DRAFT NOTE FOR DISCUSSION AND AGREEMENT 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

1. BACKGROUND AND PURPOSE OF THE DOCUMENT

- (1) The issue of the presence of potentially misleading terms in the trade names of biocidal products was raised at the meeting of the Standing Committee on Biocidal Products in December 2022, in the context of the discussion on the Union authorisation of a biocidal product family for which some of the trade names contained the prefix 'bio'. An initial discussion took place at that meeting. Another case, of a Union authorisation for which one of the trade names contained the term 'organic', was discussed at the same meeting.
- (2) Several Member States were of the view that the presence of the term 'bio' in the trade name, hence on the label of the biocidal product, might give the user the impression that the product has a better profile and lower risk than other biocidal products, since the term 'bio' is perceived by most consumers as equivalent to 'organic'. These trade names would be in conflict with the provisions of Article 69(2) of the BPR, which sets out that labels must not be misleading in respect of the risks from the products to human health, animal health or the environment, and should not be allowed.
- (3) A similar discussion, with a focus on the term 'eco', took place in closed session at the 95th CA meeting in March 2022. On that occasion, Member States agreed that a clear criterion on whether to allow the term 'eco' on the label of biocidal products cannot be established and a case-by-case analysis is needed, in dialogue with the applicant that should provide justifications for using those terms. The case of 'eco' being part of a company name has also been discussed and it was agreed that in this specific situation the use of 'eco' on the label can be allowed, since it is a contraction of 'economics' and it does not contravene the provisions of Article 69(2) of the BPR in that case.

2. RELEVANT LEGAL PROVISIONS AND FURTHER CONSIDERATIONS

- (4) Article 69(2) of the BPR sets out that the labels must not be "misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy and, in any case, do not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or similar indications."
- (5) Article 25(4) of Regulation (EC) No 1272/2008 (CLP Regulation) provides that "Statements such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or any other statements indicating that the substance or mixture is not hazardous [...] shall not appear on the label or packaging of any substance or mixture".
- (6) Article 6 of Directive 2005/29/EC (Unfair Commercial Practices Directive, UCPD) provides the definition of misleading action towards the consumer and sets out that "a commercial practice shall be regarded as misleading if it [...] deceives or is likely to deceive the average consumer [...] in relation to one or more of the following elements, and in either case causes or is likely to cause him to take a transactional decision that he would not have taken otherwise: [...] the main characteristics of the product, such as its availability, benefits, risks, execution, composition, [....]." (emphasis added).
- (7) With regard to misleading environmental claims, the Commission Guidance on the interpretation and application of the UCPD¹ reads that "Environmental claims are likely to be misleading if they consist of vague and general statements of environmental benefits without appropriate substantiation of the benefit and without indication of the relevant aspect of the product the claim refers to. Examples of such claims are 'environmentally friendly', 'eco-friendly', 'eco', 'green', 'nature's friend', 'ecological', 'environmentally correct', 'climate friendly', 'gentle on the environment', 'pollutant free', 'biodegradable', 'zero emissions', 'carbon friendly', 'reduced CO2 emissions' 'carbon neutral', 'climate neutral' and even the broader claims of 'conscious' and 'responsible'. [...] If vague and ambiguous claims are used, the qualifications need to be sufficiently detailed so that the claim cannot be understood in any other way than the way the trader intended. [...]".² (emphasis added).
- (8) In its judgement in case T-86/19³ concerning the registration of a trademark related to a biocidal product (BIO-INSECT Shocker), the General Court concluded that "the presence of the term 'bio' on the biocidal products [...] suffices to establish a sufficiently serious risk that the consumer will be deceived."

² Commission Notice 2021/C 526/01 further explains that "[i]f a trader uses environmental statements in its company name, brand name, product name etc., and the name is used for marketing purposes, such marketing is subject to the same substantiation requirements as those which apply to other environmental claims in marketing communications, unless the company can prove that this name has no environmental connotation or existed already before".

2/4

¹ Commission Notice 2021/C 526/01, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC1229(05)&from=EN

Judgment of the General Court (Ninth Chamber) of 13 May 2020, case T-89/19, SolNova AG v European Union Intellectual Property Office: https://curia.europa.eu/juris/liste.jsf?num=T-86/19&language=EN, paragraph 89.

