

Review of an approval of an active substance

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)²⁷.

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.

²⁷ Ref: Article 15 of the BPR

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.

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 taken into account 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 BPs²⁸. 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.

²⁸ Ref: Article 15(3) of the BPR

COST



RELATED FEES

No fees are applicable 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

Approval of active substances

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

Annex I amendment

» <http://echa.europa.eu/regulations/biocidal-products-regulation/annex-i-amendment>

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>

Submission**• Submission instructions**

Active substances

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

- Active substance approval
- Approval of an active substance in an additional product-type
- Amendment of Annex I to the BPR (first inclusion of an active substance or amendment of restrictions)

Q&As

» <http://echa.europa.eu/support/qas-support>