (10):** | PAH18 minus PAH8 |
| **CH and B[a]A** | Sum of chrysene and benz[a]anthracene |
| **FL** | fluoranthene, a component present in relatively high amounts and present in the creosote products |
| **PH** | phenanthrene, the main marker component and present in the creosote products |

| | |
|---|---|
| **PY** | pyrene, a component present in relatively high amounts and present in the creosote products |

Results for 'contact fruit' were available from study 1 only (4 different trials results). Median and highest residue results (from n=4) are presented in the summary below. Contact fruits were fruits which were considered to have had direct contact with the wooden stakes and are not as a result of representative sampling.

Results for controls were taken from all studies (studies 1, 2 and 3). These represent results where no creosote stakes were used in the trials. There were two control sites per study, representing pear (2), apple (2), plum (1) and cherry (1). The results across all of these tree fruit types were combined. For the evaluation of the control results for study 3, where there were different results for lab 1 or lab 2, the higher value of the two was used to derive the summary residues statistics, so that only one value per trial was 'used' (to produce the median and highest residue result estimates across the trials, from n=6).

Results for non-contact fruits were combined across the three studies, 19 trials, combining the data for apple, plums, cherries and plums. Of these trials, 2 were pears and only one was plums, and so there were not equal sufficient trials to make between species comparisons. The data also combined the data for new and old (or mid) term creosoted wood stakes, so across the trials these 'influencing factors' were included in the trials results (n=19 rather) than separated out, in order to derive summary statistics of median and highest residue results.

The non-contact fruits were generally either fruits that were considered to not have been in contact with the wood stakes (study 1) or were taken in a random way that was seeking to take a representative sample not targeted to fruits that had been in contact with the stakes (study 2 and 3). For the latter the applicant explained that these were considered representative of commercial practice in terms of a harvested 'bulk lot' from which the sample was obtained and was not targeted to obtain contamination hot-spots.

In study 3, differing results were obtained from two different laboratories, lab 1 and lab 2. Two different sets of data were obtained across the 19 'non-contact fruit trails across the three studies). Set A non-contact = Results from study 1, study 2 and study 3 lab 1 (n=19)

Set B non-contact = Results from study 1, study 2 and study 3 lab 2 (n=19)

Each trial site had only one result represented in the data sets (for each of set A and set B), so n=19. In study 1, for three of the (creosote treated) trials, results were sampled and obtained in both 2014 and 2015 seasons. In these trials, the residue values were highest in 2014 compared to 2015. The higher value (the 2014 sample results and not the 2015 sample results) were taken forward into the residue derivations of median and HR across all the 19 trials.

The summary of all the results (across all the three studies) based on the above approaches and principles is provided in Table A.24. The median results and the highest residue results are represented for each of controls, contact fruits, non-contact fruits (set A) and non-contact fruits (set B). These values fed into the derivation of estimation of dietary intakes which are presented in section A.6.

**Table A.24 Summary results (median and highest residues (HR)) from the fruit tree trials (data from studies 1, 2 and 3 combined).**

| Result type | PAH18: | PAH8: | PAH4 | PAHother (10) | CH and B[a]A | FL | PH | PY |
|---|---|---|---|---|---|---|---|---|
| Control Median (µg/kg) | 16.1 | 4 | 2 | 12.1 | 1 | 2.36 | 4.96 | 0.97 |
| Control Median (mg/kg) | 0.0161 | 0.0040 | 0.0020 | 0.0121 | 0.0010 | 0.0024 | 0.0050 | 0.0010 |
| Control HR (µg/kg | 40.08 | 4 | 2 | 36.08 | 1 | 12.10 | 13.50 | 3.03 |
| Control HR | 0.0401 | 0.0040 | 0.0020 | 0.0361 | 0.0010 | 0.0121 | 0.0135 | 0.0030 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| (mg/kg) | | | | | | | | |
| Contact Median (µg/kg) | 1361 | 6.05 | 4.05 | 1355 | 3.05 | 410 | 655 | 165 |
| Contact Median (mg/kg) | 1.36 | 0.0061 | 0.0041 | 1.35 | 0.0031 | 0.41 | 0.66 | 0.17 |
| Contact HR (µg/kg) | 2236 | 9.79 | 7.79 | 2226 | 6.79 | 680 | 780 | 540 |
| Contact HR (mg/kg) | 2.24 | 0.0098 | 0.0078 | 2.23 | 0.0068 | 0.68 | 0.78 | 0.54 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Non-Contact Set A Median (µg/kg) | 56 | 4 | 2 | 52 | 1 | 7.7 | 36 | 2 |
| Non-Contact Set A Median (mg/kg) | 0.056 | 0.0040 | 0.0020 | 0.052 | 0.0010 | 0.0077 | 0.036 | 0.0019 |
| Non-Contact Set A HR (µg/kg) | 373 | 4 | 2 | 369 | 1 | 50 | 138 | 24 |
| Non-Contact Set A HR (mg/kg) | 0.373 | 0.0040 | 0.0020 | 0.369 | 0.0010 | 0.050 | 0.138 | 0.024 |
| Non-Contact Set B | 34.8 | 4.0 | 2.0 | 30.8 | 1.0 | 6.5 | 15 | 1.9 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Median (µg/kg) | | | | | | | | |
| Non-Contact Set B Median (mg/kg) | 0.035 | 0.0040 | 0.0020 | 0.031 | 0.0010 | 0.0065 | 0.015 | 0.0019 |
| Non-Contact Set B HR (µg/kg) | 265 | 4.0 | 2.0 | 261 | 1.0 | 50 | 110 | 24 |
| Non-Contact Set B HR (mg/kg) | 0.265 | 0.0040 | 0.0020 | 0.261 | 0.0010 | 0.050 | 0.110 | 0.024 |