3. Possible options to address the matter

- (9) Following the initial discussion at the 78th meeting of the Standing Committee in December 2022, the Commission consulted Member States on a possible distinction between products which are intended solely for professional users and those intended for the general public. Such a distinction could be justified considering that, in line with the provisions of Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, and with the Council Recommendation of 18 February 2003 concerning the improvement of the protection of the health and safety at work of self-employed workers, it can reasonably be expected that professional users, which use biocidal products during their professional activity, are provided appropriate information and training⁴ allowing them to acquire knowledge of the risks of biocidal products regardless of the trade name on the label.
- (10) In their reactions, Member States pointed to the fact that Article 69(2) makes no distinction between professional users and the general public (while other articles in the BPR make reference to specific user categories for instance Articles 19(4) and 69(1) which refer to the general public). Member States also noted that:
 - Some products are authorised for both professional and non-professional users;
 - The professional user is not defined by the level of knowledge of biocidal products, but by the fact that (s)he uses biocidal products in the course of her/his professional activity;
 - In large organisations, biocidal products even though used by professional users who may have more knowledge on biocides than non-professional users might be purchased by persons in specific departments, who do not have that knowledge;
 - It cannot be excluded that non-professional users have access to products intended for professional users.
 - (11) Possible suggested options for the way forward are:
 - (i) Not allowing 'bio', 'eco' and other terms likely to be misleading (for instance 'green', 'nature', 'natural', 'organic'⁵) as prefix or suffix in the trade names of any biocidal product. In this approach the applicant would be requested to change the trade names in question.

Elements to be considered:

- In case the applicant fails to replace those trade names, competent authority/Commission will remove those names from the SPC and grant a 'partial' authorisation (or non-authorise the product if the trade name in question is the only one for that product)
- It is to be noted that proper labelling is not expressly included among the conditions for granting an authorisation set out in Article 19(1) of the BPR. However, Article 19(3) of the BPR provides that "a biocidal"

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⁴ According to Article 6(1) of Council Directive 89/391/EEC, 'the employer shall take the measures necessary for the safety and health protection of workers, including prevention of occupational risks and provision of information and training, as well as provision of the necessary organisation and means.'

⁵ The list is not to be intended as exhaustive.

product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 20." Article 20(1)(a)(ii) requires the submission of a summary of the biocidal products characteristics, including the information referred to in points (a), (b) and (e) to (q) of Article 22(2), which in turn refers to the trade name of biocidal products (point (a)). This means that the trade name falls within the scope of the evaluation by the competent authority, and it has to be ensured that, insofar as it appears on the label, it is not misleading pursuant to Article 69(2) of the BPR.

Under this option a common approach is needed on how to address:

- a) Cases in which the company name contains these terms and the company name is 'transferred' in the product trade names. According to the Guidance on the interpretation and application of the UCPD mentioned above, "if a trader uses environmental statements in its company name, brand name, product name etc., and the name is used for marketing purposes, such marketing is subject to the same substantiation requirements as those which apply to other environmental claims in marketing communications, unless the company can prove that this name has no environmental connotation or existed already before."
- b) Products with trade names containing such terms for which applications for national/Union authorisation are ongoing. It is suggested that the approach be applied for ongoing applications for authorisation.
- c) Products with trade names containing such terms which were authorised under the BPR (by national authorisation/mutual recognition procedure and Union authorisation). In order to ensure equal treatment of economic operators, competent authorities and the Commission would need to amend the authorisation granted for such products. This would be done by means of amendments pursuant to Article 48(c) of the BPR, according to which the authorisation holder has to be informed of the intention to amend the authorisation and given the opportunity to provide additional information (in this case alternative trade names). The timelines for this exercise would need to be agreed; alternatively it could be agreed to amend the authorisations at the moment of their renewal.

As illustrated in the Annex to this document, more than two hundred authorisations for products with trade names containing 'bio' have been granted through national authorisation/mutual recognition and a few ones by Union authorisation.

- d) Products with trade names containing such terms which are temporarily allowed on the market of Member States under the provisions on Article 55(1) of the BPR (notably Biobor JF). Article 55(1) only provides a derogation from Articles 17 and 19, not specifically from Article 69. Would there be legal grounds to allow a specific exemption for these products, or should the company be contacted to change the name of the product?
- e) Products with trade names containing such terms which were/are made available on the market under the transitional rules. While the making available on the market of these products can be regulated by national rules, as provided for in Article 89(2) of the BPR, other provisions of the

BPR, including those on labelling and advertising of biocidal products at Articles 69(2) and 72(3) of the BPR, are applicable also to these products.

(ii) <u>Case-by-case/product-by-product analysis.</u> In this option the applicant would be requested to provide arguments as to why the trade names in question are not misleading.

Under this option the following elements need to be considered:

- a) This approach would introduce an element of subjectivity, as justifications related to different applications would be assessed by different persons (and/or in different Member States), who might have a different understanding of what an acceptable justification is. This may result in unequal treatment of an applicant across different Member States (e.g. the same name is authorised in one Member State, but not in another) as well as of different applicants (in the same Member State, but even more across different Member States). To avoid such discrepancies there would be a need for coordination among Member States (i.e. in the Coordination Group)., also with a view to developing over time a list of examples of acceptable justifications.
- b) If agreed, this approach would also apply to ongoing authorisation applications for such products and to authorisations already granted, which will have to be amended by competent authorities/the Commission within set deadlines or at the moment of renewal.

4. ACTION REQUESTED

(12) Member States are invited to discuss the options suggested and agree the way forward.