

Practical guide on research and development (Article 56)

December 2021

ABC

Disclaimer

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Practical guide on research and development (Article 56)

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WHY**PRINCIPLES BEHIND THE OBLIGATION/PROCESS**

According to Article 56 of the Biocidal Products Regulation ((EU) No 528/2012) (BPR) tests and experiments for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal products (BP) or a non-approved active substance (AS) intended exclusively for use in a BP may take place only under certain conditions¹.

In particular, the BPR requires that the person responsible for the experiment or test draws up and maintains written records which have to be made available to the competent authority (CA) upon request.

Furthermore, where the experiments or tests may involve or result in release to the environment of the BP, the person responsible for the experiments or tests needs to notify the CA of the Member State (MS) where the experiment or test will occur.

WHO**WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?**

Any person intending to carry out an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised BP or a non-approved AS intended exclusively for use in a BP. These provisions are only applicable to ASs and products that would normally need to be approved or authorised according to the BPR to be made available on the market and used.

More precisely, as stated in CA document CA-Nov14-Doc.7.5² the provisions should only apply to companies intending to start:

- (a) The activity of research and development on new active substances (i.e. substances not on the EU market for biocidal purpose before 14 May 2000).³
- (b) The activity of research and development on existing ASs which do not benefit from the transitional provisions⁴. It can concern, for instance, existing ASs which were not supported under the Review Programme and for which companies submitted applications for approval under Article 11 of Directive 98/8/EC

¹ Ref: Art 56 BPR

² <https://circabc.europa.eu/sd/a/f50810e3-e752-4c55-b608-85799b13603b/CA-Nov14-Doc.7.5%20-%20Final%20-%20Application%20of%20R&D%20provisions.doc>

³ Article 3(1)(e) of the BPR).

⁴ Ref: Articles 89 (i.e. not part of the review programme) and 93 of the BPR

(BPD) or will submit, applications for approval, or applications for Annex I inclusion under the BPR.

- (c) The activity of research and development on BPs containing the ASs listed under (a) and/or (b).
- (d) After the date of approval or inclusion into Annex I to the BPR, the activity of research and development on the concerned existing or new AS (e.g. developing a new use of the AS within the scope of the approved product-type (PT)), and new BPs containing them.

WHEN

TIMELINES, AND DEADLINES RELATED TO THE OBLIGATION/PROCESS



When planning the experiments or tests that may involve or result in release to the environment of the BP, the applicant needs to consider that the notified tests or experiments cannot be started before 45 days have passed from the notification.

WHAT

INFORMATION REQUIREMENTS AND SOURCES



Article 56 of the BPR lists the requirements for maintaining written records of experiments or tests, and for their notification when the experiments or tests may involve or result in release to the environment. *BSM Application instructions: How to submit an application for national authorisation* available on ECHA's website explains what types of information files should be prepared and included in a notification of experiment or test.

ECHA provides more advice on information requirements as given by Annexes II and III to the BPR and assessment of the information in the *Guidance on information requirements* available on ECHA's website.

The person responsible for the experiment or test shall draw up and maintain written records, to be made available to the CA upon request, containing the following information:

- identity of the product or the active substance,
- information on labelling,
- quantities supplied,
- contact information of those persons who received the product or the active substance,
- a dossier containing all available data on possible effects on human or animal health or impact on the environment.

HOW**PROCEDURE TO FOLLOW****Creation of a IUCLID dossier**

The person submitting a notification of an experiment or test is required to submit the data using a IUCLID format.

The following documents describe how to create and complete a 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.

Submitting and processing an application

The notification of experiment or test should be submitted through R4BP 3 to the MSCA where the experiment or test will occur. Following confirmation that the submission has passed the initial checks by ECHA, the application will be forwarded to the relevant CA. The CA draws up an opinion if it decides to prohibit or impose conditions on the experiment or test.

Notifiers need to monitor the status of their submission and receive/react to requests from the authorities in R4BP 3. If the applicant fails to meet a deadline, e.g. for requesting any additional information, the application may be rejected or the processing may be completed disregarding the information that has been provided after the deadline.

RESULT**OUTCOME OF THE OBLIGATION/PROCESS**

The respective CA may issue an opinion prohibiting or imposing conditions on the experiment or test, if the proposed experiments or tests are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on the environment. Examples of such conditions include measures to reduce the exposure e.g. quantities of the product or active substance that can be used in the experiment/test or on the extension of the areas to be treated.

In the absence of an opinion from the CA after 45 days from the notification, notified tests or experiments may take place.

The CA must inform the other CAs and the Commission of its decision.

TO NOTE**EXCEPTIONS AND PARTICULAR CASES**

For BPs regulated in accordance with national rules during the transitional period established under Article 89 of the BPR, the provisions of Article 56 of the BPR do not apply. Nevertheless, each MS can decide to establish specific provisions on research and development under their national rules for these situations.

COST**RELATED FEES**

Fees are not foreseen for this process.

HELP**TO CONTACT FOR FURTHER INFORMATION****ECHA Helpdesk**

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

MSCA's contact details

<http://echa.europa.eu/contacts-of-the-member-state-competent-authorities>

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

Research and development

<http://echa.europa.eu/regulations/biocidal-products-regulation/bpr-research-and-development>

Relevant Biocides competent authorities meetings documents

<https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a>

CA-Nov14-Doc.7.5 – Final: Guidance on the application of provisions on Research and Development under Article 56 of the BPR

Guidance on Biocides legislation

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

Submission

- Submission instructions
<http://echa.europa.eu/support/dossier-submission-tools/r4bp/submit-applications-for-national-authorisation>
 - Notification of experiment or test

- **Biocides Submission Manuals**
<http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals>
 - BSM Technical guide: How to prepare a biocides dossier
 - BSM Technical guide: How to use R4BP 3
 - BSM Application instructions: How to submit an application for national authorisation

- **IUCLID Manuals**
<http://iuclid6.echa.europa.eu/support>

Q&As

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