Age of creosote wood stakes:

Across the three studies, different periods of aging of the creosoted wood stakes at the treated sites were considered to seek to compare difference in levels of PAHs in fruits for sites where creosote has been used for wood stakes, where the stakes are relatively new stakes (e.g. three years) or whether the stakes are old (e.g. 20 years). Please refer to Table A.25 below. The comparison in this table has only considered the ages with terms of 'new' or 'old' wood stakes and has left out trials with age of creosote stakes outside of these extremes. The comparisons made are for the non-contact fruit samples (samplings where fruit were taken that had not been in direct contact with the stakes) as these were taken in all the studies (studies 1, 2 and 3). The results show some variation. Soil type could also be an influencing factor which is difficult to discern as the soil types were only stated for study 1. There is a possible indication of residues being higher for the sites with the relatively newer age of creosote stakes, but this is not consistent. It is clear that creosote is persistent over time and old wood stakes (20 years etc) can still result in raised PAH residue levels in fruits (non-contact) compared to background exposure levels (where no creosoted stakes have been used).

**Table A.25. A comparison of sum PAM (PAH18) in non-contact fruits for the various trials where creosote stakes have been used as relatively new wood stakes in orchards (3 to 5 years) in comparison to older wood stakes (14 to 22 years of use).**

Note: Although (site 9 Study 3) the orchard was installed in 2017, the creosote treated stakes were installed in 2015 prior to the orchard being replanted in 2017. Site 9 was selected as a site which was newly planted, yet producing orchard. This site was planted 3 years before sampling, with the creosote-treated stakes being in the ground from two years prior.

SumPAH18 as calculated by HSE assuming the residues found at <LOQ were at the LOQ as explained at the start of this section. The sum PAH values calculated by the applicant (and presented in tables A.7 (study 1), A.14 (study 2) and A.19 and A.20 study 3) did not include summation of values for <LOQ).

| Age of wood stakes | Study | Site | Fruit tree | Years of use of creosote stakes | SumPAH18 residue in µg/kg |
|---|---|---|---|---|---|
| Old | 1 | 2 (loam) | Apple | 20 | 35 |
| New | 1 | 1 (loam) | Apple | 3 | 148 |
| Old | 1 | 4 (clay) | Pear | 20 | 135 |

| | | | | | |
|---|---|---|---|---|---|
| New | 1 | 3 (clay) | Pear | 3 | 41 |
| Old | 2 | 2 | Apple | 22 | 27 |
| New | 2 | 4 | Apple | 4 | 91 |
| New | 2 | 5 | Apple | 5 | 105 |
| New | 2 | 10 | Apple | 3 | 79 |
| Old | 3 | 1 | Plum | 14 | 275 lab 1, 33 lab 2 |
| Old | 3 | 2 | Cherry | 14 | 74 lab 1, 37 lab 2 |
| New | 3 | 9 | Cherry | 3(5) | 40 lab 1, 26 lab 2 |

The values summarized in this section (Table A.24) were used for the dietary risk assessment in section A.6 below Indicative consumer risk assessment). Median residue values were used for chronic exposure assessment for consumers and highest residues were used for acute exposure assessment for consumers.

## *A.6 Indicative consumer risk assessment*

An indicative consumer risk assessment has been performed since a residues definition for dietary risk assessment is not being proposed as the residue findings are of concern (since it is concluded that creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded (see section 12.2 on Reference values (HSE toxicological assessment)). However, an indicative risk assessment comparing dietary intakes to the consumer DMEL (health-based reference value) has been performed in this section.

