

Renewal of national authorisation and authorisations subject to mutual recognition

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The Biocidal Products Regulation ((EU) No 528/2012 (BPR)) states that an authorisation of a biocidal product (BP) can be granted for a maximum period of 10 years⁸¹. Article 31 of the BPR sets out the procedure for the renewal of a single national authorisation granted by the Member State competent authority (MSCA).

Supplementary rules for the renewal of authorisations subject to mutual recognition (MR) procedures and having the same terms and conditions with limited exceptions⁸² (grouped renewal), in all the Member States (MSs) where renewal is sought, are laid down in the MR Renewal Regulation (Commission Delegated Regulation (EU) No 492/2014).

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

An application for the renewal of national authorisation (NA) can be made by, or on behalf of, the authorisation holder(s) (AH) of the original authorisation(s). Accordingly, the applicant may have a person/entity handling the practical issues related to the application and renewal procedure on behalf of the AH.

The AH is the person/entity established within the European Union (EU)/ European Economic Area (EEA), who is responsible for placing the BP on the market in a particular MS⁸³.

WHEN



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

An application for the renewal of NA including those subject to MR shall be submitted at least 550 days before the expiry date of the NA. In the case of the applications for renewal of NA, subject to or granted through

81 Ref: Article 17(4) of the BPR.

82 Ref: Article 1(3) of the MR Renewal Regulation.

83 Ref: Article 3(1)(p) of the BPR.

MR, the applications need to be made to the reference MS and the MSs concerned at the same time.

Phasing-out period for BPs

If an application for renewal has not been submitted, or is rejected, or additional information on the request of the MS has not been submitted by the applicant, the BPs shall be taken off the market within 180 days after the expiry date of the initial authorisation. An additional maximum period of 180 days can be granted for the use of existing stocks⁸⁴.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

BSM Application instructions: national authorisations, available on the European Chemical Agency's (ECHA) website, outlines the different types of information files that should be prepared and included in an application for renewal.

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.

HOW



PROCEDURE TO FOLLOW

Creation of a IUCLID dossier:

An application must always include a IUCLID dossier with, at minimum, the information on the product composition. Where relevant, the technical and scientific data also have to be included in the IUCLID file.

The following documents describe how to create and complete a 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.

Submission and processing of an application:

The application for renewal of NA should be submitted through R4BP 3:

- for renewal of a single NA, to the receiving MS. Any authorisation can be treated as a single NA, including an authorisation granted through mutual recognition, which does not meet anymore the conditions laid down in Article 1(2)(3) of the MR Renewal Regulation;
- for grouped renewal of NAs, subject to or granted through mutual MR, to the reference MS and all MS(s) concerned. In case of several NAs linked together by mutual recognition, which have different AHs and for which there is an agreement that they will be renewed together, the AHs may agree who will make the grouped application on their behalf and nominate the company in charge of submitting the renewal using

⁸⁴ Ref: Article 52 of the BPR.

the “Nomination” functionality in R4BP 3.

Following confirmation that the submission has passed the initial checks by ECHA, the application will be forwarded to the relevant MS(s) for validation and evaluation. At a very early stage, the receiving/reference MSCA decides whether a full evaluation of the application for renewal is necessary or not. Full evaluation takes 365 days. If a full evaluation is not necessary, the evaluation has to be completed in 180 days. The receiving/reference MSCA may request the applicant to submit additional data.

The respective competent authority(s) (CA) take(s) a decision on the renewal of an authorisation. In the context of renewal, subject to or granted through MR, in some cases granting the renewal of an authorisation requires a decision by the European Commission (COM) or an agreement by the Coordination Group (CG) (see below).

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, or, at a later stage, request for any additional information, the application may be rejected or the evaluation may be completed disregarding the information that has been provided after the deadline.

Applicants will find the relevant information and instructions for submitting and following up the application for renewal through R4BP 3 in the [BSM Application instructions: national authorisations](#) available on ECHA's website.

ECHA's website gives details on the assessment procedure in relation to this process.

Derogations

For renewal, subject to or granted through MR, any of the MSs concerned may propose to refuse to renew an authorisation or to adjust its terms and conditions based on the following grounds⁸⁵:

- the protection of the environment;
- public policy or public security;
- the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;
- the protection of national treasures possessing artistic, historic or archaeological value;
- the target organisms not being present in harmful quantities; or
- an active substance is a candidate for substitution.

In each case, a detailed justification is required to be communicated from the MS concerned to the applicant. The MS concerned seeks to reach agreement with the applicant on the proposed derogation.

