Biocidal Products Committee

New information in active substance and Union authorisation opinion forming

Date: 22 November 2022	Agreed at BPC-45

1. Background

During the opinion forming for an application for active substance (AS) approval or Union authorisation (UA) process new information might need to be submitted. The BPC agreed on the procedures on submission of new information during the opinion forming process of active substance approval (AS) (BPC-13)[1] and application for Union authorisation (UA) (BPC-33)[1] to address these cases.

At BPC-44, the BPC members agreed based on a proposal from a Member State that applicants do no longer need to have new information readily available at the time of the WG meeting; the WG still can request data provided that all other criteria are fulfilled.

In addition, the SECR noted that there are some differences in the criteria applied for both processes (AS and UA). The SECR considers that the criteria should be aligned between processes.

Moreover, it appears currently that during the opinion forming process acceptance of the new information very much depends on whether the evaluating Competent Authority (eCA) is willing to accept such information and perform an evaluation. In line with the current procedures, during the opinion forming process, new data may be submitted only upon request of the WG at this process step[2].

Considering the above, the SECR reviewed the AS and UA procedures and prepared the present document with the aim to establish a harmonised approach paying special attention to situations where the proposal of the eCA may change substantially following the commenting period and/or Working Group meetings. Substantially is to be understood as new information impacting the conclusion of whether the conditions of Articles 4 and 19 Biocidal Products Regulation (BPR) are met or not.

2. Introduction

In principle, there should be no need to request new information during the opinion forming phase as the eCA has the competence to request additional information considered necessary for carrying out the evaluation (see Articles 8(2) and 44(2) of the BPR). Consequently, the data package should be complete for the eCA to conclude on the evaluation before it is submitted for the opinion forming to ensure a smooth opinion forming on robust data.

[1] Available on ECHA website Biocidal Products Committee - ECHA (europa.eu) - Introducing new information during the peer review process of active substance approval and Introducing new information during the peer review process of an application for Union authorisation

[2] Without prejudice to the Procedure for the submission, evaluation and dissemination of data generated after active substance approval and Post authorisation conditions for Union authorisation

The BPR does not foresee submitting new information during the opinion forming. Consequently, no new information should be requested and incorporated after the submission of the evaluation by the eCA.

The practice has shown that there are nevertheless circumstances under which new data becomes exceptionally relevant: i) 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 opinion forming process, leading to a data gap; ii) refining the evaluation to prevent a non-approval/non-authorisation as a consequence of changes during the opinion forming phase.

3. Harmonised approach to provide new information during the opinion forming process

Exceptionally allowing the provision of further information should be handled restrictively and follow clear, transparent and non-discriminatory criteria. Not allowing submission of new information during the opinion forming at all would lead to undesired results. Although straightforward and in line with the objectives of the BPR, it may lead to situations where a non-approval is recommended or the authorisation cannot be granted (for certain uses/products) due to the missing information or unacceptable risks identified in spite of the existence of data which might have removed this concern.

New information can be submitted during the opinion forming process when all the following conditions are met:

- the Working Group requests new information and specifies the precise nature of the information needed;
- new information must be submitted by the applicant or a MSCA within 10 working days after the day of the conclusion of the WG to invite provision of further information;
- the 270- and 180-day time limit[3] must be adhered to;
- the same information should not have been formally requested previously by the eCA to be provided by the applicant during the validation or evaluation phase;
- the new information has the potential to change the outcome of the evaluation of the eCA:
    - from a proposal for approval to a proposal for non-approval (or *vice versa*) or severe restrictions on a specific use for active substances;
    - from authorising to not authorising (certain uses/products) for UA (or *vice versa*).

Adhering to the criteria and timeline is necessary to ensure due process and allow to consider the newly provided information in the assessment. Information submitted after the deadline will not be accepted by the WG or BPC.

[3] As referred to in Article 8(4) BPR: "Within 270 days of receipt of the conclusions of the evaluation, *the Agency shall prepare and submit to the Commission an opinion on the approval of the active substance".* As referred in Article 44(3) BPR: "*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."*

If it is concluded at a Working Group that new information can be submitted, a peer review of this information is required and an "ad hoc follow-up" process is used as described in the working procedures[4] for active substance approval and Union authorisation. 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 requested by the Working Group directly into the relevant documents to be submitted for the BPC and also submit an explanatory document to the BPC concerning the evaluation of the new information.

3.1. Additional considerations for Active Substances

Some specific considerations are described below.

For AS process in exceptional situations the evaluation may be put on hold during the opinion forming, 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 the same general principles still apply, and no new information can be submitted during the period when the evaluation is put on hold, unless specifically requested by the Working Group.

Furthermore, this general approach concerning new information does not apply fully to 'backlog dossiers'[5] for active substances. These dossiers are in different stages of the opinion forming process where eCAs have sometimes already accepted, under exceptional circumstances and by a specific deadline, 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 opinion forming (i.e. the discussion at the Working Groups), the same principles as above apply: only the Working Group can conclude if new information can be submitted.

Finally, during the public consultation for potential candidates for substitution (in AS approval process), information on the active substance may be 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.

4. Concluding remarks

As a general best practice for AS and UA processes and to avoid requesting information late in the process, eCAs and applicants are urged to discuss on a regular basis with the objective to submit to ECHA an Assessment Report which is fit-for-purpose for the opinion forming. 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.

The procedure is applicable as soon as published on ECHA website.

[4] Working procedure for active substance approval and Working procedure for Union authorisation applications.
[5] 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.