Biocidal Products Committee

Introducing new information during the peer review process of active substance approval

Date of document: 20 January 2016	Agreed at BPC-13

1 Introduction

The issue of new information during the peer review process of active substance approval has been raised several times. The SECR was requested to prepare a document on this issue with the aim to establish a harmonised approach and pay special attention to situations where the proposal of the evaluating competent authority (eCA) may change from approval to non-approval (or vice versa) following the commenting period and Working Group meetings.

A draft proposal was prepared by the SECR for BPC-12. A revised proposal was prepared and agreed upon at BPC-13.

2 Problem definition

Under the Biocidal Products Directive (BPD) there was no legal time limit for the start of the peer review process up to the Commission decision on inclusion on Annex I. Following the commenting period or as a follow-up of the Technical Meeting, applicants sometimes were given the opportunity to submit new information.

New information can consist of any information according to Annex II for the active substance or Annex III of the Biocidal Products Regulation (BPR) for the (representative) biocidal product. The nature of it can vary and may include for example: i) (eco)toxicological, environmental fate or efficacy testing; ii) information on exposure for a use included in the evaluation; iii) introducing a use not yet included in the evaluation; iv) information relevant for setting the reference specification. Information can be readily available by the applicant or still needs to be generated.

In principle there should be no need to request new information as the eCA has under the BPR (and had under the BPD) the possibility to request additional information considered necessary for carrying out the evaluation as stated in Article 8(2) of the BPR. Consequently, the data package should be complete in order for the eCA to conclude on the evaluation before it is submitted for peer review.

The BPR contains no provision on the possibility to submit new information during the peer review process. It therefore can be assumed that it is the intention of the BPR that after the submission of the evaluation by the eCA no new information is requested and incorporated.

The main reasons for adding new information are: i) information initially considered acceptable by the eCA is considered of insufficient quality or not adequate (see Article 7(3) of the BPR) by the commenting MSCAs during the peer review process, leading to a data gap; ii) refining the evaluation to find an acceptable use to prevent a non-approval proposal.

The BPR has created a new situation as the time limit for delivering the BPC opinion is 270 days from the start of the peer review. This applies to submissions under Article 7 of the BPR as well as the Review Programme as indicated in Article 7 of Regulation 1062/2014[1].

During the public consultation for potential candidates for substitution, sometimes information on the active substance is submitted. This is not the purpose of the public consultation: applicants are requested to consult during the evaluation phase with the eCA as early as possible, if they have new information relevant for the evaluation.

Practice has shown that currently information is sometimes requested during the peer review process either through the commenting phase after the accordance check or following discussions at the Working Groups. Consequently, there is a need to come to a harmonised approach.

If it is allowed to submit new information during the peer review process, practice shows that it will in the majority of cases not be possible to meet the 270 day time limit. However, this depends on the kind and availability of information.

3 Analysis of possible options and way forward

The first option to be considered is to not allow new information to be added during the peer review process. Although this is a straightforward option being in line with the objectives of the relevant provisions in the BPR and Regulation 1062/2014, it may lead to situations where a non-approval is recommended due to data gaps or unacceptable risks identified in spite of the existence of data which might have removed this concern. Therefore, this option is not considered appropriate and some flexibility should be provided.

It must be recognised that allowing new information to be submitted during the peer review process may jeopardise the 270 day time limit for the BPC opinion and/or the objective of delivering 50 BPC opinions per year for the Review Programme.

Therefore new information can be submitted during the peer review process only when all the following conditions are met:

- the 270 day time limit must be adhered to;
- limited to situations where during the peer review the outcome of the evaluation of the eCA is significantly changed: the conclusions lead instead of a proposal for approval to non-approval (or vice versa) or severe restrictions are imposed on the use of the active substance which were not included in the original proposal from the eCA;
- limited to situations where the new information is readily available and can be submitted by the applicant or a MSCA directly after the Working Group. The new information has to be submitted 10 working days after the Working Group. A strict time limit is required due to the limited time to submit and incorporate the new

[1] Article 7(2) of Regulation 1062/2014 states that "The Agency shall submit the opinion to the Commission within 270 days of the start of the preparation.", which is interpreted as 270 days after passing the ECHA accordance check as described in the working procedure for the active substance approval process (available from the ECHA web-site).

information by the eCA in the evaluation[2].

- the Working Group has agreed that new information is required and which information is required.

In summary, the only point in time when new information can be added during the peer review is during the Working Group discussions where it can be decided that and if so which specified information will be added. If it is decided at a Working Group that new information can be submitted, a peer review of this information and the consequences for the evaluation is introduced. For this peer review the "ad hoc follow-up" process will be used as described in the working procedure for active substance approval. It is expected that most frequently the new information will relate to refinement of the exposure assessment by refining a scenario, or adding another use where also efficacy studies may need to be submitted. However, the new information may also relate to refinement of the effect assessment or reducing uncertainty, and consequently assessment factors, by submitting (eco)toxicological information.

During the peer review, non-acceptance of core data already accepted by the eCA should in principle not occur. MSCAs are urged in case of doubts on the acceptability of data for a certain endpoint to consult via an early WG discussion other MSCAs to avoid these situations from happening during the peer review process.

The proposal does not apply fully to 'backlog dossiers'[3]. These dossiers are in different stages of the peer review, where eCAs have sometimes already accepted the submission of additional information following the commenting phase or a discussion at the Technical Meeting. After this information is provided to the eCA for the next step in the peer review (i.e. the discussion at the Working Groups), the same principles as above apply: only at the Working Group it can be decided if new information can be submitted.

In exceptional situations the evaluation may be put on hold during the peer review, for example if it appears necessary to await the RAC opinion as the active substance may meet (following the discussion at the Working Group) the exclusion criteria. In such situations no new information can be submitted during the period when the evaluation is put on hold, unless specifically requested by a Working Group meeting. The principles described above apply once the peer review is continued.

In addition to the principles described above, eCAs and applicants are urged to consult on a regular basis with the objective to submit to ECHA an evaluation fit-for-purpose for the peer review process.

The SECR is willing to engage in consultations before the evaluation is submitted to ECHA or to organise early Working Group discussions.

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[2] The time between the WG and the BPC is, depending on the process flow, between approximately 80 and 140 days where the revised CAR needs to be submitted to the SECR 26 days before the BPC.
[3] 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. For the "backlog" dossiers at least the commenting round has already taken place so for these dossiers the issue is related to introduction of new information during or after the commenting round. Article 7(2) of Regulation 1062/2014 also applies to these dossiers.