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Guidance document on the definition of 'similar conditions of use across the Union' in accordance with Article 42(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

(C/2025/3004)

A. BACKGROUND

Biocidal products must be authorised before they are made available on the market and used in the EU. This is in accordance with Article 17 of Regulation (EU) No 528/2012 ([1]), the Biocidal Products Regulation (BPR). The BPR provides for different application procedures to obtain such authorisation. As an alternative to applying for national authorisation and mutual recognition to gain access to the individual markets of the Member States, applicants can apply for Union authorisation to gain access to the Union market in all Member States (Article 41 BPR).

Applications for Union authorisation can only be made for certain types of biocidal products. Article 42(1) BPR explicitly excludes certain products from Union authorisation and establishes that products that are not explicitly excluded are only eligible if they have similar conditions of use across the Union. Applications for Union authorisation submitted to the European Chemicals Agency (ECHA) must include a confirmation that the biocidal product would have similar conditions of use across the Union in accordance with Article 43(1) BPR.

Article 42(2) BPR requires the Commission to draw up guidance documents on the definition of 'similar conditions of use across the Union'. Over time some common understanding of the concept has been reached with Member States competent authorities for biocidal products in the Commission expert group of the competent authorities for biocides (CA meeting) ([2]).

The purpose of this document is to provide guidance on the definition of 'similar conditions of use across the Union' as a prerequisite for applying for Union authorisation for biocidal products. It also provides some practical guidelines on the expected content of the confirmation that the biocidal product has similar conditions of use across the Union which must be submitted with an application for Union authorisation.

B. DEFINITION OF SIMILAR CONDITIONS OF USE ACROSS THE UNION

The following aspects are relevant in defining 'similar conditions of use'.

1. Products explicitly excluded from Union authorisation

Article 42(1) BPR explicitly excludes biocidal products that contain active substances that fall under Article 5 BPR and those of product-types (PT) 14, 15, 17, 20 and 21 as defined in Annex V of the BPR from the scope of Union authorisation. Applications for Union authorisation cannot be submitted for such biocidal products.

The use of biocidal products containing active substances meeting the exclusion criteria is restricted to Member States in which at least one of the conditions of Article 5(2) BPR is met. A Member State-specific assessment is required for these products, potentially leading to different conclusions for the Member State's territories.

The excluded PTs cover products for which Member States may refuse to grant authorisations on grounds of animal welfare in accordance with Article 37(4) BPR, or for which experience has shown that harmonising conditions of use has proven particularly difficult in the mutual recognition procedure. Those products have therefore been excluded from the scope of Union authorisation as they are considered to have different conditions of use in the Member States, and it would not be possible to conclude on a common, harmonised authorisation.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Group E03125 - Competent Authorities for Biocidal Products (Regulation (EU) No 528/2012.

While biocidal products of other PTs are not generally excluded from the scope, they are not automatically eligible for Union authorisation. Instead, it must be established for each individual application that the biocidal product concerned would have similar conditions of use across the Union. This must be confirmed by the applicants when they submit the application.

Products containing active substances which are candidates for substitution in accordance with Article 10(1) BPR are not excluded from Union authorisation if they do not fall under Article 5, but such products may potentially have different conditions of use in Member States as a result of the comparative assessment in accordance with Article 23 BPR. In this situation, prospective applicants should therefore consider whether to apply for a Union or national authorisation, to avoid complex discussions, or the risk of a decision not granting the Union authorisation if it is eventually concluded that the product does not have similar conditions of use across the Union.

2. **The purpose of the requirement of 'similar conditions of use across the Union'**

The co-legislators included the possibility to apply for Union authorisation in the BPR to facilitate the making available on the market throughout the Union of certain biocidal products with similar conditions of use in all Member States (recital 26 BPR). So, while the purpose of Union authorisation is to provide market access in all Member States through a single Union procedure, this possibility is limited to products which have similar conditions of use in all Member States. The purpose of this limitation of the scope is to ensure that the authorisation of the product can actually and effectively be handled under a single, centralised procedure based on one assessment and that the Commission can conclude on a single, harmonised authorisation. Different use conditions of a product in the different Member States require individual assessments by each Member State, which conflicts with the idea of a single, centralised procedure. This also applies to situations where the conditions of use would need to differ due to objective reasons, such as differences in climatic conditions or in the presence of target organisms in the Member States.

