ECHA
EUROPEAN CHEMICALS AGENCY

Technical Agreements for Biocides

Cross-cutting issues

June 2020

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Preface

The Technical Agreements for Biocides (TAB) intends to provide in a concise format the general agreements of the four Working Groups (WG) and of the Biocidal Products Committee (BPC) which have not yet been included in any other BPR related guidance documents.

This document is intended to cover the technical/scientific agreements of the WG and/or BPC that have general relevance and to create a general database of questions where an agreement has already been reached. The agreements contained in this document are applicable for all relevant scientific fields. This document is therefore complementary to the field-specific TABs maintained by each WG (analytical methods and physico-chemical properties, efficacy, environment and human health).

The TAB is publicly available on the ECHA website and on the public S-CIRCABC Interest Group[1].

The answers presented in the document are those agreed by the WG and/or BPC. They are not the official view of ECHA, nor are they legally binding. It is not an authoritative source of information, and when in doubt, the original documents cited should always be consulted. A reference is given to the last WG or BPC meeting or Technical Meeting (TM) where the agreement was reached. Type of entry, publication (reference) date and applicability dates are given per each entry as follows:

Table 1 Type of TAB entries and applicability dates

	Applicability of the TAB entry	
Type of entry in the TAB	**(A) for active substance approval**	**(B) for product authorisation**
a) Editorial changes of the existing guidance	As of the reference date	As of the reference date[2]
b) Clarification/interpretation of the existing guidance (clarification /explanation)	As of the reference date	As of the reference date[2]
c) New guidance as new technical scientific advice is given which triggers new data requirements	six months after the reference date[3]	2 years after the reference date[4]

[1] https://webgate.ec.europa.eu/s-circabc/w/browse/ae26a5d2-a19b-42b8-a173-19bef3375d49

[2] CG document Doc. no. CG-33-2019-07, Date of applicability of: A) Technical Agreements of Biocides (TAB) entries and B) Conclusions of the Working Groups on the technical questions referred from CG https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/00cafca0-81f6-44c2-8aaf-05cb1cbcff93/CG-33-2019-07%20AP%2014.3%20Date%20of%20applicability_TAB%20entries_CG%20quest_rev1.pdf

[3] Applicability time of new guidance and guidance-related documents in active substance approval, BPC-31, https://echa.europa.eu/documents/10162/4221979/applicability_guidance_jan_16_en.pdf/0b9c0634-eb54-4805-8b5e-b95f09a05632

[4] CA document CA-July12-Doc.6.2d, Relevance of new guidance becoming available during the process of authorisation and mutual recognition of authorisations of biocidal products, https://echa.europa.eu/documents/10162/23036409/ca-july12-doc_6_2d_final_en.pdf

d) New guidance as new or updated technical scientific advice is given in order to have a harmonised approach on how the assessment should be done (without new data requirements)	six months after the reference date[3]	2 years after the reference date[4]
e) New guidance not triggering new data requirements where: • no guidance was available at all for a certain issue • new guidance is correcting major mistakes of former guidance • new guidance is considerably more reliable than former guidance.	As of the reference date[3]	Not defined by any CG/CA/BPC document, therefore same deadline as for d)

For more information on rules regarding applicability of guidance and TAB entries see BPC-31 document "Applicability time of new guidance and guidance-related documents in active substance approval", CG document Doc. no. CG-33-2019-07 and CA document CA-July12-Doc.6.2d (see footnotes 2, 3, and 4).

Procedure

TAB does not require a formal endorsement by the Biocidal Products Committee or the WG because the document records agreements made at the WG or BPC and included in their minutes. It is a living document that will be updated over time. Any suggestions on the need to change the content can be sent at any time to BPC-WGs@echa.europa.eu.

1. In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors

Version 2 (WG-III-2017)

The following document intends to clarify the principles for information requirements and risk assessment of the precursors of in situ generated active substances but also sheds some light on the information requirements for the active substances generated in situ.

https://echa.europa.eu/documents/10162/13564/situ_as_precursors_wg_recommendation_+2017_en.pdf

Type of entry:	d
Publication date:	21 July 2017
Date of applicability for active substances:	21 January 2018
Date of applicability for products:	21 July 11 2019

2. Principles for the assessment of endocrine disrupting properties in active substance approval

Version 1 (BPC-25)

The following document describes in more detail the principles for the determination of the endocrine-disrupting properties for active substances in the evaluation and peer review process up to the adoption of the opinion of the Biocidal Products Committee. In addition, it describes also the principles for the consultation of the ED Expert Group.

https://echa.europa.eu/documents/10162/4221979/principles_ed_assessment_in_approval_active_substance_process_en.pdf

Type of entry:	e
Publication date:	26 April 2018
Date of applicability for active substances:	26 April 2018
Date of applicability for products:	26 April 2020

3. ED assessment for active substances where the CAR was submitted before entry into force of the BPR: literature review

Version 1 (BPC-29)

The following document clarifies the approach for the assessment of endocrine disrupting properties for active substances where the CAR was submitted before entry into force of the BPR.

https://echa.europa.eu/documents/10162/4221979/ed_literature_review_en.pdf

Type of entry:	e
Publication date:	26 February 2019
Date of applicability for active substances:	26 February 2019
Date of applicability for products:	26 February 2021

4. Interpreting the definition of relevant impurities

Version 1 (BPC-31)

There has been a need to clarify the definition of relevant impurities, since different interpretations of the definition have been applied in biocides active substance approval among MSs. The scope of the following document is limited to clarifying the definition of relevant impurities and providing the principles and practical guidance on the assessment of whether an impurity is relevant.

https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/00f7cfb3-9339-413e-b5d9-37cf01bfb5df/BPC-31_relevant%20impurities_final.docx

Type of entry:	d
Publication date:	20 February 2020
Date of applicability for active substances:	20 August 2020
Date of applicability for products:	20 February 2022