NOTE AGREED BY MEMBER STATES' COMPETENT AUTHORITIES FOR BIOCIDAL PRODUCTS

This document is drafted in the interest of consistency of the implementation of Regulation (EU) No 528/2012 and with the aim of finding an agreement between Member States' Competent Authorities for biocidal products on a harmonised approach. Please note, however, it does not represent the official position of the Commission and 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: Presence of potentially misleading terms in biocidal products trade names - update

1. BACKGROUND AND PURPOSE OF THE DOCUMENT

(1) At the CA meeting in March 2023, the Commission services provided the note CA-March23-Doc.4.16, concerning the presence of potentially misleading terms in the trade names of biocidal products and proposing two options for the way forward, namely (i) not allowing potentially misleading terms as prefix or suffix in the trade names of any biocidal product or (ii) case-by-case/product-by-product analysis.

(2) The majority of Member States were in favour of the first option. It was therefore considered to have an agreement in principle on that proposed way forward. However, several points under that option have to be agreed before proceeding with the implementation of the approach.

(3) Member States were requested to provide their view on the various points of discussion. Written comments from eight Member States and one industry association were received by the Commission services.

(4) The purpose of this note is to summarise the main points of discussion and to propose a way forward.

2. MAIN POINTS OF DISCUSSION

(5) The points for discussion and agreement concern these elements:

- Application of the approach to ongoing applications for national/Union authorisation

Member States agreed to start applying the approach to the ongoing applications for product authorisation.

- Application of the approach to authorisations granted under Regulation (EU) No 528/2012 (the BPR)

Considering the related workload and need to prioritise the allocation of resources, most Member States were in favour of an amendment of the authorisations (to

replace/remove those trade names) at the moment of their renewal. One Member State was of the view that waiting several years before amending the authorisation is not appropriate, as it would lead to different treatment of the products/applicants - some being allowed to have those trade names until the renewal and some (in the case of new applications for authorisation) not being allowed. That Member State was in favour of setting a common deadline for applicants to change the affected trade names.

- Application of the approach to products made available under the transitional measures

Three Member States provided their view on this point, and they were in favour of applying the approach also to products made available on the market under the transitional rules. No modalities of application were suggested in Member States' comments. Since the transitional rules vary greatly among Member States (in some of them a process akin to BPR authorisation is foreseen, in other ones a notification of making available on the market suffices and some Member States do not have a comprehensive database of all products available on the market), the enforcement of the implementation of the approach would be left to the market surveillance authorities, which could lead to a non-harmonised situation.

- Application of the approach to products allowed on the market under the provisions of Article 55(1) (temporary permits)

Member States having provided comments on this point noted that Article 55(1) provides for a derogation from the provisions of Articles 17 and 19. Article 17 sets out that *"Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69"*, hence the derogation from Article 17 implies a derogation also from the requirements in Article 69(2). According to this interpretation, the agreed approach would not be applicable to products allowed on the market in accordance with Article 55(1).

Moreover, Article 69(2) sets an obligation on the authorisation holder, who, according to the definition in Article 3(1)(p), is 'responsible for the placing on the market of a biocidal product in a particular Member State or in the Union and specified in the authorisation'. In the case of a temporary permit under Article 55(1) there is no placing on the market, but 'making available or use […] under the supervision of the competent authority'.

- Application of the approach to cases in which the company name contains potentially misleading terms and the company name is used as part of the product trade names

Two Member States provided their view on this point and considered that, since the name of the company is anyway present on the label, the complete name can be used in trade names, but not specific terms detached from the name. For instance, in the case of company 'Ecolab', including 'Ecolab' in a trade name would be acceptable, but not including only 'eco-'.

(6) Member States having provided comments suggested that a list of terms which are not allowed in the trade names be developed and regularly reviewed and updated. Specific exceptions would be included in the list. The list could be updated with a certain frequency at the CA meeting.

3. PROPOSAL FOR THE WAY FORWARD

(7) Considering the agreement at the CA meeting of March 2023 on the application of the option (i) described in paragraph (1) and the written comments provided by Member States after that meeting, it is proposed as follows:

- The agreed approach is to be applied by Member States and the Commission to the ongoing applications for national authorisation and Union authorisation, respectively. Applicants will be requested to replace trade names containing potentially misleading terms. Where they fail to do so, the affected trade names will be removed from the SPC and authorisation to be granted (or the product will not be authorised if the trade name in question is the sole name included in the SPC).
- Where the company name or a specific technology developed by a company contains a potentially misleading term, this name may appear in the trade name, but only completely and not only the specific term which is part of it.
- The agreed approach is to be applied to authorisations already granted under the BPR at the moment of their renewal or earlier, if at the request of the applicant.
- The agreed approach may be applied to products made available on the market under the transitional rules. The market surveillance authorities should be informed of the approach agreed by competent authorities.
- The agreed approach will not apply to products made available on the market in accordance with the provisions of Article 55(1) of the BPR.

(8) A non-exhaustive list of terms not allowed in the trade names of biocidal products is provided in the Annex to this document. The list is based on suggestions from Member States and indicates cases in which exceptions apply. It is suggested that the list is reviewed (and updated if needed) annually at the CA meeting.

(9) Member States agreed on the proposed way forward and on a non-exhaustive list of non-allowed terms, as provided in the Annex.

Annex

	Term*	**Exceptions****
1	‘bio’	‘biocide’/’biocidal’, ‘biofilm’
2	‘natur‘/ ‘nature’/ ‘natura’	‘denatured’ (and translations in EU languages)
3	‘organic’	
4	‘eco’, ’ecological’	
5	‘green’	- description of the colour (e.g. green liquid) - PT 2 products: if ‘green’ is a reference to the target organism (green algae)
6	‘safe’	

* the translations of the terms in the EU languages are considered to be included in the list

** if the term is part of the company name, that name is allowed in the trade names