



The European Wood Preservative
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To Whom it may concern

European Wood Preservative Manufacturers Association **position paper**
on the Order of issued pursuant to Article R. 522-16 of the Environmental Code
and relating to the conditions for using certain categories of biocidal products
prepared by the Republic of France
Notification number 2016/0364/F - C00C

Ministry responsible

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Dear Sirs and Madam,

The European Wood Preservative Manufacturers Association (EWPM) represents manufacturers of wood preservative Biocidal Products in the European Union. Members are based in or operate in, all of the member states of the E.U. and represent the leaders in the market.

The EWPM wishes to express their concern regarding certain aspects of the Order prepared by France. We provide further comments on the specific areas of concern, but overall consider that without these points being addressed the provisions within this order are inconsistent with, and go beyond the Biocidal Products Regulation (BPR 528/2012) which is the applicable regulation concerning the making available on the market and use of biocidal products in the EEA. Unless this order is amended, it will impact the functioning of the BPR and would place unnecessary restrictions on our Members biocidal products without legal justification.

As background, the Member State France submitted a notification to the European Commission, Growth Directorate General – single market for goods/Prevention of Technical Barriers- on 18th July 2016 for the purpose legally defining and specifying the conditions for using certain categories of biocidal products with a view to preventing the potential human health and environmental risks posed by these products.

<http://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2016&num=364&mLang=EN>

It was justified by the transfer of marketing authorizations now issued by the French Agency for Food, Environmental and Occupational Health & Safety instead of formerly granted by the Ministry of the Environment.

“...In this context, the provisions of the Environmental Code have changed as a result, and now state that ‘the conditions for using certain categories of biocidal products [may] be established by a joint Order of the Ministers for the Environment, Labour and Health, with a view to ensuring the effectiveness of these products and preventing the potential human health and environmental risks likely to arise from these activities’....”

The EWPM considers that the following specific points have to be clarified in order to avoid misinterpretations and negative consequences for the use of biocidal products underlying existing regulations as 528/2012/EU (BPR) and 1272/2008/EC in general:

Article 2 (wood preservatives authorised for use by the general public)

The draft order includes a restriction that “A wood preservative is not authorised to be made available on the market for use by the general public when the conclusions of the risk assessment for this product performed pursuant to Article 30 of the aforementioned Regulation (EU) No 528/2012 are that gloves must be worn for at least one usage or one type of packaging, or when it is classified as a skin sensitiser category 1 in accordance with the aforementioned Regulation (EC) No 1272/2008 and when it contains at least one active substance classified as a skin sensitiser category 1A in accordance with said Regulation.

When authorising a biocidal product under the BPR, where a risk assessment for a specific use or packaging is found not to show a safe use, that use would not be expected to be included as part of the authorisation decision. However, where other uses of that same product are shown to be safe, including those by the general public, those safe uses are considered acceptable and included in the BPR authorisation. That is not to say that a biocidal product, such as a wood preservative that requires PPE to demonstrate a safe use cannot be authorized for use by the general public.

It should also be noted that the same authorisation of a biocidal product/Biocidal Product Family can include more than one user category (Industrial, Trained Professional, Professional and General public). There are a number of clear examples of this for wood preservative products under the BPR. Due to the different exposures experienced by industrial and professional users, safe uses often include the use of gloves by these user groups. Indeed, some of the risk assessments under the BPR for certain user groups (e.g. industrial) / application method combinations presume gloves are worn and therefore the authorisation would include the use of gloves by default for those users.

Therefore, in line with the BPR, if the Competent Authority under the BPR concludes that gloves must be worn for at least one usage or one type of packaging, then there is no justification that the product is entirely banned for use by General Public.

The proposed restriction in this Order that a wood preservative biocidal product should not be authorised for use by the general public when it contains at least one active substance classified as a skin sensitizer category 1A

Concentration limits of sensitizing active substances are clearly defined in the current CLP regulation 1272/2008. A single national demand that a wood preservative must not be authorised for the general public if it contains at least one active substance classified as a skin sensitiser category 1A (regardless of its concentration) goes beyond this CLP regulation binding for ALL European Member States. The EWPM considers that the consequences of this article in the Order for the use of other biocidal product types, besides wood preservatives would be extremely significant. Given that this clear exceeds the recommendations of the document CA-Sept.13-Doc6.2.a-Final.Rev1 which was agreed by all Member States in 2013 concerning the use of sensitizing substances, this requires further consideration.



The EWPM considers that Article 2, undermines the obligations and rules for the authorisation and use of Biocidal Products laid down under the BPR as well as the legal obligations and rules of harmonised classification and decisions of the ECHA Risk Assessment Committee (RAC) according to CLP regulation. Consequently, we request deletion of Article 2 and ask France to follow the Commission guidance on products containing skin sensitizers for use by non-professionals (see above).

Article 3 (wood preservatives authorised for professional use)

The EPWM considers that making the use of appropriate personal protective equipment (PPE) compulsory when using wood preservative products authorised for use by professional users again goes beyond the requirements and purpose of the BPR. Where the risk assessment for a particular use of a wood preservative shows acceptable risk without PPE, then it is authorized as such and not overridden by an arbitrary view. The EWPM considers that the mandatory use of PPE when it is shown not to be required is not good practice and request deletion of article 3.

Article 4 (wood preservatives used by soaking)

The draft Order proposes to restrict the use of wood preservatives containing the active substance IPBC in dipping/soaking application processes to only entirely automated processes.

The EWPM consider that there is absolutely no justification for such a restricted provision and this perhaps results from a misunderstanding of the situation. As part of Article 4(4) mutual recognition dispute procedures under the Biocidal Products Directive 98/8/EC, a concerned Member State questioned the risk assessments for certain IPBC containing wood preservative products and disputed the acceptance of the mutual recognition of their automatic dipping uses that had been determined to be safe by the Reference Member State.

Firstly, it is important to note that where some of these products contained both manual and automatic dipping uses, the manual dipping use was not disputed and so was not part of the Article 4(4) disputes. Since the manual dipping uses were not contested they were not subject to the eventual Commission implementing Regulations that resulted from these dispute procedures. As it stands, Article 4 of the Order would prevent manual dipping or partially automatic dipping uses of IPBC containing products, even if safe uses have been demonstrated. This would clearly be unacceptable for the EPWM and its members.

Secondly, the provisions that resulted from these dispute procedures agreed at the PA&MRFG and Coordination Group meetings and that are specified in the relevant Commission implementing regulations (for example EU Commission Implementing decision 2014/756/EU, 2014/402/EU and 2014/757/EU) must only be considered specific to those products cited in those regulations. It should not be considered as a 'general rule' for all IPBC containing wood preservative products used by automatic dipping and to do so would be unacceptable. The background is that the decision within those implementing regulations to include certain provisions concerning labelling in those specific authorisations, was based upon the risk assessments for those specific contested products. The risk assessments were specific for those products due to their data sets and IPBC concentration. So it is not appropriate to impose such a restriction on all IPBC containing products. Where a risk assessment for an IPBC containing wood preservative demonstrates a safe use for dipping processes, whether manual, or partially automated or automated, these uses should be authorised in accordance with the BPR.

Moreover, such specific condition in France for IPBC PT8 products will considerably impede the mutual recognition process for PT8 products in the EU.

We have serious concerns regarding this draft Order and its impact on the BPR procedures and our Members products. We, as EWPM, therefore request that you consider these comments and ensure that the document is amended accordingly.

Yours sincerely.