Practical guide on renewal of national authorisation and authorisations subject to mutual recognition

February 2024

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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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V1		October 2016
V2	Editorial improvements, update of Section "Exceptions and particular cases"	December 2021
V2.1	A reference in footnote 7 was corrected	March 2022
V3	Editorial improvements and clarifications throughout the document; Alignment of the section 'settlement of disagreements' with the updated *Working procedure for resolving disagreements_ver18:* Resolving disagreements on mutual recognition, renewal, changes, simplified notification and Article 48 procedure: working procedure for the Coordination Group; Alignment of the section `EXCEPTIONS AND PARTICULAR CASES' with relevant CA documents concerning the renewal of rodenticides and wood preservatives, as well as Commission Regulation (EU) 2023/2596 of 21 November 2023; Update of relevant documents and guides.	February 2024

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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 years[1]. Article 31 of the BPR sets out the procedure for the renewal of a single national authorisation (NA) 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 exceptions[2] (grouped renewal), in all the Member States (MSs) where renewal is sought, are laid down in the Commission Delegated Regulation (EU) No 492/2014 (Renewal Regulation).

The same rules as for a single BP also apply for a biocidal product family (BPF)[3].

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

An application for the renewal of 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 MS[4] and is specified in the authorisation.

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

[1] Article 17(4) of the BPR.
[2] Article 1(3) of the Renewal Regulation.
[3] Ref. Article 3(1)(s) of the BPR.
[4] Article 3(1)(p) of the BPR.

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 stocks[5].

WHAT

INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

BSM Application instructions: How to submit an application for National Authorisation, 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 an IUCLID dossier with, at minimum, the information on the product composition. Where relevant, the technical and scientific data must also be included in the IUCLID file.

The following documents describe how to create and complete an IUCLID dossier:

- *IUCLID manuals,* available on the IUCLID website
- *BSM Technical guide: How to prepare a biocides dossier*, available on ECHA's website;
- *BSM Technical guide: How to use R4BP 3,* available on ECHA's website.

[5] Ref: Article 52 of the BPR.

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 MR, which does not meet anymore the conditions laid down in Article 1(2) and (3) of the Renewal Regulation. Authorisations granted through the same biocidal product (SBP) procedure also need to be treated and renewed as an NA;
- for grouped renewal of NAs, subject to or granted through MR, to the reference MS and all concerned MS(s). In case of several NAs linked together by MR, 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 the "Nomination" functionality in R4BP 3. Grouped renewal of authorisations granted through the SBP procedure is not possible.

Following confirmation that the submission has passed the initial checks by ECHA, the application for renewal of a single NA will be forwarded to the relevant MS(s) for acceptance[6],decision whether a full evaluation of the application for renewal is necessary or not[7] and evaluation[8]. Following confirmation that the submission has passed the initial checks by ECHA, the application for renewal of an NA subject to, or granted through MR will be forwarded to the relevant MS(s) for acceptance[9], validation[10], decision whether a full evaluation of the application for renewal is necessary or not[11], and evaluation[12]. Full evaluation takes 365 days. If a full evaluation is not necessary, the evaluation must be completed in 180 days. The receiving/reference MS may request the applicant to submit additional data.

The respective MSCA takes 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 an agreement by the Coordination Group (CG)[13], or a decision by the European Commission (COM)(see below).

[6] Ref: Article 31(4) of the BPR.
[7] Ref: Article 31(5) of the BPR.
[8] Ref: Article 31(6) of the BPR.
[9] Ref: Article 3(4) of the Renewal Regulation.
[10] Ref: Article 3(5) or (7) of the Renewal Regulation.
[11] Ref: Article 4(1) of the Renewal Regulation.
[12] Ref: Article 4(2) or (3) of the Renewal Regulation.
[13] The CG is set up based on Article 35(1) of the BPR.

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, for a 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: How to submit an application for National Authorisation* 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 concerned MSs may propose to refuse to renew an authorisation, or to adjust its terms and conditions based on the following grounds[14]:

- 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 concerned MS to the applicant. The concerned MS seeks to reach agreement with the applicant on the proposed derogation.

[14] Ref: Article 7(1) of the Renewal Regulation and Article 37(1) of the BPR.

If an agreement between the two is not reached, or no reply is received from the applicant within 60 days of that communication, the concerned MS informs COM who takes a final decision on the derogation. COM may ask the ECHA for an opinion on scientific and technical issues (through the Biocidal Products Committee (BPC)) to conclude on its decision[15]. If the COM has not adapted a decision within 90 days of being informed, then the concerned MS may implement their proposed derogation[16].

