

VCI position on

CHANGES TO THE CONCLUSIONS OF THE EVALUATION OF BIOCIDAL PRODUCTS

Legal Background

A Union authorisation (UA) for a biocidal product is valid throughout the EU.¹ Applicants wishing to apply for Union authorisation must submit an application to ECHA. Besides, a Member State must have agreed to take the role of the evaluating competent authority (eCA). The application must be accompanied by a corresponding written confirmation.²

The evaluating competent authority (eCA) fulfils a key responsibility in the evaluation:

- » The eCA validates the application by checking whether the relevant information for an authorisation application has been submitted. This does not involve an assessment of data quality, but merely a **check of completeness**.³
- » If the application is considered incomplete, the eCA informs the applicant of the additional information required and grants a **reasonable period of time to supplement** the application.⁴
- » Following validation, the eCA evaluates the application within 365 days and submits its **product assessment report (PAR)** and the conclusions of the evaluation to ECHA.⁵
- » Prior to this submission, the applicant has the opportunity to provide written comments on the eCA's conclusion. The eCA must take **due account of these comments in the final version**.⁵ Usually, points of disagreement are resolved through discussion between the applicant and the evaluating competent authority.
- » The **next steps** in the process are the
 - » **ECHA's opinion** within 180 days⁶, and the
 - » adoption of **an implementing regulation** or an implementing decision by the Commission.⁷ At the request of a Member State, certain conditions in the authorisation may be adapted to the territory of that Member State.

» The conclusions of the evaluating competent authority must be decisive for the authorisation of a biocidal product.

» The final version of the evaluation must take due account of the applicant's comments.

¹ BPR, article 41

² BPR, article 43 (1)

³ BPR, article 43 (3)

⁴ BPR, article 43 (4)

⁵ BPR, article 44 (1)

⁶ BPR, article 44 (4)

⁷ BPR, article 44 (5)

Recent Experience

Following the submission of the assessment report by the eCA, discussions regarding the substantive content of these reports are becoming increasingly common within ECHA's committees.

- » In some cases, Member States' comments raise new aspects that were not considered in the eCA's evaluation.
- » Significant changes may occur after the submission of the assessment report by the eCA:
 - » Change in formulation type
 - » Assignment to a product type
 - » Substantial changes to the description of use or application concentrations
 - » Changes to the product's stated shelf life
 - » Risk assessment, e.g. due to changes to exposure scenarios
 - » More stringent risk mitigation measures

These kinds of changes may result in intended uses no longer being covered. They may lead to supply chain issues, or cause data gaps in the dossier that was originally validated as complete.

- » It is no longer possible to submit new data at this time.
- » The applicant has no opportunity to participate in the discussion or to present his point of view. As a rule, the applicant's contribution when attending meetings is limited to answering specific questions.
- » The document adopted by the BPC Working Group may differ significantly from the original draft of the assessment report, without this having become apparent during the applicant's comment period. This means that the applicant has no opportunity to respond to critical comments.

If authorisation is not granted for certain applications for reasons raised very late in the process – and through questions or comments to which the applicant has no opportunity to respond – this may result in important products suddenly and unpredictably becoming unavailable.

VCI Assessment and Request

We regard as highly problematic any significant changes made to the eCA's assessment report after its submission, without the applicant being given the opportunity to comment on the proposals and to defend his product or application dossier.

In our view, the current practice contradicts the procedures set out in the BPR, which entrusts the evaluation not to a committee but to a single evaluating competent authority and, furthermore, grants the applicant the opportunity to participate in key stages of the process.

The significant influence of the BPC working groups at such a late stage in the procedure – carrying the risk of an unexpected outcome – constitutes, in our view, a process error.

We therefore call for a correction.

- The competency of the evaluating competent authority and its in-depth knowledge of the relevant dossier must be taken into account.
- Each Member State should support a decision on amendments to the dossier submitted by the eCA and take responsibility for it.
 - An active vote would contribute to prevent individual opinions from being imposed through passive acceptance.
 - Written form accompanied by appropriate justification and reasonable deadlines, would enhance the binding nature and ensure transparency in the process.
- The applicant must be given the opportunity to comment on the final draft of the assessment report or on points that have been amended compared with the report submitted by the eCA. The final version must take due account of these comments. Only such measures can ensure that the right to be heard is properly respected.
- In the interests of planning certainty, aspects that have not been addressed by a certain stage in the procedure (e.g. in the RCOM or Commenting Table) must not be raised spontaneously at a later stage. A binding overview should be presented at the start of the procedure.

The adoption of an assessment report must take place under fair and transparent conditions. The basis for this is a balanced discussion between all authorities, involving the applicant. In the case of mutual recognition procedures for national authorisations, it is important to uphold these principles, too.

These requirements help to ensure legal and planning certainty for applicants, to uphold the right to be heard, and to prevent the sudden and unforeseeable loss of important biocidal products and uses in the EU.

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