

Proposal to discontinue the chemical similarity check service performed in the context of BPR

65th Meeting of the Management Board 29-30 March 2022

Proposal

The Management Board is invited to **adopt the proposal to discontinue the chemical similarity check service** under the Biocides Product regulation. This service has been offered by ECHA from Q1/2014.

Background

The chemical similarity check (CSC) service under the Biocidal Product Regulation was started in Q1/2014 based on a decision of the Management Board¹ (MB) and in agreement with the Commission². The purpose is to provide applicants with an expert judgment, on which they can rely to prepare their application for product authorisation as well as for negotiations on data sharing. The check can be requested for active substances for which no final decision on the approval has yet been adopted by the Commission. The CSC was not foreseen under BPR, and is of a voluntary nature. General information is available on the ECHA website³.

The MB Decision establishing the CSC foresees a review: *"After having finalised 50 services for a chemical similarity check the Agency will inform the Management Board... on the experience gained and, where appropriate, prepare a proposal amending this Decision."* Experience gained has shown that this service offers no added value for industry or for ECHA, and the proposal is to discontinue it, although the number of 50 services has not been reached yet. Since the start of the service, only five CSC applications have been submitted to ECHA. One was assessed with an outcome. Four cases were not assessed beyond pre-check, either because the applicant withdrew the case after discussing with ECHA, or there was insufficient information to assess the case. No charges were received for the four cases as the pre-check is done before invoicing.

Rationale

The discontinuation of the service is justified by the following arguments discussed in more detail below and supported by the experience gained from the actual cases:

- there is no interest from industry for this service,
- uncertainties related to the scientific assessment and to the reliability of the outcome are high, and therefore the service has limited added value to the applicants
- resources needed at ECHA for the service are not compensated by the charges.

No interest from industry for the service is clear as only five CSC applications have been received, all individual applications. There have been no joint applications.

The uncertainties related to the scientific assessment (individual applications), and the limited added value to the applicant is caused and demonstrated by:

- Compositional information on the active substance under approval is needed for the assessment. The level of available information depends on the stage of the approval process and often changes depending on the stage. Therefore, it may not be possible to

¹ [Management Board Decision 31/2013](#)

² [COMMISSION DECISION of 29.11.2013; C\(2013\) 8349](#)

³ <https://echa.europa.eu/regulations/biocidal-products-regulation/chemical-similarity-check-service>

do any CSC assessment, or the outcome may change depending on the information available at a certain moment in time.

- CSC cannot pre-empt / replace an assessment of technical equivalence (TE). When the active substance is approved, TE still needs to be established separately before product authorisation, if the active substance does not come from the reference source.
- CSC outcome may differ from the outcome of a TE Tier I assessment carried out at a later stage, due to the limitations explained above regarding the availability of compositional information for the active substance under approval.
- Due to these uncertainties the CSC outcome does not guarantee the chemical similarity (or dissimilarity) with the active substance under approval and is therefore of limited added value to the applicant. In three actual cases the applicant decided to withdraw the application in the pre-check phase after discussing these limitations with ECHA.
- The outcome of the only assessed CSC case was referenced by the concerned companies in data sharing negotiations. These negotiations were followed by a data sharing dispute and two appeals.⁴ These events demonstrated that the CSC outcome may have consequences to the concerned companies although the general limitations of the check are outlined in the outcome document. This further emphasises the need to discontinue the service as the assessment outcome is of uncertain nature.

The overall resources used are not compensated by the income received: Resources are needed for the pre-check and the actual assessment of the cases, and for maintaining the service in general (update of manuals etc.). When the case is terminated in the pre-check phase there is no income received to compensate the resources used (four actual cases). The number of finalised cases (one) is too low to conclude whether the related charges could be sufficient. However, for the one assessed case the assessment was complex and time-consuming.

Follow-up: If the proposal to discontinue the service is adopted, the MB Decision 31/2013 needs to be revoked. Practical steps to close the service include e.g., i) informing external stakeholders and relevant ECHA units about the discontinuation and the related timelines, and ii) updating the ECHA documents, IT tools and webpages relevant to the service.

Alternative options

Alternative options have not been considered, as there is no need for this service, as demonstrated by the lack of interest from industry, and it consumes additional resources.

Drawbacks

As outlined above, there are no drawbacks to discontinuing the service. The criticism that may follow could include questioning why ECHA initially started the service. However, there are also other ECHA processes that have been offered earlier but are now deprioritised/discontinued due to resource constraints and the need to re-allocate resources.

Attachments:

N/A

For questions: ofelia.BERCARU@echa.europa.eu [director in charge] with copy to mb-secretariat@echa.europa.eu

⁴ Appeals A-014-2016 and A-009-2019