24 April 2024

Instructions for providing comments related to substances which are potential candidates for substitution and meeting the exclusion criteria under the Biocidal Products Regulation

1. Scope of the consultations for the substances meeting the exclusion criteria according to Article 5(1) of the BPR

To decide if the active substance meeting the exclusion criteria may be approved or not, a consultation is organised to collect information on:

(1) whether the conditions for derogation set out in Article 5(2) of the BPR are satisfied, and
(2) the availability and suitability of alternatives to the active substance

As regard to the derogation criterion set out in Article 5(2)(b) of the BPR, the following information is of particular relevance:

- is the active substance used to prevent or control a serious danger to human health, animal health or the environment? If yes, for which use(s) within the product-type?
- Are there any suitable and sufficient alternatives on such use(s)? Detailed use descriptions and justifications must be provided for each use.

As regard to the derogation criterion set out in Article 5(2)(c) of the BPR, the following information is of particular relevance:

- is the ban of the active substance leading to negative impact on society? If yes, for which use(s) within the product-type, what are the nature and the level of the impacts on society for the concerned use(s)?
- Are there any suitable and sufficient alternatives on such use(s)?
- Detailed use descriptions, quantification or qualification of the impacts on human health and the environment of such uses and justifications must be provided for each use of the active substance and of the alternatives.

To facilitate the assessment of the contributions and the decision-making process, the submitter must:

- indicate clearly which derogation condition of Article 5(2)(a), (b) and/or (c) of the BPR the submitter considers met or not met, providing a detailed justification and/or
- provide information on the availability of suitable alternatives, providing a detailed justification.

Derogations to exclusion for an active substance are analysed product-type per product-type, and use per use within the product-type, therefore **it is essential that solid justifications are provided for each product type and intended use which is supported for derogation. When submitting comments via the webform, the information submitted should always be applicable to all the PT-Use combinations selected**. If the information varies depending on the specific PT-Use combination, please make separate submissions.

For substances meeting the exclusion criteria of BPR Art.5(1) the availability of suitable alternatives is a key consideration for deciding on the approval of the substance. Therefore, **if you wish to provide justifications on derogation conditions according to BPR Art.5(2) please also provide information on alternatives and explain how this is linked with your argumentation related to the derogation conditions**.

The submitter should also consider the recommendations provided for in the guidance on "Submission of information in the consultation on potential candidates for substitution under the Biocidal Products Regulation". For instance, when the submitter indicates the existence or absence of alternatives in its contribution, they must be precise about the use that they refer to, the name and identity of alternative active substances or non-chemical methods to control target organisms, etc.

2. Who should provide information during the consultations?

It is important that interested parties (manufacturers of biocidal active substances, users of biocidal products, sector concerned, providers of alternatives, academia, authorities, non-governmental organisations, etc.) contribute to the consultation to collect valuable information for the decision-making process, in particular on the existence or absence of suitable alternatives.

Contributors must provide information with sound justifications, and not mere statements.

3. Publication of information

The information submitted may be non-confidential or confidential. However, it is highly recommended to **submit the information as much as possible as non-confidential** and to keep the information claimed confidential to a minimum. If you claim information to be confidential, you will need to provide a solid justification (see the guidance on "Submission of information in the consultation on potential candidates for substitution under the Biocidal Products Regulation"). Any information claimed confidential will only be available to members of the Biocidal Products Committee (BPC), the Member State competent authorities, the BPC Secretariat in ECHA and the European Commission. Non-confidential information will be published on ECHA's website.

During the consultation, the following information related to the active substance being a potential candidate for substitution/meeting the exclusion criteria is made public as a basis to collect information from third parties:

- substance identity (name and EC/CAS numbers)
- product-type(s)

- a description of the intended use(s) presented by the applicant
- which condition(s) of Article 10(1) and, if applicable, of Article 5(1) of the BPR are met by the active substance
- non-confidential analysis of alternatives and socio-economic analysis/impact assessment prepared by the applicant or the evaluating competent authority (if available)

The information collected through the consultation is made publicly available, unless claimed confidential with adequate justifications.

The confidential and non-confidential information received in the consultation will be taken into account in the Biocidal Products Committee (BPC) opinion.

The European Commission together with Member States will then take into account the information collected when deciding whether to approve or not the concerned active substance.

The ECHA guidance listed above and available on this page are useful references for providing detailed justifications.

4. Useful references

For all submissions, the following ECHA guidance documents are useful references for providing detailed justifications:

- Submission of information in the consultation on potential candidates for substitution under the Biocidal Products Regulation
- Analysis of alternatives to biocidal active substances
- Socio-economic analysis under REACH