**Livestock dietary intakes:**

A livestock dietary intake assessment has been undertaken using the Dietary Burden Calculator 'OECD pesticides_mrl_guidelines_animal_model_2017'. This is the assessment tool used in GB for the livestock dietary assessment of pesticides; it can also be used for biocides.

The dietary burden has been performed according to the approach presented in the OECD Guidance document on residues in livestock, series on pesticides No 73 for a total of 9 animal species.

The following assumptions have been made:

1. The highest likely inclusion rate of all crops which may have been 'treated' has been used with the proviso that the aggregate does not exceed 100% diet; in this case only apple pomace

2. All produce eaten which may have been treated, has been treated and contains residues as summarized below;

3. There is no loss of residue during transport, storage, preparation of feed or processing prior to consumption

The only residue input was 0.056 mg/kg for (wet) apple pomace, since apple is the only fruit crop arising from the requested uses which is fed to livestock. The residue was calculated as PAH18 for each trial considering all the residue values for non-contact fruit (see the explanation of the data combined as 'non-contact' fruit in section A.5.4). The value of 0.056 mg/kg is the median value of sum PAH18 across all 19 trials (combining data from study 1, study 2 and study 3 (and taking only the trial values from lab 1 (the highest compared to lab 1 and lab 2) for study 3, so using the data for 'set A' rather than 'set B' which represents the highest median value of the non-contact fruits data values (from n=19))).

There is an alternative proposed use of creosote for use on fence posts, used for containing livestock. This use (and possible licking of fence posts by livestock) has not been considered at the same time as the apple exposure (arising from creosoted wooden posts used in fruit orchards), as it is unlikely that livestock fed apple pomace will also be livestock contained in the fence posts. Therefore, the results below in Table A.26 are only in relation to the use of creosote to treat wooden posts used in fruit tree production.

**Table A.26 Median/maximum dietary burden of creosote by domestic animals following use of creosoted stakes for growing fruit trees**

(The median is the same as the maximum as the trials median residue for apple pomace is the only relevant residues input (the highest residue is not used for apple pomace))

Note: When several diets are relevant (e.g. cattle, sheep and poultry “all diets”), the most critical diet is identified from the maximum dietary burdens expressed as “mg/kg bw per day”. The most critical commodity is the major contributor identified from the maximum dietary burden expressed as “mg/kg bw per day”

| Relevant groups | Dietary burden expressed in mg/kg bw per day<br>Median | Dietary burden expressed in mg/kg bw per day<br>Maximum | Dietary burden expressed in mg/kg DM<br>Median | Dietary burden expressed in mg/kg DM<br>Maximum | Most critical diet | Most critical commodity | Trigger exceeded (Yes/No)<br>0.004<br>mg/kg bw |
|---|---|---|---|---|---|---|---|
| Cattle (all diets) | 0.0034 | 0.0034 | 0.14 | 0.14 | Beef cattle | Apple<br>Pomace, wet | No |
| Cattle (dairy only) | 0.0027 | 0.0027 | 0.07 | 0.07 | Dairy cattle | Apple<br>Pomace, wet | No |
| Sheep (all diets) | 0.0030 | 0.0030 | 0.07 | 0.07 | Lamb | Apple | No |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | Pomace, wet | |
| Sheep (ewe only) | 0.0023 | 0.0023 | 0.07 | 0.07 | Ram/Ewe | Apple<br>Pomace, wet | No |
| Swine (all diets) | | | | | | | No |
| Poultry (all diets) | | | | | | | No |
| Poultry (layer only) | | | | | | | No |

As dietary intakes are below the trigger of 0.004 mg/kg bw/day, there is no need for a livestock feeding study to support the use of creosote in support of the proposed use. Significant residues in livestock would not be anticipated in products of animal origin arising from the assessed use of creosote on wooden stakes used for fruit trees.

**Consumer (human) dietary intakes (indicative consumer risk assessment only):**

The toxicological assessment has concluded the following in regard of a reference value to compare dietary intakes against. (see Toxicological Evaluation, section 4).

A DMEL for the consumer of 0.3 µg/kg bw/day (= 0.00030 mg/kg bw/day)

This health-based guidance value, the consumer DMEL, is applicable for comparison of chronic dietary intakes and also acute dietary intakes. The toxicological assessment observed that the value is derived specifically for chronic exposure assessment, and that it is likely to be conservative for acute exposure assessment but can be used for this purpose. HSE's toxicological evaluation states "This is a chronic value. There are no appropriate data to derive an acute DMEL. However, as in theory, it is possible that even one single exposure could lead to genetic damage and eventually to carcinogenicity, this chronic value should also be used when assessing acute exposure scenarios. It should be noted, however, that for acute exposures, the chronic DMEL is an extremely conservative value.".

