Introducing new information during the peer review process of an application for Union authorisation

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Agreed at BPC - 33

1 Introduction

During the peer review process of an application for Union authorisation sometimes new information has been included. This document is prepared by the SECR with the aim to establish a harmonised approach paying special attention to situations where the proposal of the evaluating Competent Authority (eCA) may change substantially following the commenting period and/or Working Group meetings. By substantially it is meant that introducing new information has an impact on the conclusion of whether the conditions of Article 19 are met or not.

It is noted that a similar document already exists for active substance approval: "Introducing new information during the peer review process of active substance approval" agreed at BPC-13 and available from the ECHA web-site. Similar principles are applied in the present document.

2 Problem definition

The peer review for the first Union authorisation applications started in 2017 and since then more than 10 applications have gone through this process. For some of these applications new information was included during the peer review process on efficacy and physico-chemical properties[1].

In principle, there should be no need to request new information as the evaluating Competent Authority (eCA) has under the Biocidal Products Regulation (BPR) the possibility to request additional information considered necessary for carrying out the evaluation (see Article 44(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 reason for adding new information is that information which is initially considered acceptable by the eCA, is considered of insufficient quality or not adequate by the commenting Member State Competent Authorities (MSCAs) during the peer review process.

[1] The cases have concerned so far testing on corrosiveness to metals.

As indicated above, new information has already been requested sometimes 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.

3 Analysis of possible options and way forward

The first option to be considered is to not allow new information to be submitted during the peer review process. Although this is a straightforward option being in line with the objectives of the relevant provisions in the BPR, it may lead to situations where (certain uses) cannot be authorised 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 is proposed that new information can only be submitted during the peer review process when all the following conditions are met:

- the 180 day time limit[2] must be adhered to;
- limited to situations where during the peer review the outcome of the evaluation of the eCA is changed: the conclusion leads to a proposal for not authorising (certain uses) which was not included in the original proposal from the eCA submitted for peer review or vice versa;
- limited to situations where the new information is readily available and can be submitted by the applicant or a MSCA 10 working days after the Working Group. A strict time limit is required due to the limited time to submit and incorporate the new information by the eCA in the evaluation;
- in exceptional and justified cases a deviation from the above mentioned timeline of "10 days after the Working Group" can be accepted;
- 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 submitted during the peer review is during the Working Group discussions where it can be decided that and if so which information will need to be submitted[3]. If it is decided at a Working Group that new information can be submitted, a peer review of this information is required. For this peer review, the "ad hoc follow-up" process shall be used as described in the working procedure for Union authorisation in steps 18 - 21. It may be that, due to the short time period between the Working Group and BPC, the "ad hoc follow-up" process is not possible. In such cases – which should be the exception - the eCA can incorporate the new information (previously agreed by the Working Group) directly into the relevant documents to be

[2] As referred in Article 44(3): "*Within 180 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.*" In the Working procedure for Union authorisation applications (available from the ECHA web-site) this is implemented as the start of the commenting phase (step 5) after a positive accordance check by ECHA and the finalisation of the BPC opinion (step 39).

[3] In case the information is already available this can be provided for example during the commenting phase and subsequently the Working Group can decide if it will be considered.

submitted for the BPC and submit also – which has been the practice so far – an explanatory document to the BPC concerning the evaluation of the new information.

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

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

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