Warsaw, September 23rd, 2013

S T A T E M E N T of
Polish Association of Cosmetics and Home Care Products Producers
on
the proposal of the European Commission to amend the Biocidal Products Regulation (EU) No 528/2012

Polish Association of Cosmetics and Home Care Products Producers welcomes the correction of the Biocidal Products Regulation (BPR).

The aim of the Commission's proposal is to clarify ambiguous terms in the recently adopted BPR (22 May 2012). This is because of the complexity of the issue and time pressure in the negotiations. Polish Association of Cosmetics and Home Care Products Producers supports the correction but is further clarifying certain elements of the legal text. The intention is not to delay the adoption of the proposal that is so important at the time of the date of application of the BPR (1st September 2013). **Without reopening any substantive issues nor challenging the safety aspects of the Regulation, the proposals of Polish Association of Cosmetics and Home Care Products Producers are nonetheless crucial to secure predictability and harmonised implementation of the BPR notably in view of the long transitory period. These elements are particularly important considering that the biocides industry is an SME industry[1].**

Biocidal product family (Art. 19.6 and Art. 3.1(s))

The concept of biocidal product family helps authorities and industry save consequent workload and resources by permitting that closely related products benefit from a unique authorisation. However the current BPR text prevents the inclusion, in a given biocidal product family, of biocidal products with less severe classification than the higher-risk formulation on which the product family is based despite similar exposure levels, very close composition and proven efficacy.

This is inconsistent with:

- The objective of the Regulation to encourage the development of lower risk biocidal products;
- Recital (36) and Article 3(s) of the BPR as regards the definition of a biocidal product family, providing that variations in composition for non-active substances should not adversely affect the level of risk (meaning that all products within the biocidal product family should have the same or lower risk);
- The frame formulations approach (existing in the Biocides Directive) which does not require all closely related products to have the same classification.

Polish Association of Cosmetics and Home Care Products Producers proposal:
Risk being driven by hazard (reflected by the classification) and exposure, for other products of the family to have the same or lower risk either the hazard profile should be the same or lower, or the exposure, or both. The risk assessment for the biocidal product family should therefore be based on the worst case scenario, i.e. the "reference product" of the family with the composition and use with the highest risk, and lower risk products be

[1] SMEs account for more than 70% of the companies in the market, and up to 100% in some Member States. Large multinationals that participate in the market represent small and specific business units which must compete for R&D resources within the company.

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allowed in the product family. The reference to Annex VI ensures that different types of effects (human health and environment) are assessed and substances of concern taken into account. (See Appendix)

Transitional measures (Art. 89.4 and 93.2)

Bringing biocidal products, so far regulated under national scheme, in compliance with the BPR will require significant labelling changes related to new authorisation conditions. Considering the length and complexity of the supply chains, for products on shelves to comply with new labelling requirements within 180 days from the date of decision of the authority will imply costly product recalls. In addition, it is often impossible to anticipate compliance with the BPR without breaching national law that will apply for the product until the time of the new authorisation. Many of these labelling changes, although going beyond the strict definition of administrative changes provided in the Regulation, do not affect the safety of products that have been on the market for years:

- 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));
- aligning the directions for use, frequency of application and dose rate (art. 69(2)(g));
- aligning directions for the safe disposal (art. 69(2)(j));
- aligning the expiry date (art. 69(2)(k));
- aligning frequency of use/time of application (art. 69(2)(l)).

Polish Association of Cosmetics and Home Care Products Producers proposal:
The need to operate product recalls is clearly disproportionate when labelling changes do not affect either the safe use of the products, or their efficacy. We therefore propose that a list of labelling changes, such as those referred to in article 69(2)(a, c, d, e, f, g, j, k, l), that do not affect either the safe use of the products, or their efficacy, benefit from a 365-days timeframe that effectively allows to comply with new labelling requirement without product recalls. Other labelling changes would still be subject to a 180-days timeframe.

APPENDIX – AMENDMENTS

Amendments #1 & #2 - Biocidal Products Family

Article 19 – paragraph 6

Conditions for granting an authorisation

Regulation (EU) No 528/2012	*Amendment*
6. In the case of a biocidal product family, a reduction in the percentage of one or more active substances may be allowed, and/or a variation in percentage of one or more non-active substances, and/or the replacement of one or more non-active substances by other specified substances presenting the same or lower risk. The classification, hazard and precautionary statements for each product within the biocidal product family shall be the same ***(with the exception of a biocidal product family comprising a concentrate for professional use and ready-for-use products obtained through dilution of that concentrate).***	6. In the case of a biocidal product family, a reduction in the percentage of one or more active substances may be allowed, and/or a variation in percentage of one or more non-active substances, and/or the replacement of one or more non-active substances by other specified substances presenting the same or lower risk. ***The risk assessment for the biocidal product family conducted according to the common principles set out in Annex VI shall be based on the composition(s) and use(s) with the highest risk level for human health and animals, and environment respectively.*** For each product within the biocidal product family, the classification, hazard and precautionary statements shall be the same ***as, or of a lower concern than, those of the worst-case composition(s) evaluated in the risk assessment, and the level of exposure shall be the same as or lower than the worst case use(s) evaluated in that assessment.***
A biocidal product family shall be authorised only if ***all the biocidal products within it, taking into account the permitted variations referred to in the first subparagraph,*** are expected to comply with the conditions set out in paragraph 1.	A biocidal product family shall be authorised only if the permitted variations ***in composition and the uses*** referred to in the first subparagraph ***can be easily identified in the application together with their respective classification, hazard and precautionary statements and any appropriate risk mitigation measures, and if*** all the biocidal products within the family are expected to comply with the conditions set out in paragraph 1.

