



To the: European Commission
DG SANTE
DDG2 - Unit E.4 – Pesticides and Biocides
F101 07/060
B-1049 Brussels/Belgium

Subject: Report about authorization of biocidal product which contain creosote as active substance in Spain.

The Spanish Competent Authority has authorised a biocidal product family with creosote containing two biocidal products on 13th September 2018. The active substance creosote meets the criteria of substitution according to the article 10.1. a) of Regulation (EU) n° 528/2012 and for this reason a comparative assessment report in accordance with Article 23 of the BPR has been performed.

The 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 establishes that: *“biocidal products containing creosote should be authorised only for applications where, all local and other circumstances taken into account, no appropriate alternatives are available. When an application is made for product authorisation or mutual recognition, the Member State receiving the application should therefore ask the applicant for an analysis regarding the technical and economic feasibility of substitution. Based on this analysis and any other information available to it, an authorising Member State should justify their conclusion that there are no appropriate alternatives and report the justification to the Commission at a stage when product authorisations can be expected to have been granted. In this context, 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...”*

No guidance have been developed under the biocidal products Directive 98/8/EC (BPD) in order to facilitate for applicants or evaluating Member States how to comply with this provision. The Spanish Competent Authority considers however that a comparative assessment made in accordance with Article 23 of the BPR covers the aspects that shall be considered according to the specific provision.

Once the Spanish Competent Authority has granted the authorization of biocidal products contained creosote by mutual recognition in sequence, we proceed to inform the Commission about our conclusions.

Uses authorised in Spain for creosote containing product are preventive protection of:

- Railway sleepers
- Poles for electricity and telephone lines.



Based on the comparative assessment performed by ES CA according to the mode of action and resistance, it is considered that there is one product that have been authorized under BPR or BPD which can replace the creosote in order to protect wooden railway sleepers, poles for electricity and agricultural fencing. However, it is not possible to give a quantitative comparison with the alternative biocidal product for risk characterization. For Creosote, it is concluded that there are sufficient MOEs at the European impregnation plants, acceptable uses are identified as far as acceptable uses can be said to exist for a carcinogen. The biocidal product alternative is not a product carcinogen and their exposure assessment and risk characterization is acceptable and in relation with the environmental risk the use of both biocidal products, creosote containing products and the biocidal product alternative, do not pose any risk to the groundwater compartment and in addition, the biocidal product alternative presents lower risk to the environment than creosote containing products.

Therefore, the alternative biocidal product have a significantly lower overall risk for human health, animal health and the environment.

On the other hand, concerning the practical and economic disadvantages, the alternative biocidal product has any potential economic disadvantage as to the costs of transition from one treatment to another.

In some cases long term experience is needed to finally decide if the alternative is sufficient enough to replace creosote-treated wood – and this information is not available at the time of decision alternatives report.

Regarding non-chemical alternatives the conclusions were the following:

- about alternative materials to be used for railway sleepers, the conclusion was that the wooden sleeper still represents a very high percentage in existing sleepers and that a hypothetical replacement would have a considerable economic impact.
- in relation to alternative materials for utility poles to be used for electric power transmission and telecommunication, the conclusion was that they have registered 3,380,445 poles, of which 94.32% are made of wood. There are posts made with other materials (concrete, composites ...) The concreted poles are used for specific needs, the fiberglass, although efforts are being made to do so there are still no commercial products available and the metal poles is not considered for reasons of safety and electrical insulation but cannot be considered as an alternative to wooden posts. So they cannot be considered a viable alternative to wood poles.




- for the use of alternative materials for fence post to be used for in agricultural sector, ES CA has limited knowledge on the extent to which creosote treated wooden posts are used for fencing in Spain. The applicant has not submitted any information which addresses the situation in Spain concerning the current use or need of creosote treated posts.
- by last, alternative materials to be used for in marine installations, the conclusion was that ES CA has very limited information on the extent to which creosote treated wood are used in different marine installations such wharfing and piling compared to other materials. The applicant has not submitted any specific information concerning the situation in Spain. Neither has information concerning marine constructions been submitted by other stakeholders such as manufactures of alternative materials or by end users.

Therefore, not fully feasible to apply methods (non-chemicals alternatives) for replacing of creosote-treated wood in relation to applications submitted by the applicant because would have positive impact on socio-economical and practical aspects in comparison with currently used of creosote products/creosote protected wood.

Applicant has also requested for authorization of creosote products for use in marine installations. But no analysis the situation has submitted in Spain addressing the need of creosote treated wood to be used for marine applications. There was no sufficient information submitted to prove that there aren't chemicals and non-chemical alternatives for creosote product for use in marine installations. Therefore this use cannot be authorized in Spain.

With all this the Spanish Competent Authority concludes that it has not been determined viable alternatives to the creosote and the family is authorized.

Madrid

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