3. **Conditions of use**

For Union authorisations the BPR requires that the 'conditions of use' of the biocidal product are similar across the Union. 'Use' is defined in Article 3(1)(k) BPR as '*all operations carried out with a biocidal product, including storage, handling, mixing and application* (…)'. The conditions of use are included in the content of the authorisation in accordance with Article 22 BPR and are specified in the summary of product characteristics (SPC).

'Conditions of use' should be understood in a broad sense to refer to all aspects related to the use of the product, including, for example, the exact description of the use of the product, the target organisms, application doses and instructions for use, risk mitigation measures, the category of users, first aid instructions and emergency measures to protect the environment, instructions for the safe disposal, storage conditions and shelf-life of the product.

In the context of a Union authorisation, the applicant proposes the conditions of use of a product as part of the draft SPC submitted with the application, which are then assessed by the evaluating competent authority and the ECHA Biocidal Products Committee and set eventually by the Commission according to the outcome of the assessment in the SPC annexed to the Commission Implementing Regulations granting the Union authorisation.

4. **Similarity across the Union**

For Union authorisation, the BPR requires that the conditions of use of the biocidal product are 'similar'. Some examples of synonyms of 'similar' are 'comparable' and 'alike'. Since the intention of the concept of Union authorisation is to grant access to the Union market through a single centralised procedure based on one common assessment, the conditions of use for the product should, in principle, be the same across the Union. Limited differences in the conditions of use are acceptable if they remain comparable and do not lead to the need for a specific additional assessment.

In some previous applications for Union authorisation, certain differences concerning elements which are not defined in detail by the BPR were accepted and included in Union authorisations to the extent that Union legislation leaves room for differences at national level. In such situation, the conditions of use set in the authorisation are sufficiently generic to ensure that national or local requirements in Member States are covered. This concerns, for instance, national differences between Member States in their definitions of the user categories 'professional' and 'trained professional' which are not harmonised by the BPR, references to lower national occupational exposure levels (OEL) for certain substances in the context of Council Directive 98/24/EC ([3]) or differences in national rules of disposal in the context of Directive 2008/98/EC ([4]).

Differences in, for example, application doses, dilution rates and target organisms usually require a specific additional assessment, as they may lead to differences in the risk and efficacy of the product and are normally not considered 'similar' conditions of use.

5. **Conclusion**

The requirement for 'similar conditions of use across the Union' for all products that are not explicitly excluded from Union authorisations was included to ensure that the application for product authorisation can actually and effectively be handled under a single, centralised procedure based on one assessment within the timeframes provided in the BPR and that the Commission can conclude on a single, harmonised authorisation. Applicants applying for Union authorisation should therefore ensure that the proposed conditions of use are, in principle, the same and should not include any differences in the conditions of use in different Member States. Only very limited differences in the conditions of use are acceptable, provided that the conditions of use remain similar. This can, for example, be the case when existing Union legislation leaves room for differences at national level and national rules differ in Member States and those differences do not require a specific additional assessment.

If it should be concluded by the Commission that there are no similar conditions of use across the Union for the product, a Union authorisation may not be granted, as the requirements for such authorisation are not met.

C. **GUIDELINES ON THE CONFIRMATION OF SIMILAR CONDITIONS OF USE TO BE PROVIDED BY THE APPLICANT**

As part of their application for Union authorisation, applicants need to provide confirmation that the biocidal product would have similar conditions of use across the Union (Article 43(1) BPR). Without such confirmation, the application is considered incomplete. The evaluating competent authority should therefore check in the validation step if the confirmation was provided by the applicant with the application. If the confirmation is missing, the evaluating competent authority should request it, in accordance with Article 43(4) BPR, and reject the application if it is not submitted upon this request. When evaluating the application, the evaluating competent authority should assess if there are similar conditions of use across the Union having regard to section B of this guidance, based on the information provided by the applicant in the confirmation and the information available to the evaluating competent authority. ECHA's opinion on the application submitted to the Commission (Article 44(3) BPR) should clearly conclude on whether this condition for Union authorisation is considered fulfilled as a basis for the Commission decision on the authorisation in accordance with Article 44(5) BPR.

1. **Expected content of the confirmation**

The content of the confirmation provided by the applicant should be meaningful for the procedure and contribute to the assessment of the requirement of having similar conditions of use across the Union by the authorities. It should clearly state whether the conditions of use proposed by the applicant for the authorisation are the same or whether they differ.

([3]) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 05/05/1998, p. 11, ELI: http://data.europa.eu/eli/dir/1998/24/2024-04-08).

