References:

European Commission DG Growth Notification number: 2016/0364/F (France)

Document: "Arrete_Biocides_AMM_2016-09-12_ConsultPublic" / NOR: DEVP1612190A

Comments of the European Union IPBC Task Force on Title II of the draft order from FRANCE "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"

Title II – Provisions applicable to wood preservatives

Article 4 (wood preservatives used by soaking)

The use of wood preservatives containing the active substance IPBC (Iodopropynyl butylcarbamate – CAS: 55406-53-6) in a soaking process, is only authorised for entirely automated processes.

Comments of the European Union IPBC Task Force:
The restriction that IPBC wood preservatives can only be authorised for entirely automated processes for soaking (dipping) treatments is not in accordance with REGULATION (EU) No 528/2012 (BPR). A product shall be authorised under the BPR if the conditions laid down in Article 19(1) of the BPR are met. Risk mitigation measures or restrictions of intended uses should only need to be applied if these conditions are not fulfilled. If the results of the human health and environmental exposure and risk assessments demonstrate that the use of the biocidal product does not pose a concern and the other criteria under Article 19 (1) are also met, the biocidal product should be authorised without any restrictions. This applies to all active substances and PTs and therefore it should also be applied to IPBC in PT8.

The COMMISSION DIRECTIVE 2008/79/EC of 28 July 2008 on IPBC in PT8 does not contain specific conditions for the use of IPBC PT8 products in dipping processes. Therefore, such conditions which would need to be considered in general in the product authorisation process for IPBC products are not existent.

It is not stated in the draft order from France for which reason this restriction was proposed. We assume that the restriction is based on the discussion regarding automated dipping processes on individual IPBC PT8 products in 2013/2014. After this discussion, the decision, whether a restriction to fully automated processes is required, had been taken for each individual product and is reflected in Commission Implementing Regulations of the respective PT8 products (please refer to Commission Implementing decision 2014/756/EU, 2014/402/EU and 2014/757/EU). The discussion was related to the results of the human health exposure and risk assessment for automated dipping processes for these products. The outcome of the risk assessments for a product and use depends on several specific conditions (e.g. active substance concentration in the product, concentration of the product in the treatment solution or dermal absorption properties) and should not be generalised to the intended use of an active substance. Please note that products containing IPBC have been approved for manual dipping processes.

Conclusion:

- The restriction in the draft order from France that IPBC PT8 products should only be authorised in dipping processes for entirely automated processes, is not in accordance with

REGULATION (EU) No 528/2012 (BPR). It is not in line with Article 19 of the BPR where it is stated that a product shall be authorised if the conditions of Article 19 (1) are met.

- Furthermore, it does not consider the properties of individual products (e.g. concentration of an active substance in the product) and the results of risk assessments performed with individual products.

- The restriction comprises all IPBC PT8 products although such a general restriction for IPBC in PT8 had not been defined in the review process. DanishEPA, evaluating competent authority for IPBC in PT8, agreed by e-mail of 17 October "*that products containing IPBC can be authorised for a number of other uses, that don't contain automated processes, as this isn't a restriction described in the CAR.* They agreed further *"that the decision by the Commission dated 29.10.2014 as well as the implementing decision of 25.6.2014 relates to specific products and their evaluation, and not all PT8 IPBC products."*

- The restrictions for IPBC products designed for the above mentioned application would be for no reason considerably stricter than for all other PT8 products.

- A specific condition in France will considerably impede the mutual recognition process for PT8 products in the EU.

The Task Force holds the opinion that Article 4 of the draft order should be deleted.

Furthermore, please find below the comments from the European Union IPBC Task Force on Article 2 and Article 3 of Title II of the draft order from France. Although these two Articles do not refer specifically to IPBC products, both Articles will have a considerably impact on the authorisation of wood preservatives and therefore also on IPBC based PT8 products.

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

"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."

Comments of the European Union IPBC Task Force:
The Article 2 of the French order proposal on wood preservatives authorised for use by the general public is not in accordance with Regulation (EU) No 528/2012 (BPR) and Regulation (EC) No 1272/2008 (CLP). In addition, it goes beyond the note for guidance of the Commission related to "Authorisation of biocidal products classified as skin sensitisers requiring PPE for non-professional users" as laid down in document CA-Sept.13-Doc6.2.a – Final.Rev.1 (amended by CA-May14-Doc.5.2.a).

The first 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 […] are that gloves must be worn for at least one usage or one type of packaging […] (emphasis added)" is rather general and neglects important provisions of the BPR.

A biocidal product shall be authorised under the BPR if the conditions laid down in Article 19 (1) of the BPR are met. For conclusion on criterion (iii) under point (b) of Article 19 (1) related to unacceptable effects on human health, a human health exposure and risk assessment needs to be performed

according to Annex VI of the BPR. Generally, this risk assessment is performed per intended use (i.e. separately for professional and non-professional uses) and application type (i.e. separately for manual or automated processes, spraying or brushing applications etc.).

Based on these risk assessments, it may be demonstrated that, even if no personal protective equipment is worn, one or several intended uses of the biocidal product do not pose a concern to the non-professional user (i.e. the general public). In this case, and if the other criteria under Article 19 (1) are also met, the wood preservative should be authorised without any restrictions.

