

Renewal of an approval of active substance

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

Active substances should be regularly examined to take account of developments in science and technology. Therefore, an active substance is approved for a maximum of 10 years. The active substance is approved for less than 10 years in particular when it meets the exclusion or substitution criteria set out under the Biocidal Products Regulation ((EU) No 528/2012) (BPR). An application to renew the approval of an active substance/product-type (PT) combination must be made before the initial approval period expires. Chapter III of the BPR addresses the procedure of renewal including conditions, which have to be met for a renewal to be granted.

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Usually, the applicant is expected to be the same person who applied for the original active substance approval; however, a different company can also apply. The application can be made on behalf of a task force, including new or different members from the original applicant(s).

In particular, when several companies are seeking renewal of the same active substance/PT combination, they are encouraged to create a task force and make one submission. The applicant may have a person/entity handling the practical issues related to the application on its behalf (e.g. a consultant).

Note that the renewal process also has consequences for inclusion on the Article 95 list. See the Practical Guide chapter on *Article 95: List of active substances and suppliers*.

WHEN



TIMELINES RELATED TO THE OBLIGATION/PROCESS

The application for renewal of the active substance approval for a given PT should be submitted to the European Chemicals Agency (ECHA) at the latest 550 days before the expiry date of the approval of the active substance for this PT. If the application relates to more than one PT, it should be made at the latest 550 days before the earliest expiry date.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

An applicant is obliged to provide in all cases²²:

- the name of the competent authority (CA) that it proposes should evaluate the application for renewal and written confirmation that the CA agrees to do so;
- all data required under Article 20 of the BPR that has been generated since the initial approval or previous renewal has been granted i.e. new relevant data regarding requirements listed in Annexes II or III to the BPR (including data requested or answers to issues raised and left open at the time of the initial approval);
- an assessment of whether the conclusions of the initial or previous assessment of the active substance are still valid;
- any supporting information related to that assessment, if not already available in R4BP 3.

For active substances that meet the exclusion criteria set out under Article 5(1) of the BPR, it is also required to provide justifications that at least one of the conditions set out in Article 5(2) is met, to justify that the approval of the active substance may be renewed.

These justifications for derogation should be provided for each individual Member State (MS), unless the grounds for derogation are the same and valid for all MSs across the EU.

In addition, to make sure that the overall data package for the active substance is available for renewal or review, all studies that were assessed for the first approval of the active substance should be reported and attached in the IUCLID dossier.

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 for Biocides*, available on ECHA's website.

Issues to consider:

If the applicant is a small or medium-sized enterprise (SME), it may be entitled to a reduced fee. Note that ECHA needs to recognise the SME status of the applicant, before submitting an application for renewal. For more information on the recognition of an SME status and on how to

²² Ref: Article 13 of the BPR

HOW



submit relevant documentation see ECHA website²³.

PROCEDURE TO FOLLOW

Creation of a IUCLID dossier:

The applicant seeking renewal of an approval of an active substance needs to submit the data using an IUCLID format.

The following documents describe how to create a complete IUCLID dossier:

- *IUCLID manuals*, available on the IUCLID website
- *BSM Technical guide: using IUCLID* available on ECHA's website.
- *BSM Technical guide: using R4BP 3*, available on ECHA's website.

Submitting and processing an application:

The application for renewal of the active substance approval should be submitted through R4BP 3. Following confirmation that the submission has passed the initial checks by ECHA, the application will be forwarded to the evaluating CA (eCA) for evaluation.

At an early stage, the eCA decides whether a full evaluation of the application for renewal is necessary or not. Full evaluation takes 365 days and allows applicants to submit additional data requested by the eCA. If a full evaluation is not necessary, the evaluation has to be completed in 180 days.

Evaluation is followed by a peer review performed by ECHA through the Biocidal Products Committee (BPC) which issues an opinion. The duration of the peer review depends on the type of the evaluation: 270 days for a full evaluation and 90 days if the eCA evaluation is not a full one. On the basis of the BPC opinion, the European Commission (COM) takes a decision on the renewal of the approval of the active substance²⁴.

Applicants 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 payment of fees, the application may be rejected.

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

- *BSM Technical guide: using R4BP 3*
- *BSM Application instructions: active substances*

More information related to invoicing and R4BP 3 can be found in the *BSM Process of invoicing in R4BP 3*.

²³ <http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr>

²⁴ Ref: Articles 13-14 of the BPR

RESULT



OUTCOME OF THE OBLIGATION/PROCESS

On the basis of the ECHA opinion, the COM shall decide whether or not to renew the approval of the active substance/PT²⁵.

The renewal of an approval of an active substance shall be for a maximum period of 15 years for all PTs to which the approval applies. If the active substance meets the substitution criteria, the approval will be renewed for a maximum of seven years with the exception of substances meeting exclusion criteria, which are renewed as long as they fulfil the criteria of Article 5(2) of the BPR. Such substances may be renewed for a maximum of five years.

If the outcome of the process is that the active substance approval is not renewed or if the conditions for approval are amended, the MSs or, in the case of a Union authorisation, the COM, shall cancel or, where appropriate, amend the authorisations of biocidal products (BPs) in the PTs concerned containing that active substance, and shall grant a period of grace for disposal, making available on the market and use of the BPs. 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.

Where the approval of the active substance is likely to expire before a decision has been taken on its renewal, the COM may adopt a decision postponing the expiry date of approval for a period sufficient to enable it to examine the application.

COST



RELATED FEES

Both ECHA and national fees are applicable for this process.

ECHA fees related to this process are described in Annex I to *Commission Implementing Regulation (EU) No 564/2013*. Additional fees may be applicable for additional PTs, when full evaluation is necessary and if the substance is a candidate for substitution.

Note that small or medium-sized enterprises (SMEs) may be entitled to a reduced fee, see ECHA's website²⁶.

National fees related to the application for renewal of active substance approval may vary between CAs and are established in national legal acts of each MS. The applicant is responsible for checking and paying the specified amount of fees to the chosen eCA.

²⁵ Ref: Article 12(1) of the BPR

²⁶ <http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr>

HELP



For more information about the CA's fees, the applicant should contact the designated national CA or its helpdesk.

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

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

Relevant Biocides competent authorities meetings documents

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

CA-Sept14-Doc.5.2 – Final – Complementary guidance regarding the renewal of anticoagulant rodenticide active substances and biocidal products

Guidance on Biocides legislation

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

Submission

- Submission instructions

Renewal of an active substance approval

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

- Biocides Submission Manuals

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

BSM Technical guide: using IUCLID

- » http://echa.europa.eu/documents/10162/14938692/bsm_01_using_iuclid_en.pdf

BSM Technical guide: using R4BP 3

- » http://echa.europa.eu/documents/10162/14938692/bsm_02_using_r4bp3_en.pdf

BSM Application instructions: active substances

- » http://echa.europa.eu/documents/10162/14938692/bsm_04_active_substances_en.pdf

BSM Process of invoicing in R4BP 3

- » http://echa.europa.eu/documents/10162/14938692/bsm_09_invoicing_en.pdf

- IUCLID Manuals

- » <http://iuclid6.echa.europa.eu/support>

Q&As

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