ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on technical equivalence

December 2021

Disclaimer

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The intention of the provision of Article 54 of the Biocidal Products Regulation EU No 528/2012 BPR is to enable the European Chemicals Agency (ECHA) to determine the similarity of the chemical composition and hazard profile of active substances that may differ from the one that was evaluated for the purpose of approval (reference source).

The assessment of technical equivalence (TE) is required when the active substance to be used in a biocidal product (BP) differs from the reference source of the approved active substance by having a different manufacturing process, a different manufacturing location or a different manufacturer.

A positive decision on the TE of the active substance issued by ECHA is a required element in the application for a BP authorisation (Commission Delegated Regulation (EU) No 837/2013 amending Annex III to the BPR).

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Manufacturers or suppliers of alternative sources of active substances (including the Review Programme[1] participants and supporters of new active substances following a change in the reference source) who wish to sell their actives to product formulators. Formulators may also apply for TE when the manufacturers or suppliers of their active substance do not have an interest to apply for TE.

The applicant may have a person/entity handling the practical issues related to the application on its behalf (e.g. a consultant).

[1] The Review Programme is a Commission work programme for reviewing all existing biocidal active substances. The programme was set up under the Biocidal Products Directive and continues under the Biocidal Products Regulation.

WHEN

TIMELINES, DEADLINES AND TRANSITIONAL PERIOD RELATED TO THE OBLIGATION/PROCESS

Companies may request the assessment of the TE of their active substance once the decision on the approval of the active substance has been adopted. Since ECHA's decision on TE must be included in an application for a BP authorisation, the deadlines relevant for BP authorisation applications (where applicable) need to be considered when submitting an application for TE.

For BPs containing existing active substances, and already on the market under national laws, the BP authorisation application must be made by the date of approval of the active substance, as explained in the Practical Guide chapters on national authorisation and Union Authorisation, otherwise the products must be removed from the market within 180 days of the active substance approval date. (A product authorisation application can also be made later but until it is granted the products must be removed from the market).

For BPs containing new active substances, and therefore not already available on the market, there is no deadline for the product authorisation application.

In all cases, however, TE applications should be made well ahead of the foreseen submission date of the respective product authorisation application to accommodate for the time needed for the processing of the TE applications.

WHAT

INFORMATION REQUIREMENTS AND SOURCES

Information requirements

BSM Application instructions: technical equivalence and chemical similarity, available on ECHA's website, explains what types of information files should be prepared and included in an application for TE.

Section 3.3 in the *Guidance on applications for technical equivalence*, available on ECHA's website, provides more advice on information requirements of the TE application and provides suggestions for further reading. For further details on the relevant information requirements, applicants should refer to Annex II to the BPR and the *Guidance for information requirements for Biocides*, available on ECHA's website.

Applicants should be aware when compiling their dossiers that the information requirements differ if they choose to apply for Tier I or Tier II TE assessment. Tier I assessment focuses on the substance identity and the impurity profile. In addition to these requirements, for Tier II toxicological and ecotoxicological data are also evaluated.

It should be noted that a five-batch analysis is always requested and that the spectral data is used to confirm the identity of the active substance. The methods of analysis should also be validated.

Issues to consider

The fee for the application for assessment of the TE will be based on the type of the application, Tier I or Tier II. It is in the responsibility of the applicants to assess which tier is appropriate for their case.

When applying for a Tier II assessment, a self-assessment of TE with the relevant toxicological and ecotoxicological data needs to be included in the application.

The applicants should be aware that each dossier can only refer to one alternative source. If several alternative sources need assessment, for example, if the company obtains their active substance from more than one source which differ in the manufacturing process, the company needs to submit separate applications for each alternative source of the active substance.

HOW

PROCEDURE TO FOLLOW

Creation of a IUCLID dossier

The applicant seeking assessment of TE is required to submit the data using an IUCLID format.

For more detailed instructions, see section 2.5 of the *BSM Application instructions: technical equivalence and chemical similarity* on how to include all required information in an IUCLID dataset.

The following documents describe in further detail how to create and complete an IUCLID dossier:

- *IUCLID manuals,* available on the IUCLID website.
- *BSM Technical guide:* How to prepare a biocides dossier available on ECHA's website.
- *BSM Technical guide:* How to use R4BP 3*, available on ECHA's website.*

Submission and processing of an application

The application for TE should be submitted through R4BP 3. Following confirmation that the submission has passed the initial checks by ECHA, the application will be evaluated by ECHA (90 days unless additional information requested). ECHA takes a decision on the TE.

