Submission of information in the consultation on potential candidates for substitution under the Biocidal Products Regulation

Version 4.0
March 2020

Disclaimer

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Version	Changes	
1.0		November 2013
2.0	Modified structure of the webform	July 2015
3.0	Adding specific instructions for active substances meeting the exclusion criteria	May 2017
4.0	- A justification for confidentiality for each comment submitted can be made - Section 4 on the submission of attachments is included - Reference to "public" consultations has been removed.	March 2020

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Reference: ECHA-20-H-05-EN
ISBN: 978-92-9481-397-8
Cat. Number: ED-03-20-131-EN-N
DOI: 10.2823/353233
Publ.date: March 2020
Language: EN

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1. Introduction

1.1 Preamble

The purpose of this document is to provide interested third parties with guidelines to submit information for the consultation on active substances considered as potential candidates for substitution.

The document will give indications in relation to confidentiality issues and on the organisation and submission of information.

1.2 Purpose of the consultation on potential candidates for substitution

When the evaluating Competent Authority concludes in its evaluation that the active substance meets the criteria for substitution of Article 10(1) of the Biocidal Products Regulation (BPR), ECHA makes publicly available information on potential candidates for substitution and will initiate the consultation as mentioned in Article 10(3) of the BPR. The purpose of the consultation is to gather relevant information, especially information on available substitutes or alternatives. The information on the availability of possible alternatives is of high importance at the product authorisation stage when a comparative assessment needs to be performed.

A special case is if the evaluating Competent Authority concludes in its evaluation that the active substance meets one of the exclusion criteria of Article 5(1) of the BPR. If so, the active substance meets the criteria for substitution of Article 10(1)(a) of the BPR. Here the information submitted on the availability of possible alternatives is already of high importance at the approval stage of the active substance: active substance which meets one of the exclusion criteria can only be approved if at least one of the conditions of Article 5(2) of the BPR is met, but when deciding whether the active substance may be approved the availability of suitable and sufficient alternative substances is a key consideration[1].

The information submitted by interested third parties will be taken into due account by the Biocidal Products Committee (BPC) before finalising its opinion. The BPC will not take into account information received after the deadline in their opinion making process.

Each consultation will last 60 days and will apply to applications for approval or renewal of the approval of an active substance, as described respectively in Article 7 or 13 of the BPR, as well as to active substances included in the Review Programme and to applications for new active substances submitted under Article 11 of the Biocidal Products Directive (BPD).

[1] See the document: CA-Nov14-Doc.4.5 - Final - Further guidance on the procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2) (available from https://circabc.europa.eu/sd/a/eaae0dc2-1715-4906-a5d5-af3932fcd7c9/CA-Nov14-Doc.4.5%20-%20Final%20-%20Processus%20Art%205(1)%26(2).doc).

2. Submission of information during the consultation on potential candidates for substitution

Interested third parties can submit information via a secure webform on ECHA's website. The webform allows the submission of information for one Product Type at a time. After sending the information the user will have the option to submit information concerning other PTs. In this case the user will be prompted to the same webform, pre-filled with the information already provided in sections I and II (personal information and organisation) and where a different PT can be selected from the drop-down list.

The information on the possible alternative and further analysis on its suitability may be provided as non-confidential or it may be claimed confidential. In this latter case a justification needs to be included for each comment on why the information should be kept confidential (cfr. section 2.1 below on confidentiality).

All non-confidential information submitted during the consultation will be made available to the BPC members, accredited stakeholders, applicant(s) and the BPC and ECHA Secretariat. The comments will appear on the ECHA website during the consultation.

Information claimed to be confidential will be available only to the BPC members and the BPC and ECHA Secretariat.

2.1 Confidentiality

Please note that any information submitted to ECHA is subject to Regulation 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information and to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents. Therefore, interested third parties submitting information during the consultation on potential candidates for substitution are asked to provide a justification for confidentiality for each comment or attachment submitted to ECHA. If the submitter's justification is sufficient and falls under one of the exceptions envisaged in Regulation 1049/2001, there will in principle be no need to request further clarification from the submitter why a request for access to part or all information marked confidential in the submission should be denied.

The submitter's justification for confidentiality should contain the following three elements:

Demonstration of Commercial Interest
Description of the nature of the third party commercial interest and demonstration that this commercial interest is worthy of protection by the non-disclosure of information. Demonstration of any specific measures the submitter has taken to keep the information claimed confidential secret to date.