This conclusion of the European Union IPBC Task Force should also be read in the context of the second restriction of the French order proposal, i.e. that "a wood preservative is not authorised to be made available on the market for use by the general public […] when it is classified as a skin sensitiser category 1 […] (emphasis added)". In particular, the note for guidance of the Commission related to "Authorisation of biocidal products classified as skin sensitisers requiring PPE for non-professional users" (CA-Sept.13-Doc6.2.a – Final.Rev.1; amended by CA-May14-Doc.5.2.a) leaves a margin of discretion regarding the interpretation of paragraph 63 of Annex VI to the BPR. In particular, in the guidance note three principles are listed that should be considered by eCAs when authorising biocidal products classified as skin sensitisers requiring PPE for non-professional users. The eCA, on the basis of a thorough case-by-case analysis of the availability and suitability of alternatives, may even come to the conclusion that there are intended uses of a biocidal product classified as skin sensitiser category 1 and intended for the general public for which the use of personal protective equipment such as gloves can be considered acceptable.

The third restriction of the French order proposal that "a wood preservative is not authorised to be made available on the market for use by the general public […] when it contains at least one active substance classified as a skin sensitiser category 1A […] (emphasis added)" is again rather general and goes beyond important provisions of the CLP such as concentration limits for classification of mixtures. Generic concentration limits (GCLs) of substances classified as skin sensitisers and triggering classification of the mixture are provided in chapter 3.4.3 of Annex I to the CLP. In addition, specific concentration limits (SCLs) may have been set for individual substances (e.g. CMIT/MIT has a harmonized SCL of 15 ppm). These trigger values of the CLP are binding for all European Member States.

According to the French order proposal, any wood preservative containing at least one active substance classified as a skin sensitiser category 1A and intended for the general public would generally be banned irrespective of the concentration of this active substance in the product and resulting classification of the wood preservative. This restriction may have a considerable impact on the use of water based wood preservatives many of which contain in-can preservatives classified as skin sensitisers. Notably, most of these in-can preservatives are skin sensitizers category 1A but are usually present at rather low concentrations not triggering classification of the wood preservatives as skin sensitising.

Consequently, based on the concentration of the active substance classified as skin sensitiser category 1A in the wood preservative, the following cases should be differentiated and carefully considered:

- The concentration of the active substance classified as skin sensitiser category 1A does not lead to classification of the wood preservative as skin sensitiser 1 (or a subcategory such as 1A or 1B): Since there is no concern for the general public, the biocidal product should be eligible for authorisation (acc. to Article 19 (1) of the BPR).

- The concentration of the active substance classified as skin sensitiser category 1A leads to classification of the wood preservative as skin sensitiser 1 (or a subcategory such as 1A or

1B): According to paragraph 63 of Annex VI to the BPR and the note for guidance of the Commission related to “Authorisation of biocidal products classified as skin sensitisers requiring PPE for non-professional users” (CA-Sept.13-Doc6.2.a – Final.Rev.1; amended by CA-May14-Doc.5.2.a), such a product may also be eligible for authorisation for the general public after a case-by-case analysis based on expert judgement (see elaboration above for the second restriction).

Based on the above, the European Union IPBC Task Force concludes that a general ban of a wood preservative for use by the general public because of (at least) one use requiring gloves, and/or because of a classification as skin sensitiser category 1, and/or because of (at least) one active substance classified as a skin sensitiser category 1A is not in line with the provisions of the BPR, and thus not justified.

Notably, it is recognized that such a general ban would lead to a disproportionate disadvantage in the European market at both the national authorisation as well as the mutual recognition stage. Finally, despite the fact that the third restriction of Article 2 only relates to wood preservatives and uses by the general public, possible future consequences for biocidal products other than wood preservatives should be well considered already at this state.

In conclusion, the Task Force holds the opinion that Article 2 of the draft order should either be deleted or the wording be amended so that is stays fully in line with the provisions of the BPR and CLP.

Article 3 (wood preservatives authorised for professional use)

“The use of appropriate personal protective equipment is compulsory when using wood preservatives authorised for use by professional users.”

Comments of the European Union IPBC Task Force:

The restriction that “the use of appropriate personal protective equipment is compulsory when using wood preservatives authorised for use by professional users” is not in accordance with Regulation (EU) No 528/2012 (BPR).

A biocidal product shall be authorised under the BPR if the conditions laid down in Article 19 (1) of the BPR are met. For conclusion on criterion (iii) under point (b) of Article 19 (1) related to unacceptable effects on human health, a human health exposure and risk assessment needs to be performed according to Annex VI of the BPR.

This assessment aims at identifying possible concerns regarding the use of the biocidal product by e.g. professional users. According to Annex VI, point 63 of the BPR, prevention and protection measures including personal protective equipment only need to be applied if otherwise the conditions laid down in criterion (iii) under point (b) of Article 19 (1) cannot be complied with.

However, the outcome of the risk assessments for a product and use (such as a professional use) depends on several specific conditions (e.g. active substance content or in-use dilution of the product, type of application such as manual or automated processes or dermal absorption of the active substance) and should, therefore, not be generalised to a “professional use”. Notably, the risk assessment may demonstrate that, even if no personal protective equipment is worn, the use of the biocidal product does not pose a concern to professional users. In this case, and if the other criteria under Article 19 (1) are also met, the wood preservative should be authorised without any restrictions (i.e. without compulsory personal protective equipment for professional users).

This approach is fully in line with e.g. the specific provisions of Commission Directive 2008/79/EC of 28 July 2008 on IPBC in PT8 stating that “in view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means (emphasis added)”.

In conclusion, the general prescription of compulsory personal protective equipment for professional users using wood preservatives neglects the properties of individual products and the outcome of human health exposure and risk assessments, and is therefore not in line with the provisions of the BPR. In addition, a specific condition in France regarding compulsory personal protective equipment for professional users will considerably impede the mutual recognition process for PT8 products in the EU.

In conclusion, the Task Force holds the opinion that Article 3 of the draft order should be deleted.