UK and (EU) PRIMo dietary intake models were used (see below sections for both chronic and acute dietary intake estimates). Both models are routinely used for GB pesticides evaluation, and so it was considered appropriate to use both models for assessment of total dietary intakes for assessment of exposure to creosote.

**Chronic (long term) dietary intake estimates – UK NEDIs and EU IEDIs- indicative assessment**

The UK NEDIs (National Estimates of Dietary Intake) and total dietary NEDIs (across all the 'treated' crops) for the active creosote and commodities listed below have been calculated for ten consumer groups as detailed in the Regulatory Update 21/2005. Furthermore, the EU IEDIs (International Estimates of Dietary Intake) and total dietary IEDIs (across all the 'treated' crops) were calculated using EU PRIMo - Pesticide Residues Intake Model (revision 3.1). A full description of PRIMo and the underlying assumptions is in the document: 'Use of EFSA pesticide residues intake model (EFSA PRIMo revision 3.1)' available at the following link:
http://www.efsa.europa.eu/en/applications/pesticides/tools

Information is also included in the PRIMo model in the tab 'Background information'

The following assumptions have been made:

1. Upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.

2. All produce eaten which may have been treated has been treated and contains residues at the median residue found in the fruit tree trials reported in this

evaluation, as given in Table A.23, section A.5.4. The crops covered in this assessment were all pome fruits and all stone fruits. Since low level residues were also found in controls, the dietary intakes have also been calculated for these samples, the non-treated crops.

3. There is no loss of residue during transport or storage, or processing of foods prior to consumption.

There are 4 sets of calculations to account for the different residue samples taken/analysed:

i. Controls: derived from the trials sites results where no creosote wood treatments were used (n=6 trials across studies 1, 2 and 3)

ii. Contact fruits: derived from study 1 (n=4 trials) for fruits sampled that were considered to have been in direct contact with the wood stakes

iii. Non-contact fruits: set A. Fruits sampled from trees, sampling not directed at fruits that had been in contact with wooden stakes. Set A = Results from study 1, study 2 and study 3 lab 1 (n=19)

iv. Non-contact fruits: set B. Fruits sampled from trees, sampling not directed at fruits that had been in contact with wooden stakes. Set B = Results from study 1, study 2 and study 3 lab 1 (n=19)

Furthermore the dietary intakes were calculated for the following three scenarios:

a. PAH18= sum of the components analysed – includes EFSA (2008) PAH8

b. Phenanthrene – the main 'marker' component, which of all individual creosote components comprises the highest calculated dietary intake

c. Sum of chrysene and benz[a]anthracene- these are the only two components of the EFSA (2008) PAH8 that are present in creosote

The relevant intakes are presented in Table A.27. The results are not presented for each of the consumer groups, just the most critical consumer group (the consumer group which had the highest total chronic dietary intake). Also the individual crop NEDI results are not presented here, just the total dietary intakes calculated across the crops for which residue values were inserted into the models (pome fruits and stone fruits). However, all individual NEDIs were calculated and all the consumer groups were covered (UK model covering infants, toddlers, children of varying age, adults, vegetarians and elderly, and PRIMo covering all the various consumer groups in EU PRIMo covering children of various ages and adults for the various EU diets).

**Table A.27 Total chronic dietary intakes (highest total NEDIs/IEDIs, indicative consumer risk assessment only) for consumption of pome fruits/stone fruits for the critical consumer, namely toddler (UK model) and Dutch toddler (EU PRIMo model). The results are presented as a % of the consumerDMEL of 0.3 µg/kg bw/day. Emboldened values represent exceedances of the consumerDMEL.**

| Result type | PAH18 | Sum of chrysene and benz[a]anthracene | Phenanthrene |
|---|---|---|---|
| Control = No creosote stakes<br><br>%DMEL UK | **116** | 7 | 36 |
| Control = No creosote stakes<br><br>%DMEL EU | 83 | 7 | 27 |
| Non-Contact fruits - A<br><br>%DMEL UK | **402** | 7 | **258** |
| Non-Contact fruits - A<br><br>%DMEL EU | **293** | 7 | **190** |
| Non-Contact fruits - B<br><br>%DMEL UK | **250** | 7 | **108** |
| Non-Contact fruits - B<br><br>%DMEL EU | **183** | 7 | 80 |
| Contact fruits<br><br>%DMEL UK | **9771** | 22 | **4702** |
| Contact fruits<br><br>%DMEL EU | **7143** | 17 | **3437** |

