

# Report in accordance with requirements in Directive 2011/71/EU regarding creosote

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## Swedish Chemicals Agency

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# 1 Background

Pursuant to Directive 2011/71/EU<sup>1</sup>, the active substance creosote was included in Annex I to Directive 98/8/EC (BPD)<sup>2</sup> on 1 May 2013.

Biocidal products containing creosote may only be authorised for uses where the authorising Member State concludes that no appropriate alternatives are available. The conclusion shall be based on an analysis regarding the technical and economic feasibility of substitution, which the Member State shall request from the applicant, as well as on any other information available to the Member State.

According to a specific provision in directive 2011/71/EU Member States authorising biocidal products containing creosote in their territory shall submit a report to the Commission no later than 31 July 2016 justifying their conclusion that there are no appropriate alternatives and indicating how the development of alternatives is promoted.

In Directive 2011/71/EU it is also stated that, to increase transparency, it is appropriate to require Member States to include in the report their information on how the development of alternatives is promoted in accordance with Article 6(2) of Regulation (EC) No 850/2004, either directly or by reference to a published action plan.

This report aims to summarise some of the conclusions drawn when authorising creosote containing biocidal products in Sweden.

## 2 Authorised products and uses

### 2.1 Applications for creosote products in Sweden

The Swedish Chemicals Agency received applications for product authorisation and establishment of a frame formulation under Directive 98/8/EC. On 1 September 2013, the Directive (98/8/EC) was replaced by the Regulation (EU) No 528/2012 (BPR). The applications were then transformed to applications for authorisation of biocidal product families. According to the transitional measures, Article 91 in BPR, applications for biocidal product authorisations submitted under Directive 98/8/EC and for which the evaluation not have been completed by 1 September 2013 shall be evaluated in accordance with that directive but with the following exceptions;

- where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 5.1 is met, the biocidal product shall be authorised in accordance with Article 19,

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<sup>1</sup> Commission Directive 2011/71/EU of 26 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include creosote as an active substance in Annex I thereto

<sup>2</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

— where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 10 is met, the biocidal product shall be authorised in accordance with Article 23.

The active substance creosote meets the criterion according to Regulation (EC) No 1272/2008 for classification as carcinogen in category 1B and fulfils therefore the exclusion criterion in Article 5.1(a) of the Biocidal Regulation. Creosote fulfils also the criterion in Article 5.1(e) by containing constituents that have been considered as persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII to Regulation (EC) 1907/2006. The biocidal products shall therefore be authorised in accordance with Article 19 in BPR.

The Swedish Chemicals Agency considers that creosote satisfies the conditions given in Article 5.2(c), i.e. 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. Creosote fulfils therefore the criterion given in Article 10.1(a) in BPR. Consequently, creosote shall be regarded as a candidate for substitution and the Swedish Chemicals Agency performed a comparative assessment in accordance with Article 23 in the same regulation as part of the assessment of the applications for authorisation for the creosote containing products.

Furthermore, in case the biocidal products contain active substances covered by the exclusion criteria in Article 5.1, the competent authorities shall, according to point 10 in Annex VI, also evaluate whether the conditions of Article 5.2 can be satisfied in their territory.

The comparative assessment shows that there are currently not sufficient alternatives for the uses authorised by the Swedish Chemicals Agency in Sweden. The outcome of the Stakeholder consultation<sup>3</sup> regarding possible alternatives to creosote, launched by the European Commission in 2008, has also been taken into consideration.

The Swedish Chemicals Agency draws the conclusion that not authorising products containing creosote for certain uses would have a disproportionate impact on Swedish society when compared to the risk to human health, animal health or the environment arising from use of the substance. Therefore, the Swedish Chemicals Agency considers that the Article 5.2 (c) is fulfilled for the authorised products.

The Swedish Chemicals also concluded that the conditions laid down in Article 19.1(b) were not fully met. However, according to Article 19.5 a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human

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<sup>3</sup> Outcome of stakeholder consultation on creosote (CA-Sept08-Doc.8.4). The report is available at CIRCABC: <https://circabc.europa.eu/sd/a/a2cab71a-bf28-4c9f-907d-93a297db8403/report%20published.pdf>

health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The Swedish Chemicals Agency considers that the biocidal products families may be authorised in Sweden with the support of Article 19.5 for the uses, with associated conditions, that are specified in the Swedish decision.

## 2.2 Other uses, such as creosote products for treatment of wood to be used for fence posts in the agricultural sector and products for treatment of wood to be used for marine applications were not authorised, as the Swedish Chemicals Agency concluded that there are alternative methods available for these uses in Sweden. **Authorised products**

The Swedish Chemicals Agency has authorised four biocidal products families under Biocidal Products Regulation (EU) No 528/2012 (BPR)<sup>4</sup> including a total of nine biocidal products (PT 8) with creosote as the active substance<sup>5</sup>.

