DISCLAIMER: This document has been agreed on 3 July 2018 during the CG-30 meeting. The document CA-Nov14-Doc.5.8-Final will be updated accordingly after the conclusion of the Working Party on the Biocidal Product Family concept.

Best practices for eCA agreement and pre-submission meetings related to applications for biocidal product families

Background and purpose of the note

When applicants are in the planning phase for designing an application for a biocidal product family (BPF) a number of considerations might rise.

According to the BPR, Annex III (2): "*The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set out in Article 62(2), applicants may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out"(emphasis added).*

In order to solve as many issues as possible and discuss the foreseen approach before the submission of the application, it is therefore essential that the applicant seeks the agreement of the competent authority (CA) that will be acting as reference member state (rMS) in case of mutual recognition (MR) procedures or as evaluating CA in case of Union authorisation (UA) procedures (the "eCA" hereinafter). On the other hand, this forecasting of applications will enable the eCA to adequately plan the workload in the future and adapt the necessary resources accordingly.

Once an eCA has agreed to act as such, it is suitable that organization of pre-submission physical meetings is discussed as early as possible between the applicant and the eCA. The formal setting of the meetings may be adapted on a case by case basis, ranging from physical to virtual meetings or telephone conferences.

Although the eCA is committed to provide the applicant with all necessary information in order to enable him to prepare a proper dossier, it should be made clear that the dossier's content and quality is in the full and sole responsibility of the applicant. It is also necessary to make a clear distinction between the support an eCA can provide equally to all applicants and the specific assistance an applicant can get from a professional consultancy. In consequence the extent of support provided by the eCA at the pre-submission meeting(s) will have certain limitations and can in no case anticipate the final outcome of the evaluation.

This note outlines a step-wise approach for finding an agreement with the eCA and the preparation of pre-submission meetings.

Step 1 – Contacts by the applicant and eCA agreement

When the applicant has not yet decided on which CA to approach regarding signing an eCA agreement, the applicant can approach several CA's and ask for a meeting. These contacts should start as soon as possible, and not later than 18 months before the expected date/deadline for the submission of the application.

This meeting should be attempted scheduled fairly shortly after the CA has been contacted by the applicant, so the applicant has time to contact and set up meetings with other CA's if the contacted CA is not willing to act as eCA. The applicant should strive for a signed eCA agreement at the latest 1 year before the expected date/deadline for the submission of the application.

It is suggested that such a first meeting should be mainly a presentation of the BPF by the applicant, including a minimum of information concerning the structure (i.e. AS(s), PT(s), intended use(s), user category/ies, the number of meta-SPCs foreseen and the number of products in the BPF), as well as other relevant information (e.g. list of foreseen cMSs in case of MR procedures, number of existing products covered by the BPF, etc.). This information should be submitted to the approached CA at the latest 1 week before the meeting date.

After the meeting, the CA should then inform the applicant of its decision on whether to sign an eCA agreement as soon as possible (e.g. not later than 2 weeks), so that in lack of agreement, the applicant could contact other CAs.

Once the applicant has the agreement of an eCA, he should not contact new CAs and should inform other CAs he might have contacted of the eCA agreement.

Step 2 – Pre-submission meetings

After an eCA agreement has been signed, actual pre-submission meeting(s) can be organized. In general, only one physical meeting is held for an application. In this context, it is important to have a common understanding about when and how pre-submission meeting(s) have tio be held, as well as the suitable content for discussion.

When?

Pre-submission meetings should take place during the year before submission of the application.

Limitations

Before the pre-submission takes place the applicant should be informed about the following limitations of the support the eCA can provide:

- The eCA is willing to provide all necessary support to the applicant, but it cannot and will not replace the assistance the applicant can get from his own experts or by hiring a consultancy.
- Any recommendation provided by the eCA is based on the data provided for the meeting and does not anticipate the final outcome of the dossier evaluation.
- The eCAs comments are non-binding recommendations and it is still up to the applicants how to implement these recommendations or even find a better solution. The applicant is fully responsible for the quality and appropriateness of the data submitted with the application.
- The eCA in general is not in the position to participate in the development of new test strategies or approaches for exposure and/or risk assessment and risk mitigation measurements. For such developments the applicant is well advised to rely on his own expertise or hire external expertise

on his own expenses. However, the applicant is invited to present his intended strategy and discuss it with the eCA on a generic level.

What to discuss?

The following issues might be relevant for discussion in relation to BPF applications:

- 1st level: Overall information on the BPF. What is the argumentation for similar uses, similar composition and similar levels of risk and efficacy within the whole BPF?
- 2nd level: Meta SPCs. How many meta-SPCs are planned, how are they divided and what is the argumentation for this division?
- Are there any specific information requirements that are needed for the BPF?
- Testing strategy in order to secure that the whole range of the meta-SPC is covered for the assessment, i.e. for:
  - Physical/chemical: including definition of representative products at BPF/Meta SPCs level
  - Efficacy : including definition of representative products at BPF/Meta SPCs level and co-formulant impact on efficacy and the definition of the worst case (soiling etc.). In case of lacking guidance the testing strategies need to be agreed with the eCA, possibly in a written procedure.
  - Human/animal health
  - Environment
- Definition of worst case risk assessments for environment and human/animal health
- Where relevant, Article 5(2) assessment and/or comparative assessment.
- Practical issues, such as expected eCA fee for the suggested BPF (rMS should urge the applicant to contact ECHA regarding their fees) the applicant should be asked if he meets the criteria for SME status (fee relevant) and timelines regarding the application submission and authorisation process.

How to organize?

The following setting and responsibilities are suggested:

- The applicant contacts the eCA and clarifies any relevant administrative procedure to be followed for the meeting request (e.g. where relevant, any forms to be filled-in, fees to be paid, etc…).
- Not later than two weeks before the meeting, the applicant forwards a suggested agenda (based on the proposal above) and background documents for the meeting, as well as specific questions for the different parts of the evaluation. The applicant will have to provide the overview of the BPF according to the overview template agreed upon at CG-22[1]. On this background the eCA can decide on which expert participation is suitable at the meeting.
- The length of the meetings will be established by the eCA according with the agenda proposed by the applicant (e.g. from a few hours to a full-day).
- At the meeting the applicant briefly presents the intended use(s) of the products covered by the BPF and the eCA gives recommendations and advice on the issues brought forward. The eCA gives an

[1] Available at https://echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents

indication on whether the BPF structure and the worst case(s) identified by the applicant might beacceptable or not. In case the eCA based on the presented data, disagrees during the pre-submission meeting, the applicant shall address these concerns before the submission of the application.

- The meeting should identify specific scope or PT allocation issues, as well as technical matters for which there is no agreed harmonized approach. In these cases the eCA might need to consult the other member states (e-consultations of one of the WGs, HelpEx, or e-consultation of the CG, depending on the issue) in order to obtain a proposed way forward.
- The applicant must prepare minutes from the meeting which are afterwards checked (and updated if needed) by the eCA. These minutes should reflect all the items discussed and action points arising from the meeting and the relevant deadlines.