To give some context to these results, chrysene and benz[a]anthracene are the two components of the EFSA PAH8 substances that are presented in creosote. EFSA 2008,

considered the contamination scenarios for PAH8 present in food. EFSA 2008 estimated an overall average dietary exposure across European countries for which data are available of 1729 ng/day (28.8 ng/kg b.w. per day (equivalent to 0.000029 mg/kg bw/day) assuming a body weight of 60 kg) for PAH8 (range: 1415-2136 ng/day). Based on the fruit samples data obtained in this evaluation (and covering pome and stone fruits), the estimation of highest UK and EU total dietary intakes for PAH8 for both control and non-contact fruits was calculated to be 000086 mg/kg bw/day (total NEDIs for UK toddlers) and 0.000060 mg/kg bw/day (total IEDIs for Dutch toddlers))

**Results (chronic):**

The results of this indicative consumer risk assessment show that the consumer DMEL is even exceeded for the chronic exposure estimates representing sum of the PAHs in the untreated controls, but at a lower level (compared to the 'treated' samples). The UK total dietary intakes for UK toddlers based on untreated control fruits represented 116% of the consumer DMEL of 0.3 µg/kg bw/day (based on sumPAH18).

Clearly , the highest dietary intakes were for the contact fruits, with highest UK dietary intakes for UK toddlers at 9771% of the consumer DMEL of 0.3 µg/kg bw/day based on sumPAH18).

The applicant has explained how the non-contact fruit are regarded as representative of fruits that are harvested commercially (and not the 'contact fruits'). The results are complex due to the results presented for the different laboratory analyses (in study 3). However, for these residues samples, the highest UK and EU total dietary intakes for UK and Dutch toddlers represented 183% to 402% of the consumer DMEL of 0.3 µg/kg bw/day (based on sumPAH18).

Even for non-contact fruits, the results for phenanthrene alone represented up to 248% of the consumer DMEL of 0.3 µg/kg bw/day (based on phenanthrene levels found). The applicant has noted that phenanthrene, one of the components in creosotes is thought not be one of the components that might confer carcinogenic properties; however specific toxicity data to address the toxicology profiles of individual creosote constituents have not been submitted.

The chronic dietary intakes calculated in the indicative dietary risk assessment indicate that an expectation of long term effects on health cannot be excluded arising from the assessment of the fruit tree uses of creosote.

**Acute (short term) dietary intake estimates – UK NESTIs and EU IESTIs - indicative assessment**

The UK NESTIs (National Estimates of Short Term Intake for the active creosote and commodities listed below have been calculated for ten consumer groups as detailed in the Regulatory Update 21/2005. Furthermore, the and EU IESTIs (International Estimates of Short Term Intake) were calculated using EU PRIMo - Pesticide Residues Intake Model (revision 3.1). A full description of PRIMo and the underlying assumptions is in the document: 'Use of EFSA pesticide residues intake model (EFSA PRIMo revision 3.1)' available at the following link:

http://www.efsa.europa.eu/en/applications/pesticides/tools

Information is also included in the PRIMo model in the tab 'Background information'

The following assumptions have been made:

1. Upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.

2. All produce eaten which may have been treated has been treated and contains residues at the median residue found in the fruit tree trials reported in this evaluation, as given in Table A.24, section A.5.4. The crops covered in this assessment were all pome fruits and all stone fruits. Since low level residues were also found in controls, the dietary intakes have also been calculated for these samples, the non-treated crops.

3. There is no loss of residue during transport or storage, or processing of foods prior to consumption.

There are 4 sets of calculations to account for the different residue samples taken/analysed:

i. Controls: derived from the trials sites results where no creosote wood treatments were used (n=6 trials across studies 1, 2 and 3)

ii. Contact fruits: derived from study 1 (n=4 trials) for fruits sampled that were considered to have been in direct contact with the wood stakes

iii. Non-contact fruits: set A. Fruits sampled from trees, sampling not directed at fruits that had been in contact with wooden stakes. Set A = Results from study 1, study 2 and study 3 lab 1 (n=19)

iv. Non-contact fruits: set B. Fruits sampled from trees, sampling not directed at fruits that had been in contact with wooden stakes. Set B = Results from study 1, study 2 and study 3 lab 1 (n=19)

Furthermore the acute dietary intakes were calculated for the following three scenarios:

a. PAH18= sum of the components analysed – includes EFSA (2008) PAH8

b. Phenanthrene – the main 'marker' component, which of all individual creosote components comprises the highest calculated dietary intake

c. Sum of chrysene and benz[a]anthracene- these are the only two components of the EFSA (2008) PAH8 that are present in creosote

Furthermore the acute dietary intakes were calculated applying the following different options on variability factors (VFs) to the medium sized commodities (all pome fruits and stone fruits, except for cherries): 7, 3 and 1. See the explanation of variability factors below.

