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Framework Guidance: Analysis of alternatives to biocidal active substances



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ECHA developed in 2022 a recommended (i.e. not mandatory) framework guidance to applicants for approval of biocidal active substances but also to Member State Competent Authorities (MSCAs) on how to perform an analysis of alternatives (AoA) to active substances being candidate for substitution (CfS) according to Art. 10(1) of the Biocidal Products Regulation ((EU) 528/2012). The guidance has been adopted at BPC-45 meeting and published in January 2023.

It provides a set of elements which can be used to assess the availability of suitable alternatives to substances meeting the exclusion criteria (Art.5(1)), and substances meeting the substitution criteria (Art. 10(1)), but not the exclusion criteria. It allows a flexible approach, tailored to the case and the entity performing the analysis of alternatives (i.e. an applicant or a MSCA).



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Applicants for CfS are advised to submit analysis of alternatives to MSCAs which are as comprehensive as possible, including a public version for publication, covering the different intended uses as part of their application. The submission of an AoA is not legally required but strongly recommended to support the comparative assessment at product authorisation stage as products containing a candidate for substitution will have to be subject to a comparative assessment by the receiving/evaluating competent authority at the time of authorisation and will only be authorised if there are no suitable alternatives (Art. 23(3)).

Evaluating MSCAs also do not have a legal requirement to make an AoA per se in the active substance approval/renewal process but might be willing to make one themselves, e.g. as a complement to one submitted by an applicant.



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An analysis of alternatives is recognized to be very challenging due to numerous limiting factors such as limited and variable information on intended uses of biocidal products containing this active, limited information on number of uses, biocidal products and treated articles on the EU market, limited knowledge and expertise on the uses and potential active substance alternatives. Furthermore, approval of active substances according to different requirements and rules, different dossier types at different stages of the regulatory process also lead to uncertainties in the assessment of chemical alternatives.

Despite these limitations, such analyses conducted by the applicants for CfS can provide a useful set of information for either the substance approval/renewal or for subsequent product comparative assessment. A good quality and sufficiently detailed analysis of alternatives provided by the applicant could lighten the workload for the more specific comparative assessments at product authorization stage. The information on alternatives collected at the stage of active substance approval/renewal can also be used by third parties willing to submit information on alternatives during the third parties' consultations under Article 10(3).



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This guidance is mainly addressed to:

- The applicants to support their application for approval/renewal of a biocidal active substance which is meeting the exclusion or substitution criteria
- The MSCAs willing to perform an analysis of alternatives for active substances meeting the exclusion or substitution criteria (as a complement to one submitted by an applicant or for other reasons)

It should be seen as a recommended non-mandatory framework guideline, providing advice on how to perform and structure an analysis of alternatives for active substances candidate for substitution. It is accompanied by a template which provides a structure for reporting this analysis. Applicants of such substances are advised to use this guidance and to submit an analysis of alternatives to their eCA as part of their application. A public version of this analysis is intended to be published on ECHA's website.



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The guidance does not lead to clear-cut conclusions on the availability of suitable alternatives for the intended uses. This first version describes the desired content for AoA but not the content for the related aspects of the derogation criteria related to Art 5(2)(b)5 or Art 5(2)(c)6. For the latter criteria, the ECHA guidance on socio-economic analysis may be mainly considered.

Sources

Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance

CA-Dec22 Doc.5.4.a AoA Guidance implementation Final.docx

Template for analysis of alternatives

ECHA guidance on socio-economic analysis

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