## 2.3 Authorised uses

1. Preventive treatment of wood to be used as railway sleepers<sup>6</sup>.
2. Preventive treatment of wood to be used as poles for transmission lines<sup>7</sup>.

## 2.4 Conclusions concerning appropriate alternatives

The Swedish Chemicals Agency has conducted a comparative assessment in accordance with Article 23 of the Biocidal Products Regulation.

The comparative assessment was done in a tiered approach in accordance with the guidance document “Note for Guidance - Comparative assessment of biocidal products” (CA-March14-Doc.5.4) which was available at the time this assessment was started.

### 2.4.1 Preventive treatment of wood (pine) to be used as railway sleepers.

The result from the screening phase showed that there are so far no suitable wood preservatives in Sweden which have been authorised under BPR or BPD that could be used for protection of wooden railway sleepers. A comparison according to Tier

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<sup>4</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

<sup>5</sup> Asset numbers in R4BP: SE-0013846-0000, SE-0013848-0000, SE-0013847-0000, SE-0013849-0000. Swedish authorisation numbers: 5227, 5228, 5229, 5230.

<sup>6</sup> Use class (UC) 3 according to EN Standard 335.

<sup>7</sup> Use class (UC) 4 according to EN standard 335 with the exception of wood to be used in direct contact with fresh water.

I-B is not possible since there are no products containing creosote that have been authorised under BPR or BPD.

The Swedish Chemicals Agency has received information about a number of non-chemical alternative materials that are used for railway sleepers. However, these railway sleepers have, according to end users, not been sufficiently tested in Sweden yet. Creosote treated wooden sleepers are used in order to maintain the existing wooden lines by single replacement of damaged creosote wooden sleepers. There are, according to end users, no available alternative wooden sleepers which meet their requirements at the present time. It should be noted that a railway line represents a safety-critical field where confidence in performance and long service life of sleepers is important.

The Swedish Chemicals Agency cannot, based on this assessment, exclude that a prohibition of creosote products used for protection of railway sleepers could lead to significant economic or practical disadvantages for end users. The criteria in Article 23 are not met according to this assessment, and therefore a prohibition based on that article is not possible. The analysis shows that there are no appropriate alternatives in Sweden to creosote products for this use. This use should therefore not be prohibited or restricted based on this comparative assessment and the specific provision for creosote.

#### **2.4.2 Alternative materials for utility poles to be used for electric power transmission and telecommunication**

The result from the screening phase showed that there are so far no suitable wood preservatives in Sweden, which have been authorised under BPR or BPD, for protection of wooden poles to be used for electric power transmission and telecommunications. A comparison according to Tier I-B is not possible since there are no products containing creosote that have been authorised under BPR or BPD. Several alternative materials used for poles are presented in this report. According to end users alternative poles which may have the potential to substitute creosote treated wooden poles are not economically reasonable or are not yet sufficiently tested in Sweden. Poles used for electric power transmission and telecommunication represent a safety-critical use where confidence in performance and long service life is important. Furthermore, the submitted life cycle analyses do not give a coherent picture of which of the alternative material or creosote treated wood has the least negative impact on the studied environmental and health factors.

The Swedish Chemicals Agency cannot exclude that a prohibition of creosote products for use as protection of wooden poles for electric power transmission and telecommunications could lead to significant economic or practical disadvantages for end users. The criteria in Article 23 are not met according to this assessment, and therefore a prohibition based on that article is not possible. The analysis shows that

there are no appropriate alternatives in Sweden to creosote products for this use. This use should therefore not be prohibited or restricted based on this comparative assessment and the specific provision for creosote.

### 3 Alternatives promoted

The Swedish Chemicals Agency has only authorised such uses where the conclusion was that no appropriate alternatives are available.

There are currently no additional activities for promoting alternatives to creosote.

#### 3.1 Article 6(2) of Regulation (EC) No 850/2004

According to directive 2011/71/EU Member States, it is appropriate to require Member States to include in the report their information on how the development of alternatives is promoted in accordance with Article 6(2) of Regulation (EC) No 850/2004 (the POPs Regulation), either directly or by reference to a published action plan.

According to Article 6(2) of Regulation (EC) No 850/2004, a member state shall communicate its action plan on measures to identify, characterise and minimise with a view to eliminating where feasible as soon as possible the total releases developed in accordance with its obligations under the Stockholm Convention, to both the Commission and the other Member States as part of its national implementation plan, pursuant to Article 8.

The current Swedish National Implementation Plan only includes the substances in the Stockholm Convention. Polycyclic aromatic hydrocarbons ('PAHs'), which constitutes the main part of creosote, are not part of the Stockholm Convention. Therefore, the current Swedish National Implementation Plan does not include information on PAHs.

There is currently no separate action plan for creosote or PAHs.