EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate A – Green economy
ENV.A.3 - Chemicals

NOTE FOR GUIDANCE

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: Transition between national schemes and BPR-authorisations following active substance approvals

1.- Background and purpose of the document

(1) During the transitional period and for various reasons, some companies may have postponed any attempts to modify the composition, instructions for use or other elements[1] of their existing products, with the expectation that this could be done at the time of authorisation of their products under BPR rules.

(2) In the absence of a smooth transition regime, concerns have been expressed that changes to the composition of an existing biocidal product could force companies to support the existing biocidal product with a dossier for the existing formulation, *next to* filing a separate dossier for the reformulated product. These concerns are based on a possible interpretation of the legislative provisions that, if an application for the same formulation as the existing biocidal product is not submitted by the relevant deadline, the existing biocidal product would have to be phased out (e.g. in 12 months) before the reformulated biocidal product is authorised.

(3) The Commission services however consider that clear, simple and harmonised principles for the authorisation of existing biocidal products and the transition from national schemes to EU rules should make it possible,

[1] For example, where the product name will need to be aligned across the EU and the local name is not supported within the application for product authorisation under the EU rules.

where necessary, a smooth replacement of existing biocidal products by reformulated products. This should also avoid unnecessary double work both for companies as well as Competent Authorities.

(4) This paper therefore outlines a proposal to address the transition between national schemes and BPR-authorisations following active substance approvals.

2.- Proposed way forward

(5) The Commission services consider that a harmonised recommendation on this issue could be based on the new wording of Article 89 of BPR[2]. Pursuant to the second subparagraph of Article 89(3), those wishing to apply for authorisation "of biocidal products of that product-type" shall submit "applications" by "the date of approval of the active substance(s)".

(6) The third subparagraph of Article 89(3) sets out a global phase out period of 6 months for biocidal products "where no application … has been submitted in accordance with the second paragraph". For the sake of simplification and avoidance of undesired sales freezes, the proposed interpretation of this phasing-out provision is that it should only apply to products in the relevant active substance/PT-combination, which cannot be linked to any application for authorisation of a biocidal product or a biocidal product family submitted by the application deadline pursuant to Article 89(3).

(7) On the other hand, where a company has submitted an application for product authorisation by the date of the active substance approval with the aim to replace the existing biocidal product by another "improved" new product, The Commission services can interpret this case as covered by the second subparagraph of Article 89(3), and hence not caught by the phasing-out deadlines of the third subparagraph of Article 89(3).

(8) For the purpose of enforcement, this interpretation could be subject to the condition that the application for authorisation of the new product contains a clear identification and a short description of the existing product(s)[3] to be linked to such application. Obviously, the existing and the new product also have to contain the same active substance(s) and belong to the same PT, otherwise they would not be subject to the same authorisation application deadlines. In addition, both products should incorporate the active substance(s) in the same[4] concentration and have similar uses.

(9) Through this approach, the new BPR authorisation is interpreted in accordance with the new wording of Article 89(4), which applies to products

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2 See in the annex the amended version of Article 89(3)&(4) of the BPR.

3 Where several existing products are linked to one application, these should be listed. This will obviously be case if the application is for Union authorisation, but may also happen in case of a national authorisation.

4 Unless the modification is due to a maximum concentration level in biocidal products set by the active substance approval. This element has to be justified by the applicant within the description of the existing product(s) mentioned in this paragraph.

already made available on the market, and sets new deadlines, in particular where the Competent Authorities or the Commission impose conditions in the authorisation making it necessary to change those products.

(10) It has to be noted that the new product can only be placed on the market once it has been authorised under the BPR. Then, the "existing product" is replaced by the new one and existing stocks of the "existing product" are handled in accordance with Article 89(4) of the BPR.

Annex.

New wording of Article 89(3)&(4) of the BPR.

3. Following a decision to approve a particular active substance for a specific product type Member States shall ensure that authorisations for biocidal products of that product type and containing that active substance are granted, modified or cancelled as appropriate in accordance with this Regulation within two years of the date of approval.

To that effect, those wishing to apply for the authorisation or mutual recognition in parallel of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation or mutual recognition in parallel no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications shall be submitted no later than the date of approval of the last active substance for that product-type.

Where no application for authorisation or mutual recognition in parallel has been submitted in accordance with the second subparagraph:

(a) the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance(s); and

(b) use of existing stocks of the biocidal product may continue until 365 days after the date of approval of the active substance(s).

4. Where a Member State's competent authority, or where relevant, the Commission, decides to reject an application submitted in accordance with paragraph 3 for authorisation of a biocidal product already made available on the market, decides not to grant authorisation, or decides to impose conditions of the authorisation making it necessary to change such a product, the following shall apply:

(a) a 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;

(b) use of existing stocks of the biocidal product may continue until 365 days after the date of the decision of the authority.