Biocidal Products Committee

Applicability time of new guidance and guidance-related documents in active substance approval

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1. Introduction

At the "Workshop on reviewing the active substance assessment process" and also several times during WG meetings the issue has been raised of when new guidance or guidance related documents should be applied. The SECR prepared a proposal which was first presented at WG-II-2015 (Human Health and Environment) and further revised versions were discussed at BPC-12 and BPC-13.

This document has been drafted on the basis of these discussions, as well as written comments received from BPC members, with the aim of agreeing when new guidance or guidance related documents should be applied in the frame of **active substance approval**.

Please note that defined timelines on the applicability of guidance for **product authorisation** are provided in the CA-document CA-july2012-doc6.2d (final).

2. Proposed time of applicability

For the definition of timelines of applicability, the type of guidance document needs to be considered, as well as the different endorsement procedures:

- Guidance documents (e.g. Volumes I to V) usually go through a full ECHA consultation procedure[1] including a Partner Expert Group (PEG). In the frame of this procedure, guidance documents are **endorsed** in the frame of an **ASO/CA consultation** and are afterwards finalised by ECHA.
- Guidance *related* documents (e.g. HEAdhoc/AHEE[2] recommendations, Emission Scenario Documents (ESD), new emission scenarios) are **endorsed by the relevant WG**. They have typically been developed by a WG member or SECR, following an immediate need identified at the WG level and – besides ESD – are often prepared on a rather short notice.
- Technical agreements for biocides (TAB) provide general agreements of the Working Groups (WGs) which have not yet been included in any other BPR related guidance

[1] Please see: http://echa.europa.eu/documents/10162/13608/mb_63_2013_revision_consultation_procedure_guidance_en.pdf

[2] HEAdhoc: Ad hoc WG on Human Exposure
AHEE: Ad hoc WG on Environmental Exposure

documents. The TAB is not formally endorsed by the BPC or WG because the document records agreements of the WGs that are included in their minutes.

In this document, the term *guidance* is used to cover all types of documents listed above.

2.1 General rules for the timelines of application

Regardless of the type of guidance, the following general rules for the application of new guidance apply:

1. Applicants should apply new guidance which has been made available to all stakeholders[3] at least six months before the submission of the dossier to the eCA. The eCA should apply new guidance which has been made available to all stakeholders at least six months before the submission of the CAR to ECHA. This rule should apply to all guidance and guidance related documents, concerning both applicants and eCAs. Applicants should be further aware that the eCA may apply new guidance despite the fact that it was not a requirement at the time of dossier submission.

2. Guidance should never be applied retrospectively to substances for which the CAR has been submitted to ECHA (except for backlog dossiers) or for substances that were discussed in a WG meeting before a guidance document was applicable.

3. For backlog[4] dossiers, new guidance should be applied in accordance with the principles explained in section 2.2 below and the eCAs should update the draft final CAR before submitting it to ECHA. However, where further data requirements are triggered, these data requirements should only be applied at product authorisation stage in order to avoid duplication of work for eCAs and significant delay of the evaluation.

4. For dossiers put on hold for a significant time (> one year), the same rules apply as provided for backlog dossiers in the previous point.

5. With regard to data requirements for applicants, the guidance applicable at the time when the dossier was submitted to the eCA should apply. If further data requirements are triggered by new guidance, it should be applied only at product authorisation stage. However, applicants may be allowed to follow such late data requirements if this will enable the demonstration of a safe use. This possibility will be considered on a case by case basis, taking into consideration the approach described in the document "Introducing new information during the peer review process of active substance approval".

2.2 Exceptions for the timelines of application

The following **exceptions** from the above rule should apply to all guidance types, if not further specified otherwise:

[3] No differentiation is made between full guidance documents compared to ESDs, recommendations or the TAB: specifically for full guidance documents it takes several years until they are prepared, edited, went through the PEG process and are finally published. Stakeholders are part of the whole process and are aware of the developments from the beginning.
[4] Active substance PT combinations for which the evaluation was submitted by the eCA to the Commission before 1 September 2013, but which are not yet finalised in the peer review.

1. Provided that no new data requirements are triggered, new guidance should be applied immediately in the following cases:
   - no guidance was available at all for a certain issue.
   - new guidance is correcting major mistakes of former guidance (e.g. the supplement to the ESD for PT 13)
   - new guidance is considerably more reliable than former guidance.
2. Specific applicability timelines can be defined within the guidance which supersede the proposed general application rule.
3. If preliminary evidence indicates that applying the new guidance would not have any significant impact on the overall conclusion of the risk assessment (i.e. the conclusion of the risk assessment with regard to safe/non-safe use is not changing), the new guidance does not need to be applied. In such cases, a note should be made in the assessment report and BPC opinion that this new guidance has to be applied in future evaluations (renewal or evaluation of another product type) and/or during product authorisation, as applicable.
4. Where a recommendation or a TAB entry was developed for use in a specific CAR, it should be used immediately in that CAR. However, for other CARs submitted less than six months after the date where the recommendation would be applicable, a note could be included, indicating that recently endorsed guidance was not taken into account but should be taken into account at product authorisation.
5. 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.