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Polish Association of Cosmetics and Home Care Products Producers comments in view of the Council WP meeting on 4 November on the proposal to amend the Biocidal Products Regulation (EU) No 528/2012

In view of the Council's Working Party meeting on 4 November, Polish Association of Cosmetics and Home Care Products Producers is hereby sharing its views on the draft report adopted by the European Parliament Environment Committee on 17 October. On top of addressing inconsistencies and errors, the adopted amendments represent a huge improvement to secure predictability and harmonisation in the implementation of the Biocidal Products Regulation. This is particularly the case in the following areas:

- Biocidal Products Family;
- List of alternative suppliers;
- Treated articles.

Without reopening any substantive issues, Polish Association of Cosmetics and Home Care Products Producers calls on the Council to consider further opportunities to clarify the legal text. It is essential to enhance the workability of the Regulation and to avoid any unnecessary burden, already high on industry and authorities, for the placing on the market of biocidal products.

Biocidal product family

Biocidal product family helps authorities and industry save consequent workload and resources in terms of number of dossiers. They permit that closely related products benefit from a unique authorisation. In this respect, Polish Association of Cosmetics and Home Care Products Producers strongly supports the proposal of the European Parliament to maximise the use of the biocidal product family concept.

In line with its definition (Art. 3.1.s), a product family should be allowed to include individual products of a less severe classification than the highest-risk formulation on which the family is based. This is consistent with the objective of the Regulation to encourage the development of lower risk products. This is also in line with the frame formulations approach under the Biocidal Products Directive. Basing the risk assessment for the biocidal product family on the worst case scenario (i.e. the reference product of the family with the highest risk composition and use) ensures a manageable scope for the family whilst respecting all safety standards.

Example: Innovation in Polish Association of Cosmetics and Home Care Products Producers member companies is often on the side of co-formulants that are present in small amount (perfumes, pigments, dyes) in disinfectants. Such small changes are essential to respond to consumer needs. However, even without affecting the risk level of the product, such small changes could trigger a lower classification than the reference product.

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Prolonged phase-out for label changes

Polish Association of Cosmetics and Home Care Products Producers supports the latest discussion of the Competent Authorities on 26 September that concluded on prolonging phase-out periods for some label changes. Indeed bringing a biocidal product, so far regulated and risk-assessed under national scheme, in compliance with the BPR may require only very specific modifications of its label that do not affect the safe use of the products or its efficacy. Considering the length of the supply chain, for the labelling of the products on shelves to be BPR compliant within 180 days would imply costly product recalls that are simply disproportionate and unsustainable for companies, in particular the smallest ones. For these particular situations, it should be ensured that existing stocks for the products benefit from a longer phase-out periods. Other labelling changes related to safe use and efficacy would still be subject to a stricter timeframe (180 days). Furthermore, products for which an authorisation has not been granted are also subject to the shorter timeframe.

Examples of national/BPR labelling changes not affecting the safe use or efficacy of the products:

- aligning the wording of the active substance to the BPR wording (e.g. Ethanol vs Ethyl alcohol); and change in the metric unit use to report concentration (grams vs %) (art. 69(2)(a));
- reference to the authorisation number allocated to the biocidal product (art. 69(2)(c));
- change in the name and address of the authorisation holder (e.g. branch of the company instead of headquarters)(art. 69(2)(d));
- changing the wording of the product description to align with BPR wording (e. g. "highly viscous liquid" instead of "gel") (art. 69(2)(e));
- change in the wording of a claim (art. 69(2)(f)) (e.g. for insecticide: "effective on flying and creeping insects" replaced in the BPR by the specific name of the tested target species);
- aligning the directions for use, frequency of application and dose rate (art. 69(2)(g)) (e.g. use directions have been changed from "can be used indoor and outdoor (cellars, campings, etc)" to a more generic "to be used in and around buildings, indoors");
- aligning directions for the safe disposal (art. 69(2)(j));
- aligning the expiry date as it has been reduced to 2 years against the previous 3-5 years (art. 69(2)(k));
- aligning frequency of use/time of application (art. 69(2)(l)) (e.g. for insect repellent it has be added on pack: "do not apply more than X times a days (one application equals 3 sprays)").

Treated articles

The proposal to include "intentionally" makes the article consistent with the definition of a treated article (Art. 3.1.l). In addition, amendment 25 by Matthias Groote provides clarity as to the transition period to apply the provision.

List of alternative suppliers

Polish Association of Cosmetics and Home Care Products Producers supports that product suppliers are allowed to access the list of approved suppliers when they have all the necessary data to support an active substance dossier. In addition, a provision to update the list after the renewal process shall be added.

Classification & Labelling of products

In line with the provision of the Classification, Labelling and Packaging Regulation (EU) No 1272/2008, which also applies to biocidal products, the responsibility of classifying and labelling is with the companies who place products on the market. Yet, the BPR inconsistently transfers this responsibility to Member States Competent Authorities. Therefore any change in classification and labelling (frequent in practice) will require a

re-authorisation via the label approval prior to authorisation granting. Polish Association of Cosmetics and Home Care Products Producers urges the Council to take the opportunity of the correction exercise to address this important inconsistency and liaise with the relevant CLP authorities as required.

ECHA enforcement

Polish Association of Cosmetics and Home Care Products Producers welcomes that the European Chemicals Agency (ECHA) is tasked to provide support and assistance to Member States with regard to control and enforcement activities. This will facilitate good exchange of information between Member States.

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