Applicants need to monitor the status of their submission and receive/react to requests from ECHA in R4BP 3. If the applicant fails to meet a deadline, e.g. for payment of fees, or, at a later stage, request for any additional information, the application may be rejected or the evaluation may be completed disregarding the information that has been provided after the deadline. Only one update of the dossier is permitted in relation to a particular request. Updates of the dossier on the initiative of the applicant are not possible.

Applicants will find the relevant information and instructions for submitting and following up the application for TE through R4BP 3 in the following submission manuals available on ECHA's website:

- *BSM Technical guide:* How to use R4BP 3.
- *BSM Application instructions: How to submit an application for Technical Equivalence and Chemical Similarity*.

ECHA's website provides further details on the processing of the applications.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

Based on the assessment made by ECHA, applicants will receive a decision through R4BP 3 that:

1) For Tier I: either the TE cannot be concluded upon and the applicant should proceed to Tier II OR that the alternative and reference sources are equivalent.
2) For Tier II: the alternative and reference sources are/are not equivalent.

The decision must be attached to the application for product authorisation or where relevant to the application for an administrative change to an existing authorisation to be submitted under Implementing Regulation (EU) No 354/2013.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES

Chemical similarity check

If the active substance is not yet approved, companies can request ECHA to check the chemical similarity of the relevant sources of the active substances. Two types of applications can be submitted: individual applications and joint applications. The chemical similarity check does not replace the TE assessment obligation when the active substance is eventually approved.

The principles that apply for the chemical similarity check service are similar to those applied for TE.

More information about the chemical similarity check service and the different application types can be found on ECHA's website and in the *BSM Application instructions: technical equivalence and chemical similarity*.

Relation with Article 95

It should be noted that the assessment of TE is not required for Article 95 purposes. The listing in the active substances and suppliers list (Article 95 list) does not automatically imply the TE to an active substance. For more information on inclusion on the Article 95 list see the Practical Guide chapter Article 95: List of active substances and suppliers.

Nevertheless, a company may benefit from requesting a TE assessment from ECHA before applying to be listed in the Article 95 list. This is relevant where the company intends to acquire rights to data used to establish the reference source during the active substance approval for the purposes of inclusion on the Article 95 list. It will provide some assurances to the company that the data they are about to acquire rights to are relevant for their active substance.

Where the active substance is not yet approved, applying for the chemical similarity check by an alternative supplier before applying for inclusion on the Article 95 list may provide similar benefits. The fact that, in this case, the reference source is temporary and the active substance may not eventually be approved brings its own risks.

COST

RELATED FEES

Fees related to this process are described in the first entry of Annex III to *Commission Implementing Regulation (EU) No 564/2013*.

HELP

WHO TO CONTACT FOR FURTHER INFORMATION

ECHA Helpdesk

http://echa.europa.eu/contact/helpdesk-contact-form

National authorities providing support

http://echa.europa.eu/support/helpdesks/national-helpdesks/list-of-national-helpdesks

MORE

INFORMATION

Legislation relevant to biocides

http://echa.europa.eu/regulations/biocidal-products-regulation/legislation

Regulatory aspects

Technical equivalence

http://echa.europa.eu/regulations/biocidal-products-regulation/technical-equivalence

Chemical similarity check service

http://echa.europa.eu/regulations/biocidal-products-regulation/chemical-similarity-check-service

Guidance on Biocides legislation

http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

- Volume V – Specific Guidance - Guidance on applications for technical equivalence

Submission

- **Submission instructions**

  Technical equivalence and chemical similarity

  http://echa.europa.eu/web/guest/support/dossier-submission-tools/r4bp/technical-equivalence-and-chemical-similarity

  - Assessment of technical equivalence

- Chemical similarity check service

- **Biocides Submission Manuals**

  http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

  - BSM Application instructions: How to submit an application for Technical Equivalence and Chemical Similarity

IUCLID Manuals

http://iuclid6.echa.europa.eu/support

Q&As

https://echa.europa.eu/it/support/qas-support/browse