The relevant intakes are presented in Table A.28. The results are not presented for each of the consumer groups, just the most critical consumer group (the consumer group and commodity combination which had the highest acute dietary intake). Also the individual commodity NESTI results are not presented here, just the highest intake calculated across the crops for which residue values were inserted into the models (pome fruits and stone fruits). However, all individual NESTIs were calculated and all the consumer groups were covered (UK model covering infants, toddlers, children of varying age, adults, vegetarians and elderly, and PRIMo covering all the various consumer groups in EU PRIMo covering children of various ages and adults for the various EU diets).

**Variability factors (VF):**

A variability factor is usually applied in the acute exposure assessment. As it is a multiplication factor, the level of the variability factor can have a marked effect on the calculation outcomes. For further information, please refer to NESTI acute guidance (hse.gov.uk) .

The standard model approaches to estimating acute dietary intakes, where variation in residues is expected, e.g. to accommodate variable application of sprays to crops, are to use default variability factors of 7 for medium sized commodities, such as apples, pears and plums.

A variability factor is a multiplication factor to estimate the highest residue in a single fruit item, when the residue sample was derived on a composite sample (so a number of units, mixed in the residue sample, comprising possibly 10 or 12). Whilst unit to unit residue data can be obtained in residues work, the standard approach is to derive composite residue samples (a number of units which are mixed together in the sample to produce the analytical sample).

A variability factor is typically used in the acute exposure assessment, to reflect hotspots in residues and to account for the way a consumer on a single day might consumer one single fruit item (containing the highest residue).

For the creosote assessment, the use of the standard variability factors is uncertain; these variability factors were not established to cover the use pattern being considered in this assessment. Nevertheless, in the absence of specific data to establish how residues may vary in individual units, compared to a composite sample, for the use of creosote on fruit stakes, HSE has presented the acute risk assessments using the VFs of 7, 3 or 1 (the latter representing no VF) as options. For all these assessments, the chosen VF was applied to all the pome and stone fruit crops except cherries, as it is standard for a VF of 1 to always be used for cherries since the way cherries are consumed in a large portion (a number of cherries) is likely to be reflected by the composite residue sample.

Whilst a high VF of 7 might not be appropriate, there are other uncertainties in the assessment, as outlined in section A.5.4 which mean that it is uncertain how well the evaluation of creosote and residues and assessment is addressing the possible worst case exposure following use. On the other hand, where duplicate values were available

per trial results (for example a result for a study 1 trial site in 2014 and 2015, and in study 3 where for one particular laboratory a duplicate analysis was done months later), the highest value was represented for that trial. In the acute consumer exposure risk assessment, as per the NESTI approach, the VF was applied to the HR (composite trial result) across all the trials.

Therefore HSE considered that an option for the acute exposure assessment using a VF of 7 for medium sized commodities should be calculated, as well as (less conservatively) VF 3 and VF 1 options. These are all presented in this evaluation ( see Table A.28 for results of all these options).

**Table A.28 Highest acute dietary intakes (indicative consumer risk assessment only) for consumption of pome fruits/stone fruits for the critical consumer/commodity combination. The results are presented as a % of the consumerDMEL of 0.3 µg/kg bw/day. Emboldened values represent exceedances of the consumerDMEL. Application of this consumerDMEL to the acute exposure assessment is considered a conservative approach (since the DMEL is a value derived for the purpose of chronic assessment) as explained above. However, it can be used for the purpose of acute exposure assessment (as explained above).**

**ACUTE VF 7 (highest NESTI/IESTI) for apple (UK/infant) or pears (EU/NL toddler)**

| Result type | PAH18 | Sum of chrysene and benz[a]anthracene | Phenanthrene |
|---|---|---|---|
| Control = No creosote stakes<br><br>%DMEL UK | **1309** | 33 | **441** |
| Control = No creosote stakes<br><br>%DMEL EU | **1867** | 47 | **663** |
| Non-Contact fruits - A<br><br>%DMEL UK | **12190** | 33 | **4507** |
| Non-Contact fruits - A<br><br>%DMEL EU | **17333** | 47 | **6333** |

| | | | |
|---|---|---|---|
| Non-Contact fruits - B<br>%DMEL UK | **8637** | 33 | **3593** |
| Non-Contact fruits - B<br>%DMEL EU | **12333** | 47 | **5000** |
| Contact fruits<br>%DMEL UK | **73033** | **222** | **25470** |
| Contact fruits<br>%DMEL EU | **103333** | **313** | **36000** |