If an agreement between the two is not reached, the MS concerned informs COM who takes a final decision on the derogation. COM may ask

⁸⁵ Ref: Article 37(1) of the BPR.

the ECHA for an opinion on scientific and technical issues (through the Biocidal Products Committee (BPC)) in order to conclude on its decision⁸⁶.

This procedure can also apply when additional/different restrictions are proposed by the MS concerned, which for BPs containing an active substance which is a candidate for substitution, has made a supplementary comparative assessment to the comparative assessment carried out by the reference MS.

Settlement of disagreements

In the case of renewal subject to, or granted through MR, when any of the MSs concerned disagrees with the conclusions of the product assessment report or with the summary of the product characteristics (SPC) it must send a detailed explanation of the reasons for such a position to the reference MS, all other MSs concerned and the applicant. The points of disagreement must be referred to the CG⁸⁷ without delay by the reference MS where the MS use their best endeavours to reach an agreement. The applicant is allowed to present its point of view.

When an agreement is not reached by the CG within 60 days, the reference MS informs COM, which takes a final decision by means of an implementing act. COM may either ask ECHA for an opinion on scientific and technical issues (through the BPC) or give an opportunity to the applicant to comment in order to conclude on its decision.

RESULT



OUTCOME OF THE OBLIGATION/PROCESS

After finalising the evaluation and, in the case of MR, after reaching an agreement between reference MS and MS(s) concerned, the authorisation shall be renewed for a maximum period of 10 years, unless the active substance is a candidate for substitution (i.e. maximum of five years).

For authorisations granted through MR, the maximum validity of the renewed authorisations should be the same in all the MSs where the product is renewed.

For reasons beyond the control of the AH where no decision is taken on the renewal before the expiry date of the initial authorisation, the relevant MSCA must grant a renewal for the period necessary to complete the evaluation.

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

Renewals of authorisations of anticoagulant rodenticides

For already authorised BPs containing anticoagulant rodenticides⁸⁸, which are candidates for substitution, a comparative assessment has to be done

⁸⁶ Ref: Article 37(2) and (3) of the BPR.

⁸⁷ Ref: Article 35(1) of the BPR.

⁸⁸ Difenacoum, difethialone, chlorophacinone, bromadiolone, coumatetralyl, flocoumafen, brodifacoum, warfarin and warfarin sodium.

before their authorisations will be renewed. Applications for renewal of such products have to be submitted within the usual 550-day deadline but then the assessment will be put on hold by the MSs until decisions on the renewal of the relevant active substance approvals are taken.

So far, the applicants have been requested to submit only an application form for renewal of product authorisation generated from R4BP 3 and relevant supporting document. Provided that an application for renewal of BP authorisation has been submitted, MSs should grant a renewal of the existing authorisation for a period necessary to complete the evaluation.

When the approval of the active substance is renewed, the applicants will have to submit all data generated since the initial authorisation was granted and potentially other information.

COST



RELATED FEES

The national fees related to the application for renewals of NA may vary between MSCAs 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 MSCA.

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

There is no fee charged by ECHA for a renewal of NA or authorisations subject to or granted through MR.

HELP



TO CONTACT FOR FURTHER INFORMATION

ECHA Helpdesk

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

MSCAs 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

Renewal of National authorisation and authorisations subject to Mutual recognition

- » <http://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/national-authorisation-renewal>

Relevant Biocides competent authorities meetings documents

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

CA-Feb13-Doc.5.1.b.a - Final: Summary of the biocidal product characteristics for a biocidal product and biocidal product family;

CA-Feb13-Doc.5.2.b - Final: Substance approval and product authorisation renewals of the anticoagulant rodenticides

CA-July13-Doc.11.3 - Final: Application of Art. 23(4) of the BPR to anticoagulant rodenticides for which the authorisation decision will be taken after 1st September 2013

Guidance on Biocides legislation

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

Submission

• Submission instructions

National authorisations

- » <http://echa.europa.eu/support/dossier-submission-tools/r4bp/renewal-national-authorisation>

Renewal of authorisation(s) (including authorisations subject to mutual recognition)

- » <http://echa.europa.eu/support/dossier-submission-tools/r4bp/renewal-of-authorisations-subject-to-mutual-recognition>

• Biocides Submission Manuals

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

BSM Technical guide: using IUCLID

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

BSM Technical guide: using R4BP 3

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

BSM Technical guide: using SPC

» http://www.echa.europa.eu/documents/10162/14938692/bsm_03_using_spc_en.pdf

BSM Application instructions: national authorisations

» http://www.echa.europa.eu/documents/10162/14938692/bsm_06_national_authorisation_en.pdf

- **IUCLID Manuals**

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

Q&As

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