This procedure can also apply when additional/different restrictions are proposed by the concerned MS, 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 concerned MSs disagree that the conditions laid down in Article 19 of the BPR are met, it must send a detailed explanation of the reasons for such a position to the reference MS, all other concerned MSs, the applicant, and where applicable, the AH. The points of disagreement must be referred to the CG[17] without delay by the reference MS. In the CG, the reference MS and the concerned MSs use their best endeavours to reach an agreement. The applicant is allowed to present its point of view.

When an agreement is not reached in the CG within 60 days, the disagreement procedure is closed, and the reference MS informs COM of the matters where agreement was not reached[18]. In addition, each concerned MS that agreed on the SPC for the renewal previously, may authorise the product without prejudice to Article 7 of the Renewal Regulation[19]. The COM takes a final decision by means of an implementing act[20] and may either ask ECHA for an opinion on scientific and technical issues (through the BPC)[21] or give an opportunity to the applicant to comment to conclude on its decision[22]. Within 30 days of notification of this decision, the reference MS and all concerned MSs either grant, refuse to grant or cancel the authorisation, or vary its terms and conditions as necessary to comply with the decision[23].

[15] Ref: Article 37(2) and 38(1) of the BPR.
[16] Ref: Article 37(3) of the BPR.
[17] Ref: Article 7(2) and (3) of the Renewal Regulation and Article 35(2) of the BPR.
[18] Ref: Article 7(3) of the Renewal Regulation and Article 36(1) of the BPR.
[19] Ref: Article 5(3) of the Renewal Regulation.
[20] Ref: Article 36(3) and (4) of the BPR.
[21] Ref: Articles 36(2) and 38(1) of the BPR.
[22] Ref: Article 36(2) of the BPR.
[23] Ref: Article 36(4) of the BPR.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

After finalising the evaluation and, in the case of MR, after reaching an agreement between reference MS and concerned MS(s), 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 four or 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[24].

For products containing a substance meeting the substitution criteria and in line with the provisions in Article 7(2) of the Regulation (EU) No 414/2013 (SBP Regulation) on changes of SBPs, where the renewal of the SBP authorisation takes place before the renewal of the reference product and it raises any significant issue, the receiving CA shall consider the appropriateness of cancelling or amending the authorisation of the linked reference product before its renewal in accordance with Article 48 of the BPR[25].

TO NOTE

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[26].

EXCEPTIONS AND PARTICULAR CASES

Renewals of authorisations of anticoagulant rodenticides

For already authorised BPs containing anticoagulant rodenticides, which are candidates for substitution, a comparative assessment has to be done 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 the comparative assessment is carried out by ECHA and there is a harmonisation of dermal absorption values to be used in the assessment of these products[27].

[24] CA-Sept14-Doc.5.7
[25] CA-Sept14-Doc.5.7
[26] Ref: Article 5(4) of the Renewal Regulation.
[27] CA-Jun21-Doc.4.1

Renewals of authorisations of wood preservative products containing Sulfuryl fluoride, Propiconazole, Tebuconazole, IPBC and/or K-HDO

For already authorised BPs containing Sulfuryl fluoride, Propiconazole, Tebuconazole, IPBC and/or K-HDO applications for renewal of such products must be submitted within the usual 550-day deadline.

However, when appropriate, the assessment will be put on hold by the reference MSs until decisions on the renewal of the relevant active substance approvals are taken.

So far, the applicants have been requested to include in their submission the elements indicated in Article 31(3) of the BPR or Article 2 of the Renewal Regulation, as appropriate, except for the assessment of whether the conclusions of the initial evaluation remain valid and any supporting information[28].

Provided that an application for renewal of BP authorisation has been submitted, MSs should grant an extension of the existing authorisation for a period necessary to complete the evaluation.

When the approval of the active substance(s) is renewed, the applicants will have to complement their application with the assessment of whether the conclusions of the initial authorisation remain valid providing any other supporting information, considering any new conditions deriving from the renewal of the active substance approval(s) and any relevant applicable guidance[29].