**ACUTE VF 3 (highest NESTI/IESTI) for apple (UK/infant) or pears (EU/NL toddler)**

| **Result type** | **PAH18** | **Sum of chrysene and benz[a]anthracene** | **Phenanthrene** |
|---|---|---|---|
| Control = No creosote stakes<br>%DMEL UK | **620** | 16 | **209** |
| Control = No creosote stakes<br>%DMEL EU | **800** | 16 | **267** |
| Non-Contact fruits - A<br>%DMEL UK | **5783** | 16 | **2137** |
| Non-Contact fruits - A<br>%DMEL EU | **7333** | 20 | **2733** |

| | | | |
|---|---|---|---|
| Non-Contact fruits - B<br>%DMEL UK | **4100** | 16 | **1703** |
| Non-Contact fruits - B<br>%DMEL EU | **5333** | 16 | **2167** |
| Contact fruits<br>%DMEL UK | **34637** | **105** | **12083** |
| Contact fruits<br>%DMEL EU | **44333** | **133** | **15333** |

**ACUTE VF 1 (or no VF applied) (highest NESTI/IESTI) for apple (UK/toddler) or apple (EU/NL toddler)**

| Result type | PAH18 | Sum of chrysene and benz[a]anthracene | Phenanthrene |
|---|---|---|---|
| Control = No creosote stakes<br>%DMEL UK | **343** | 9 | **116** |
| Control = No creosote stakes<br>%DMEL EU | **273** | 9 | 93 |
| Non-Contact fruits - A<br>%DMEL UK | **3197** | 9 | **1183** |
| Non-Contact fruits - A | **2567** | 7 | **933** |

| | | | |
|---|---|---|---|
| %DMEL EU | | | |
| Non-Contact fruits - B %DMEL UK | **2667** | 9 | **943** |
| Non-Contact fruits - B %DMEL EU | **1800** | 9 | **767** |
| Contact fruits %DMEL UK | **19153** | 58 | **6667** |
| Contact fruits %DMEL EU | **15333** | 47 | **5333** |

**Results (acute):**

The results of this indicative consumer risk assessment show that the consumer DMEL is exceeded for the highest acute exposure estimates representing sum of the PAHs in the untreated controls, but at a lower level (compared to the 'treated' samples). Even when assuming no variability factor, the UK highest acute dietary intakes (for UK toddlers consuming apple) based on untreated control fruits represented 343% of the consumer DMEL of 0.3 µg/kg bw/day (based on sumPAH18).

Clearly , the highest acute dietary intakes were for the contact fruits, with highest UK dietary intakes for UK consumers consuming apples at 19153% (no VF – toddler critical ) - 73033% (VF 7 – infant critical) of the consumer DMEL of 0.3 µg/kg bw/day based on sumPAH18).

The applicant has explained how the non-contact fruit are regarded as representative of fruits that are harvested commercially (and not the 'contact fruits'). The results are complex due to the results presented for the different laboratory analyses (in study 3). However, for these residues samples, the highest UK and EU acute dietary intakes for UK and EU consumers represented (as a % of the consumer DMEL of 0.3 µg/kg bw/day (based on sumPAH18)):

- 1800% to 3197% (no variability factor applied); and
- 4100% to 7333% (VF of 3 applied); and
- 8637% to 17333% (VF of 7 applied)).

The critical consumer group / commodity combination were either apple or pears, infant or toddlers for EU or UK models (see table above).

Even for non-contact fruits, the results for phenanthrene alone represent high dietary acute intakes. Virtually all the highest acute dietary intakes for phenanthrene calculated represented high exceedances of the consumer DMEL. The applicant has noted that phenanthrene, one of the components in creosotes is thought not be one of the components that might confer carcinogenic properties; however specific toxicity data to address the toxicology profiles of individual creosote constituents have not been submitted.

Even though the application of the consumer DMEL to the acute exposure assessment represents a highly conservative approach, the resulting estimates with the considerable degrees of exceedance of the consumer DMEL are such that the conclusion of the acute exposure assessment is that harmful effects on health cannot be excluded for the fruit tree uses. The acute dietary intakes calculated in the indicative dietary risk assessment indicate that an expectation of short term effects on health cannot be excluded arising from the assessment of the fruit tree uses of creosote.

### *A.7 Overview and conclusion*

Three fruit tree residues studies have been evaluated to consider residues arising from uses of creosotes wooden stakes as supports in food production. The studies covered pome fruits (apples and pears) and stone fruits (cherries and plums).