Article 3 – paragraph 1(s)

Definitions

Regulation (EU) No 528/2012	*Amendment*
"biocidal product family" means a group of biocidal products having similar uses, the active substances of which have the same specifications, ***and presenting specified variations in their composition*** which do not adversely affect the level of risk or significantly reduce the efficacy of the products;	"biocidal product family" means a group of biocidal products having similar uses, ***and similar composition with specified variations*** which do not adversely affect the level of risk or significantly reduce the efficacy of the products, the active substances of which have the same specifications;

Justification

The current BPR text prevents the inclusion, in a given biocidal product family, of biocidal products with less severe classification than the higher-risk formulation on which the product family is based despite similar exposure levels, very close composition and proven efficacy. This is inconsistent with:

- The objective of the Regulation to encourage the development of lower risk biocidal products;
- Recital (36) and Article 3(s) of the BPR as regards the definition of a biocidal product family, providing that variations in composition for non-active substances should not adversely affect the level of risk, meaning that all products within the biocidal product family should have the same or lower risk;
- The frame formulations approach which does not require all closely related products to have the same classification.

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Risk being driven by hazard (reflected by the classification) and exposure, for other products to have the same or lower risk, either the hazard profile should be the same or lower, or the exposure, or both. The risk assessment for the biocial product family should therefore be based on the worst case scenario, i.e. the "reference product" of the family with the composition and use with the highest risk, and lower risk products be allowed in the product family. The reference to Annex VI ensures that different types of effects (human health and environment) are assessed and substances of concern taken into account.

Amendments #3 & #4 – Transitional measures

Article 1 – point 11(c)
Amending Article 89 – Paragraph 4
Transitional measures

Commission's proposal	*Amendment*
4. Where a Member State's competent authority decides to reject the application for authorisation of a biocidal product submitted under paragraph 3***,*** decides not to grant authorisation, or decides to impose conditions of the authorisation making it necessary to change a product, the following shall apply:	4. Where a Member State's competent authority decides to reject the application for authorisation of a biocidal product submitted under paragraph 3, decides not to grant authorisation, or decides to impose conditions of the authorisation making it necessary to change a product, the following shall apply:
(a) the biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market with effect from 180 days after the date of the decision of the authority;	(a) the biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market with effect from ***365*** **days after the date of the decision of the authority** ***if the necessary change of the product relates to information referred to in Article 69(2)(a, c, d, e, f, g, j, k, l), or from*** 180 days after the date of the decision ***in other cases***;
(b) disposal and use of existing stocks of the biocidal product may continue until 365 days after the date of the decision of the authority.	(b) disposal and use of existing stocks of the biocidal product may continue until ***550 days after the date of the decision of the authority if the necessary change of the product relates to information referred to in Article 69(2)(a, c, d, e, f, g, j, k, l), or until*** 365 days after the date of the decision ***in other cases***.

Article 1 – point 12
Amending Article 93 – paragraph 2 – 1st & 2nd subparagraph
Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC

Commission's proposal	*Amendment*
By way of derogation from Article 17(1), a Member State may continue to apply its current system or practice of making available on the market biocidal products referred to in paragraph 1 of this Article for which an application was submitted in accordance with paragraph 1 of this Article until the date of the decision granting the authorisation. In the case of a decision refusing to grant the authorisation, or imposing conditions on the authorisation making it necessary to change a product, the biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market ***180 days after such a decision***.	By way of derogation from Article 17(1), a Member State may continue to apply its current system or practice of making available on the market biocidal products referred to in paragraph 1 of this Article for which an application was submitted in accordance with paragraph 1 of this Article until the date of the decision granting the authorisation. In the case of a decision refusing to grant the authorisation, or imposing conditions on the authorisation making it necessary to change a product, the biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market ***and disposed in accordance with Article 89(4)***.

By way of derogation from Article 17(1), a Member State may continue to apply its current system or practice of making available on the market biocidal products referred to in paragraph 1 of this Article for which an application was not submitted in accordance with paragraph 1 of this Article until 180 days after 1 September 2017.	By way of derogation from Article 17(1), a Member State may continue to apply its current system or practice of making available on the market biocidal products referred to in paragraph 1 of this Article for which an application was not submitted in accordance with paragraph 1 of this Article until 180 days after 1 September 2017.

Justification

Bringing biocidal products, so far regulated under national scheme, in compliance with the BPR will require significant labelling changes related to new authorisation conditions. Considering the length and complexity of the supply chains, for products on shelves to comply with new labelling requirements within 180 days from the date of decision of the authority will imply costly product recalls, including waste in raw materials. Therefore, labelling changes that do not affect either the safe use of the products, or their efficacy, should benefit from a 365-days timeframe that effectively allows to comply with new labelling requirement without unnecessary product recalls. Other labelling changes related to safe use and efficacy would still be subject to a 180-days timeframe.

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