Further details on renewals of authorisations of wood preservative products containing propiconazole

Propiconazole fulfils the exclusion criteria as it is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 since October 2018[30], and as having endocrine disruption (ED) properties with respect to humans. Hence, propiconazole meets the exclusion criteria set out in Article 5(1)(c) and (d) of the BPR. Pursuant to Article 10 of Annex VI the BPR, to grant authorisations for BPs containing propiconazole, it was assessed and concluded on EU level that the condition set out in Article 5(2)(c) of the BPR is met for the use of propiconazole for temporary treatment against wood-discolouring fungi (anti-sapstain use through industrial treatment),

[28] CA-May18-Doc.4.1- Final
[29] I.e. guidance that was applicable two years before of the date of submission of the information needed to complete the evaluation, as per document CA-July12-Doc.6.2d – Final
[30] Commission Regulation (EU) 2018/1480 of 4 October 2018

for industrial and professional treatment of structural wood in use classes 3 and 4, for industrial and professional treatment of joinery in use classes 2 and 3, and for in situ brush, spraying or injection applications by professional users in use classes 2 and 3. Thus, the approval of propiconazole was renewed for these uses with certain conditions[31].

Following the entry into force of Commission Regulation (EU) 2023/2596 of 21 November 2023, AHs have six months to complement their original applications for renewal of the BPs containing propiconazole[32]. Product authorisations can only be renewed in a MS, where the condition set out in Article 5(2)(c) of the BPR is met and in line with the specific conditions set out in the Annex of Commission Regulation (EU) 2023/2596 of 21 November 2023.

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

[31] Commission Regulation (EU) 2023/2596 of 21 November 2023
[32] CA-March23-Doc.4.11

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/386abfea-55ce-4764-8a31-f9d4f6ceaf0a

CA-Sept21-Doc.4.11: Clarifications on the scope of Regulation (EU) No 492/2014 on renewal of authorisations of biocidal products subject to mutual recognition;

CA-Sept21-Doc.4.12: Renewal of "same biocidal product" authorisations;

CA-June21-Doc.4.1 – Final: Optimisation of the second renewal process of anticoagulant rodenticides products;

CA-May18-Doc.4.1- Final: Approach for the renewal of some PT 8 products;

CA-March23-Doc.4.11: Prolongation of authorisations of PT8 biocidal products containing propiconazole;

CA-Sept14-Doc.5.4 – Final: SPC template reviewed;

CA-May15-Doc.4.6.a – Final: Updated SPC template for BPF*;*

CA-March23-Doc.4.15 – Harmonised sentences SPC AVKs;

CA-Sept14-Doc.5.7– Final: Harmonised approach to the consideration of the expiry dates of new product authorisations linked to other authorisations through certain authorisation procedures.

Relevant CG meetings documents

https://webgate.ec.europa.eu/s-circabc/w/browse/89efe476-1017-46af-8a31-6ad845f79d04

CG-52-2022-14 AP 7.2 Mutual recognition of a mutual recognition_vf: Mutual Recognition of authorisations granted by mutual recognition;

CG-51_e-c AVK PT14 waiving justifications for physical hazards_vf: Renewal of anticoagulant rodenticide biocidal products (`anticoagulant rodenticides') and waiving justifications for physical hazards;

CG-36-2019-13 AP 16.4 Harmonis document for changes applications_vf: Harmonisation of the documents for changes applications;

Relevant CG procedural documents:
https://webgate.ec.europa.eu/s-circabc/w/browse/a23c47a9-638c-427a-9b22-5b7733bf0b01

Working procedure for resolving disagreements_ver18: Resolving disagreements on mutual recognition, renewal, changes, simplified notification and Article 48 procedure: working procedure for the Coordination Group (CG);

CG-56-2023-31 AP 14.2 Guiding principles on providing data_NA-SA processes_v2: Guiding principles on handling information provided by the applicant during NA and SA processes;

CG-57-2023-07 AP 14.1 Management of new information on AS submitted for PA_vf: Management of new information on an active substance submitted for a product authorisation application.

https://webgate.ec.europa.eu/s-circabc/w/browse/916f1e1f-0de7-4748-aeb2-2ed81f91e90c

SoP for MRP_MRS processes_ver4: Standard operating procedure (SoP) for the mutual recognition (MR) process in parallel and sequence

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/submit-applications-for-national-authorisation

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

- **Biocides Submission Manuals**

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

  BSM Technical guide: How to prepare a biocides dossier

BSM Technical guide: How to use R4BP 3

BSM Application instructions: How to submit an application for National Authorisation

- **IUCLID Manuals**

  http://iuclid6.echa.europa.eu/support

Q&As

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