Demonstration of Potential Harm
Explanation of why release of the information claimed confidential would be likely to cause potential harm to the commercial interest and the specific nature of those harmful effects. A causal link between disclosure and such harmful effects should be clearly explained.

Limitation to Validity of Claim
The period of time for which the claim will be valid: until a certain date, until the occurrence of a particular event (which should be clearly specified), or indefinitely.

2.2 Providing information

The purpose of this section is to help interested third parties in providing information on potential candidates for substitution by filling in the various fields of section III (Information) and uploading attachments in Section IV of the web form.

In connection with the existence or absence of suitable alternatives it is important that information is provided for specific uses within the PT for which alternatives exist or do not exist. If alternatives exist and information is provided, this must contain the topics 1-5 described below. If suitable alternatives do not exist according to the submitter, explanations must be provided like technical limitations why there are no suitable alternatives or information on a substitution plan.

Please note that clear and specific information facilitates the decision making process related to either the approval of the active substances (for those meeting one of the exclusion criteria) or the authorisation of biocidal products.

The fields in Section III refer to information on the following topics:

1. Alternative identity and properties
You may find the following guidance useful for this section: Guidance for identification and naming of substances under REACH and CLP

(http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf).

If the alternative is a chemical substance, describe it by the following sections of Annex II, Title 1 of BPR: 2. Identity of the active substance, 3. Physical and chemical properties of the active substance, 4. Physical hazards and respective characteristics, 5. Methods of detection and identification, 6. Effectiveness against target organisms, 7. Intended uses and exposure, 11. Measures necessary to protect humans, animals and the environment, 12. Classification, labelling and packaging.

If the alternative is a micro-organism, describe it by the following sections of Annex II, title 2 of BPR: 2. Identity of the micro-organism, 3. Biological properties of the micro-organism, 4. Methods of detection and identification, 5. Effectiveness against target organisms, 6. Intended uses and exposure, 10. Measures necessary to protect humans, animals and the environment, 11. Classification, labelling and packaging of the micro-organism.

If the alternative is neither a chemical substance nor a micro-organism, provide a description of it.

If the alternative is any combination thereof, please provide all of the above.

2. Technical feasibility
Show that the alternative you propose can fulfil the function of the potential candidate for substitution.

Describe the precise functions or tasks performed by the alternative for the use(s) in question. Include a description and outcome of the process and, where relevant, under what process conditions the function must be performed.

If possible, discuss any adaptations or changes in the technology, process, procedure, device, modification of end product or other solutions necessary to replace the potential candidate for substitution for the specified use(s) (e.g., the requirements for equipment, risk management measures, energy, personnel changes and training needs, raw materials, waste, etc.) and how these affect the technical feasibility of the alternative.

If possible, include any other benefits (corporate image, compliance legislation, worker safety, relation with community, etc.) and obstacles or difficulties identified or expected in relation to replacing the potential candidate for substitution for the specified use(s).

If possible, support your analysis with information on research and development activities. Document the methodology, data sources and their reliability, assumptions made, uncertainties and their effects on the conclusions on the technical feasibility of the alternative.

3. Economic feasibility
If possible, estimate the direct and indirect costs and revenues associated with the transitioning to the alternative. Detail the methodology, the sources of data and its quality and reliability, the assumptions and uncertainties in the analysis and their impact on the conclusions of the assessment. Clearly set out the boundaries of the assessment and show the reasoning for the setting of these boundaries.

4. Hazard and risks of the alternative
Describe the risks to human health and the environment associated with the use of the alternative for which you are providing comments.

Discuss whether the transfer to the alternative would result in reduced overall risks to human health and the environment. In the risk assessment of the alternative, consider any relevant risks and effects associated with the alternative. These may also be related to other aspects affecting the overall hazard/risk reduction capacity of the transfer to the alternative, such as changes in energy or raw material consumption.

Support your analysis with information on research and development activities, if appropriate. Describe the methodology of comparing the risks of potential candidate for substitution and the alternative. Document the data sources used, their quality and reliability, the assumptions made, the uncertainties in the analysis and their impact on the conclusions of the assessment.

5. Availability
For suitable alternatives, discuss whether they are available (in the required quantity) without undue delay. Include information on the data sources and their reliability.

6. Conclusion on suitability and availability of the alternative
Conclude on the overall suitability and availability of the alternative for the potential candidate for substitution for which you are submitting this information.

7. Other comments
Include other information you may have on the alternative.

References
Ensure that the information you provide is well-referenced throughout the document. Include a list of references here.

The fields in Section IV allow the upload of both confidential and non-confidential documents supporting the information provided in Section III.