([4]) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/2024-02-18).

If they differ, the applicant should clearly highlight and explain the differences and explain why the conditions of use should still be considered similar having regard to the criteria set out in part B of this document.

If no differences in the conditions of use are included in the application for authorisation, the applicant should explain in the confirmation how it reached the conclusion that the conditions of use for the product will not differ in the Member States. The applicant should describe in the explanation which sources of information regarding the situation in Member States have been consulted, whether Member States competent authorities have been contacted regarding the situation of the product, the responses received, and the conclusions reached by the applicant.

A simple statement that the conditions of use are the same or similar across the Union is not appropriate, as it does not helpfully contribute to the assessment of the requirement. Applicants are advised to start investigating the situation of the products in the Member States well in advance before they submit the application and to explain their investigations and the outcome as part of the confirmation. This is in the applicant's interest, to avoid a situation in which the Union authorisation ultimately cannot be granted because the assessment of the application concludes that the conditions of use would not be similar across the Union, in which case an application for national authorisation and mutual recognition would have to be submitted.

2. **Sources of information on the conditions of use of biocidal products in the Member States**

Before applying for Union authorisation, applicants should gather information on the conditions of use under which the products can be placed on the market in the Member States, to assess whether they are the same or similar and whether it would therefore be appropriate to apply for Union authorisation. Applicants should consider the following sources of information:

For products that benefit from national transitional rules and have been made available on the market and used in the Member States for many years before an application for product authorisation under the BPR has to be submitted, applicants should be aware of the conditions of use for their products in the Member States and whether they differ. This experience and knowledge should be used for the purpose of the confirmation submitted with the application.

Some Member States publish information on conditions of use that apply to biocidal products on their market. The Commission has encouraged all national competent authorities for biocides to publish such information and to make it easily accessible so that it can be consulted by potential applicants for Union authorisation in preparing the application. However, the available information may not be exhaustive and other sources of information should be consulted additionally.

Applicants are encouraged to contact and consult the national competent authorities in the Member States on the conditions of use applicable to the products for which authorisation is sought before submitting the application, providing the necessary information on the products. The contact details of the competent authorities for Union authorisations are provided on the website of ECHA dedicated to information on Union authorisation ([5]).

For some issues concerning differences in the conditions of use in Member States which are not defined in detail by the BPR and to the extent that EU law allows for differences, these were considered similar, and a way forward has been found how to address them in Union authorisation. This is the case for:

a. The non-harmonised definitions of the user categories 'professional' and 'trained professional' – the following sentence was agreed for inclusion under section 6 of the SPC:

   'With respect to the "Category(ies) of users" note: 'Professionals (including industrial users) means trained professionals if this is required by national legislation.'

b. Reference to a lower national occupational exposure level (OEL) for certain substances in the SPC – a general reference to the lower national reference values is included when such values are mentioned in the SPC, for example in the risk mitigation measures:

   '…Re-entry is only permitted once the air concentration for substance "x" has dropped below "y" ppm or a lower relevant national reference value.'

([5]) https://echa.europa.eu/evaluating-competent-authorities-for-union-authorisation.

c. National/local rules for disposal

d. Inclusion of national contact details of poison centres

Member States may request the Commission to decide that certain conditions of a Union authorisation be adjusted specifically for their territory or request the Commission to decide that a Union authorisation will not apply in their territory, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1) BPR (Article 44(5), second subparagraph, BPR). The Commission assesses any such request and may accept it or reject it if it is not found to be justified. If it is accepted, such requests by Member States may lead to conditions of use being adjusted for the territory of the requesting Member State and then differing from the conditions of use in other Member States or to the situation that the Union authorisation does not apply in the territory of a Member State. A link to information concerning requests from Member States received by the Commission and the conclusion of the related Union authorisations can be found on the ECHA's website dedicated to Union authorisations ([6]) and on Circabc ([7]). This information should also be consulted by prospective applicants when preparing an application, and when deciding whether applying for Union authorisation would be appropriate.

3. **Template for confirmation**

Applicants for Union authorisation of biocidal products should use a template provided by ECHA for the confirmation of the 'similar conditions of use across the Union'. Using this template ensures that all relevant information is provided, and that the applicant consults the relevant sources of information before it submits the application and confirmation.

D. **APPLICABILITY**

This guidance applies to applications that are submitted after its publication.

([6]) https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation.

([7]) https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/fedca475-d8c0-4666-a5f3-2d09155a8457/details.