ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on data sharing under the biocidal products regulation

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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V2	Editorial improvements	December 2021

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http://echa.europa.eu/contact

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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The Biocidal Products Regulation ((EU) No 528/2012 (BPR)) prohibits repeating tests on vertebrates for the purposes of the BPR.[1]

Owners of existing data and prospective applicants are obliged to share certain data from tests and studies on biocidal active substances and products submitted to relevant authorities under the BPR or the Biocidal Products Directive 98/8/EC.[2] The aim of this is to avoid unnecessary animal testing and to share costs.

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Before performing any new tests on vertebrate animals, the prospective applicant is obliged to make an inquiry to the European Chemicals Agency (ECHA); an inquiry about other tests and studies is optional. The inquiry serves to inform the prospective applicant about the contact details of the data submitters.

Where an inquiry is made, and there are available vertebrate tests, the prospective applicant is obliged to request from the data owner to share the data. For non-vertebrate tests, the data-sharing request is optional.[3] Where a request to share data is made, the data owner and the prospective applicant are required to make every effort to reach an agreement in a fair, transparent and non-discriminatory way.[4]

WHEN

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

The prospective applicants are required to submit inquiries to share data:

- For vertebrate tests, as soon as the need for such a test has been identified and before any test is performed;
- For non-vertebrate tests, at any time.

[1] Ref: Article 62(1) of the BPR
[2] Ref: Article 62 and 63 of the BPR
[3] Ref: Article 62(2) of the BPR
[4] Ref: Article 63 of the BPR

WHAT

INFORMATION REQUIREMENTS AND SOURCES

Information requirements

To make an inquiry, you need to indicate during the submission:

- the name of the active substance when the inquiry relates to studies on active substances, or
- the relevant 'reference number' (asset number) of the biocidal product (BP) when the inquiry relates to studies on BPs.

More details on the information requirements:

BSM Application instructions: How to submit an application for active substance

BSM Application instructions: How to submit an application for national authorisation

It is also advised to consult the *Guidance on data sharing* available on ECHA's website. This document was originally created for REACH; therefore, an *explanatory note* has been added to clarify chapters that are particularly relevant to the BPR. The guidance helps the users to identify their obligations, the purpose of the inquiry process, how to conduct negotiations so as to prevent disputes and how to determine cost allocations and compensations.

Issues to consider:

Prior to submitting an inquiry to share data, prospective applicants may benefit from checking the List of active substances and suppliers *(Article 95 list)*[5] on ECHA's website to find out who manufactures or imports the same active substance or BP and contact the respective supplier to share these data. Note that the suppliers listed on the list are not always the data owners. The obligation to submit an inquiry discussed in this Practical Guide chapter are nevertheless not avoided by consulting the Article 95 list.

HOW

PROCEDURE TO FOLLOW

Inquiry to share data

The inquiry is submitted using R4BP 3. No IUCLID dossier is needed.

[5] http://echa.europa.eu/web/guest/information-on-chemicals/active-substance-suppliers

Following confirmation that the submission has passed the initial checks by ECHA, the inquiry will be processed by ECHA.

Applicants will find the relevant information and instructions for submitting and following-up their inquiry through R4BP 3 in the *BSM Technical guide: using R4BP 3*, available on ECHA's website.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

Following the inquiry to share data, ECHA provides the prospective applicants with the contact details of the data submitter to allow them to proceed with negotiations with the data owner on the sharing of the data. In parallel, ECHA informs the data submitter about an inquiry on their active substance or BP.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES

Article 95 obligation to share non-vertebrate data

For the purposes of making an application for inclusion on the Article 95 list, data sharing is mandatory for all toxicological, ecotoxicological and environmental fate and behaviour studies relating to Review Programme[6] active substances, including any such studies not involving tests on vertebrates.[7] For more information on the process of Inclusion on the Article 95 list, see Practical Guide chapter on Article 95: List of active substances and suppliers.

Data-sharing dispute claims

Where the parties fail to reach an agreement, the prospective applicant may, as a last resort, initiate a data-sharing dispute procedure before ECHA which may result in ECHA granting a permission to refer to the data. [8]

The inquiry is a formal pre-requisite for a data-sharing dispute claim. The dispute claim can be made at the earliest one month after the inquiry has been answered by ECHA.

A prospective applicant submitting a data-sharing dispute claim needs to provide documentary evidence demonstrating the efforts made by all parties compelled to reach an agreement on sharing data.

[6] 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 BPR. See Commission Regulation (EU) No 613/2013. Note that the new Review Programme Regulation is likely to be adopted in autumn 2014.
[7] Ref: Article 95(3) of the BPR.
[8] Ref: Article 63(3) of the BPR.

A data-sharing dispute claim must be submitted by the prospective applicant using the web form[9], available on ECHA's website. ECHA assesses the parties' respective efforts to reach such an agreement and takes a decision to grant or not to grant permission to refer to the relevant studies. We urge to continue negotiations even when a dispute has been submitted.

A data-sharing dispute must be settled before the application concerning that data can be submitted.

ECHA decisions on data-sharing disputes are published on ECHA's website[10].

Where the negotiations started before 1 September 2013

As under the previous legislation (Directive 98/8/EC) there was no mandatory data-sharing obligation per se, the new obligation under the BPR cannot have retroactive effect, and ECHA cannot take into consideration what was achieved or negotiated prior to 1 September 2013 in a data-sharing dispute.

Where negotiations started before the entry into application of the BPR, parties should identify the remaining points of disagreement and the points on which they have reached an agreement as of 1 September 2013. This can serve as a basis for the negotiations that must take place after 1 September 2013.

It remains mandatory for "any person intending to perform tests or studies on vertebrate animals" to submit an inquiry to ECHA and to negotiate for at least one month after receiving the relevant contact details, before being entitled to submit a data-sharing dispute claim. This applies equally to a claim for toxicological and ecotoxicological studies not involving tests on vertebrates under Article 95.

COST

RELATED FEES

No fees are applicable for these processes.

[9] https://comments.echa.europa.eu/comments_cms/Article633.aspx

[10] http://echa.europa.eu/regulations/biocidal-product-regulation/data-sharing/echa-decisions-on-data-sharing-disputes-under-bpr

HELP

TO CONTACT FOR FURTHER INFORMATION

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

MORE

INFORMATION

Legislation relevant to biocides
http://echa.europa.eu/regulations/biocidal-products-regulation/legislation

Regulatory aspects

Data sharing
http://echa.europa.eu/regulations/biocidal-products-regulation/data-sharing

Practical Guide: Special Series on Data Sharing
http://www.echa.europa.eu/web/guest/practical-guides/bpr-practical-guides

- Introduction to the BPR and SME considerations
- Data Sharing
- Letters of Access
- Consortia

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

Submission

- **Submission instructions**

Active substances

http://echa.europa.eu/support/dossier-submission-tools/r4bp/active-substances

- Inquire to share data for active substances

National authorisations

http://echa.europa.eu/support/dossier-submission-tools/r4bp/submit-applications-for-national-authorisation

- Inquire to share data for biocidal products

- **Biocides Submission Manuals**

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

- BSM Technical guide: How to use R4BP 3
- BSM Application instructions: How to submit an application for active substance
- BSM Application instructions: How to submit an application for national authorisation

Q&As

Questions and Answers on Data sharing under BPR

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