Two out of the three studies were conducted to GLP, although they could be regarded as monitoring studies as the trials did not set out the mode or dose of applying the creosote to the wood posts. It is assumed that the posts were treated at the label recommended rate; this and other uncertainties are discussed in the overall evaluation, including section A.5.4

In all studies control sites were considered, where no creosote had been used. In all of these sites there are some soil residues of polycyclic aromatic hydrocarbons (PAHs), including some of the PAHs found in creosote, but also some wider PAHs found in the soil. The soil findings are therefore indicative of some background levels of PAHs from anthropogenic sources not including the uses of creosotes. There were some low level residues of PAHs in fruits taken from the control plots.

Wood analyses were performed to determine creosote components in each study (and to compare to the profiles suggested by the results for the fruit residue analyses).

In terms of fruit samples analysed for PAH residues, study 1 residues were evaluated in contact fruits, those that had come into contact with the creosote wooden stakes (and are unlikely to be of commercial harvest quality) and also in the non-contact fruits. The latter were taken from sampling that is not targeted to fruits that have been in contact with the wooden posts but are considered representative of a commercial harvest. Studies 2 and 3 only considered non-contact fruit samplings.

The main residues found in fruits are phenanthrene, fluoranthene and pyrene, all present in creosotes. Then, in terms of prevalence, followed by some other PAH

constituents of creosotes.

Residues are much higher in the contact fruits compared to the non-contact fruits. In study 1, the total PAH levels (PAH18) in the non-contact fruits ranged from 29 to 128 µg/kg in fruits for the sites using creosoted wood stakes. The corresponding range for the contact fruits was 225 to 2069 µg/kg.

It is difficult to know the precise source of residues arising in the non-contact fruit. From the data overall it seems likely that there could be above ground transfer of residues from the parts of the trees that have had contact with the creosoted wooden stakes into the non-contact fruits, as well as there being low level uptake of the PAH residues from soil.

The residues determined in the fruits have enabled an indicative risk assessment to be performed. It is indicative, since a residues definition for dietary risk assessment is not being proposed as the residue findings are of concern (since it is concluded that creosote is a genotoxic carcinogen for which a non-threshold mechanism cannot be excluded (see section 12.2 on Reference values (HSE toxicological assessment)). In the indicative dietary risk assessment, the chronic and acute dietary intakes far exceed the consumer DMEL (see section A.6) indicating that an expectation of both long term and short term effects on health cannot be excluded arising from the assessment of the fruit tree uses of creosote.

It is not possible to propose risk mitigation measures that could reduce the indicative assessment dietary intakes to levels below the consumer DMEL. Mitigation measures and uncertainties in the assessment are discussed in section A.5.4. As noted above creosote is considered to be a genotoxic carcinogen. As such, for the proposed use of creosote on wooden posts used as supports for fruit trees (or other supports for food crops such as hops or grapevines) harmful effects on human health cannot be excluded.

## *A.8 References*

Agency for Toxic Substances and Disease Registry (ATSDR, 1995). Toxicological profile for polycyclic aromatic hydrocarbons, retrieved on 26/12/2014 from http://www.atsdr.cdc.gov/toxprofiles/index.asp

Environment Agency, 2021. Polycyclic Aromatic Hydrocarbons (PAHs): Challenges for the Environment, HMSO. https://www.gov.uk/government/publications/polycyclic-aromatic-hydrocarbonspahs-challenges-for-the-water-environment

EFSA, 2008. Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Polycyclic Aromatic Hydrocarbons in Food. The EFSA Journal (2008) 724, 1-114.

[redacted] *et al.*, 1997. Atmospheric Emission of Polycyclic Aromatic Hydrocarbons in Sampling Areas of the German Environmental Specimen Bank. Method for the Precise Measurement of Gaseous and Particle-Associated Polycyclic Aromatic Hydrocarbons in the Sub-Nanogram Range Using Deuterated Internal Standards, Chemosphere, Vol. 34

[redacted] *et al*., 2012 “Human Health Risk Assessment of 16 Priority Polycyclic Aromatic Hydrocarbons in Soils of Chattanooga, Tennessee, USA ” Water Air Soil Pollut. 2012 Nov 1; 223(9): 5535–5548

[redacted] *et al*., (2008). PAHs in background soils from Western Europe: Influence of atmospheric deposition and soil organic matter, Chemosphere 70 (9): 1596-1602.

[redacted] *et al.*, (2002). Polycyclic Aromatic Hydrocarbon Burden in Fruit and Vegetable Species Cultivated in Allotments in an Industrial Area, International Journal of Environmental Analytical Chemistry, 82 (10) 667-690.

## Appendix VIII: Confidential information

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