ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on the review of an approval of an active substance

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.

Version	Changes	
V1		October 2016
V2	Editorial improvements	December 2021

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Reference: ECHA-21-H-14-EN
ISBN: 978-92-9468-078-5
Cat. Number: ED-05-21-360-EN-N
DOI: 10.2823/702992
Publ.date: December 2021
Language: EN

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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

Where there are significant indications that the biocidal active substance no longer meets the conditions set in Article 4(1), or where relevant in Article 5(2), of the Biocidal Products Regulation ((EU) No 528/2012) (BPR), the European Commission (COM) may at any time review the approval of an active substance for one or more product-types (PTs)[1].

The COM may also review the approval of an active substance at the request of a Member State (MS) if there are indications that the use of the active substance in biocidal products (BPs) or treated articles raises significant concerns about the safety of such BPs or treated articles.

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

The review of the approval of active substance is started by the COM on its own initiative or at the request of an MS. The initial applicants for the approval will be given an opportunity to comment (see below).

WHEN

TIMELINES RELATED TO THE OBLIGATION/PROCESS

The review of an active substance approval may be initiated at any time.

WHAT

INFORMATION REQUIREMENTS AND SOURCES

On a case-by-case basis, the COM, an MS or the European Chemicals Agency (ECHA) may use any available information related to the active substance under review.

[1] Ref: Article 15 of the BPR

HOW

PROCEDURE TO FOLLOW

The COM or an MS indicates the need for a review of an approved active substance. The COM will then make the information that it is carrying out a review publicly available.

The COM will give an opportunity for the initial applicant to submit comments which are considered in its review. The COM may consult ECHA on any questions of a scientific or technical nature related to the review of approval of the active substance in question.

When such a consultation is made, ECHA will prepare an opinion within 270 days (through the Biocidal Products Committee (BPC)) and submit it to the COM. The COM will decide whether there is a need to amend or cancel the approval of the active substance.

There is no deadline given in the BPR for the length of the process.

The COM may decide to cancel or amend the approval of an active substance for one or more PTs.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

Where the COM cancels the approval or amends the conditions for approval it will adopt an implementing regulation. Where the approval is cancelled, the active substance will be removed from the Union list of approved active substances.

MSs or, in the case of a Union authorisation, the COM shall cancel or amend the authorisations of BPs in the PTs concerned containing that active substance and shall grant a period of grace for the disposal, making available on the market and use of the BPs.[2] The period of grace shall not exceed 180 days for the making available on the market, and an additional period of 180 days for the disposal and use of the BPs concerned. This is applicable unless continuing to use or make the BP available on the market constitutes an unacceptable risk to human health, animal health or the environment.

COST

RELATED FEES

No fees are applicable for this process.

[2] Ref: Article 15(3) of the BPR

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

Approval of active substances

http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances

The Biocidal Products Committee

http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

Treated articles

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

Relevant Biocides competent authorities meetings documents

https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942

Guidance on Biocides legislation

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

Q&As

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