Coordination Group – CG-33

Agenda item 14.3: 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

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1. Introduction

This document presents a proposal to address the date of applicability of technical agreements for biocides (TAB)[1] related to product authorisation, and the date of applicability of the conclusions of the Working Group (WG) related to questions referred from the Coordination Group (CG) to the WG.

Related to the TAB, the TAB records general agreements of the Working Groups (WGs) which have not yet been included in the BPR related guidance. These agreements are not formally endorsed by the BPC. TAB applicability related to the active substances approval process is included in a BPC document.[2] However, a clarification is necessary regarding the date of applicability of the TAB entries in relation to applications for biocidal products authorisations (SA, NA, UA).

In this context, it should be also clarified whether the document CA-July12-Doc.6.2d-Final[3] is applicable for TAB entries related to product authorisation or for the conclusions of the WG related to questions referred from the CG.

The proposal has been updated considering the discussion during the CG-29 and CG-30 meetings and the comments received after those meetings.

2. Proposal for discussion

A) Date of applicability of TAB entries for product authorisation

Several types of TAB entries should be considered:

[1] Technical Agreements for Biocides (TAB). Available at: https://echa.europa.eu/documents/10162/20733977/technical_agreements_for_biocides_en.pdf/4280fdc4-dfb0-405e-898e-70f3cdf62ce2

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

[3] Relevance of new guidance becoming available during the process of authorisation and mutual recognition of authorisations of biocidal products. Available at: https://circabc.europa.eu/sd/a/03bce60b-cf04-49aa-8172-e9c6a75205a7/CA-July12-Doc.6.2.d%20-%20Relevance%20of%20new%20guidance.doc

a) Editorial changes of existing guidance,

b) Clarification/interpretation of existing guidance,

c) New guidance as new technical scientific advice is given which triggers new data requirements,

d) New guidance as new technical scientific advice is given in order to have a harmonised approach on how the assessment should be done (without new data requirements).

In general the reference date of a TAB entry for product authorisation will be the date of publication of the TAB entry on the ECHA website.

The date of applicability of a TAB entry for product authorisation will depend on the type of entry:

	Type of entry in the TAB	Applicability of the TAB entry
a	Editorial changes of the existing guidance	As of the reference date
b	Clarification/interpretation of the existing guidance[4]	As of the reference date
c	New guidance as new technical scientific advice is given which triggers new data requirements	The approach agreed in the CA document CA-July12-Doc.6.2d
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)	The approach agreed in the CA document CA-July12-Doc.6.2d Deviation from this approach would be possible according to the provisions described below.

Regardless of the type of TAB entry, where further data requirements would be triggered by the new entry, the approach agreed in the CA document should be followed unless otherwise agreed by the CG and, where applicable (UA) agreed by the BPC.

ECHA will inform the CG on the new TAB entries directly after publication and review existing TAB entries and will inform about corresponding date of applicability biocidal products. This will enable the CG to discuss date of applicability of a given TAB entry belonging to category (d) if some members think that the standard approach is not appropriate for that entry.

Regarding the applicability of already existing TAB entries after incorporation in the relevant new or updated guidance document the approach agreed in the BPC document[2] should be followed:

"*Already existing recommendations and TAB entries should remain valid and applicable in case they are subsequently integrated into a guidance document. In this case, it should be stressed in the guidance document that those pre-existing recommendations and TAB entries are not affected by the rules on time of applicability that apply to the rest of the guidance document.* "

ECHA will develop a way to specify the dates of applicability of each TAB entry.

[4] This type of entry (b) does not introduce new elements, but gives clarification/explanation of the existing guidance in order a harmonised approach would be followed by the MSs.

B) Date of applicability of the conclusions of the WG on questions referred from the CG

In cases of a consultation from the CG to the WG(s) on a technical or scientific matter, the conclusions of the WG will be communicated by ECHA to the CG.

The same approach as for TAB entries should be followed, if the date of publication is available.

Where questions on specific applications are addressed, the CG will decide on the date of applicability of the conclusions of the WG on case by case basis, considering where applicable the approach agreed for different TAB entries.

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