ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on mutual recognition of biocidal products

February 2024

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	Publication
V1		October 2016
V2	Editorial improvements	December 2021
V2.1	Under the Section 'settlement of disagreements', the reference 'reference MS' was changed to 'concerned MS'	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; Update of relevant documents and guides.	February 2024

Practical guide on mutual recognition of biocidal products

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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The national authorisation (NA) of a biocidal product (BP) can be recognised in other Member States (concerned MSs) in accordance with the mutual recognition (MR) procedures to avoid duplication of the evaluation. There are two procedures: mutual recognition in sequence (MRS), which is relevant where there is an existing authorisation[1], and mutual recognition in parallel (MRP), which is relevant where the initial application for NA and the applications for MR are submitted at the same time[2].

Authorisation according to MRS/MRP should be granted under the same terms and conditions as the (initial) NA granted by the reference Member State (reference MS); however, in certain cases[3], the concerned MSs may propose to refuse to grant the authorisation or to adjust its terms and conditions.

The same rules as for a single BP also apply for a biocidal product family (BPF)[4].

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

For MRS, the application can be made by, or on behalf of, the authorisation holder (AH) of the NA in the reference MS. Accordingly, the prospective AHs (applicants) of the MR may have a person/entity handling the practical issues related to the application on their behalf (e.g., a consultant). The AH is the person established within the European Union (EU)/European Economic Area (EEA) who is responsible for the placing on the market of the BP in the reference MS/concerned MS[5] and is specified in the authorisation.

If the prospective AH in the concerned MS is a separate person/entity than the AH of the reference NA, they can also make the application, provided they obtain the necessary rights to the required data.

[1] Ref: Article 33 of the BPR.
[2] Ref: Article 34 of the BPR.
[3] Ref: 35(2) and 37(1) of the BPR.
[4] Ref. Article 3(1)(s) of the BPR.
[5] Ref: Article 3(1)(p) of the BPR.

For MRP, the application for the initial NA must be made by, or on behalf of, the prospective AH. If the prospective AH in the concerned MSs is a separate person/entity than the AH of the initial NA, they can also make the application, if they obtain the necessary rights to the required data on the active substance and BP.

WHEN

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

An application for MRP is made at the same time as the initial NA application in the reference MS. An application for MRS can be made at any point after the NA is granted by the reference MS, on the condition that this authorisation is still valid.

Specific transitional rules apply to the timing of the application for MRP in regards to existing BPs[6]:

- The application(s) for MRP in the concerned MSs together with an application in the reference MS for an initial NA must be made by the date of approval of the active substance; otherwise the products must be removed from the market within 180 days of the active substance approval date[7]. The use of existing stocks of that BP may continue until 365 days after the approval date. An MRP application can also be made at a later date but, in such a case, until authorisation is granted by the concerned MS, the products must be removed from the market of this MS.

- Where that BP contains more than one active substance for the same product-type (PT), the applications must be submitted no later than the date of approval of the last active substance for that PT. If the BP belongs to several PTs, it is only necessary to apply when all the active substance(s) contained in it has/have been approved for all relevant PTs before the deadline of the last approved.The Union list of approved active substances[8] is available on the European Chemicals Agency's (ECHA) website.

[6] "Existing biocidal products" refers in the context of this Practical Guide, to those products which have already been placed on the market of the relevant MS (as opposed to the EU market as a whole) at the date of approval of the active substance. This concerns BPs containing only active substances included in the Review Programme (Article 89(2) of the BPR).
[7] Ref: Article 89(3) of the BPR.
[8] http://echa.europa.eu/information-on-chemicals/biocidal-active-substances

- In practice, there is around a two-year time period to submit an application for MRP from the date on which the decision was taken to include all of the product's active substances. The approval date is included in the Annex to the approval decision (Commission Regulation).

The application for MRP of a new BP[9] can be submitted at any time after the decision on the approval of the (last) active substance is adopted. Such a new BP can be placed on the market of the relevant MS for the first time only when the NA from that MS has been granted.

It is recommended that MRP applications are made well ahead of the deadline to accommodate for possible rejection due to submission or payment failures before the applications are accepted for processing.

Phasing-out periods apply when the application for MRP is rejected or the reference MS decides not to grant the authorisation[10]. Existing products must be removed from the market within 180 days of the date of the rejection or decision. The use of existing stocks of that BP may continue until 365 days after the date of rejection or decision.

For MRS, the BP can only be placed on the market in the concerned MS once the authorisation is granted by this MS.

WHAT

INFORMATION REQUIREMENTS AND SOURCES

Information requirements

BSM Application instructions: How to submit an application for National Authorisation available on ECHA's website outlines the different types of information files that should be prepared and included in an application for MRP or MRS.

HOW

PROCEDURE TO FOLLOW

For an application for MRS and for MRP in the concerned MSs, an IUCLID dossier is not required. Nevertheless, an IUCLID dossier must be submitted with the initial NA application to the reference MS, as explained in the Practical Guide chapter on national authorisation. Furthermore, the SPC in .i6z format should be submitted for an application for MRS and for MRP in such official languages of the concerned MS as they may require.

[9] "New BP" refers in the context of this Practical Guide, to those products which have not already been placed on the market of the relevant MS at the date of the approval of the (last) active substance.
[10] Ref: Article 89(4) of the BPR.

Submission and processing of an application

The application for MRP/MRS 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 relevant MSCA for acceptance[11], validation[12] and granting authorisation[13].

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The respective MSCA takes a decision on the authorisation. NA will be granted in the concerned MSs within 30 days of agreement being reached on the summary of the product characteristics (SPC)[13]. In the case of MRP, this takes place only after the reference MSCA has evaluated the application (365 days). In some cases, granting the authorisation through an MRS/MRP procedure requires an agreement by the Coordination Group (CG)[14] or a decision by the European Commission (COM)(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, 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 of the application for NA through R4BP 3 in the following submission manuals available on ECHA's website:

- *BSM Technical guide: How to use R4BP 3*
- *BSM Application instructions: How to submit an application for National Authorisation*.

ECHA's website provides further details on the processing of the applications. More information related to invoicing and R4PB 3 can be found in the *BSM process of invoicing* available on ECHA's website.

[11] Ref. for MRS: Article 33(1) of the BPR. Ref. for MRP: Article 34(3) of the BPR.
[12] Ref. for MRS: Article 33(2) of the BPR. Ref. for MRP: Article 34(4) of the BPR.
[13] Ref. for MRS: Article 33(3) of the BPR. Ref. for MRP: Article 34(6) of the BPR.
[14] The CG is set up based on Article 35(1) of the BPR.

Derogations

By way of derogation from authorising a BP under the same terms and conditions through an MRS/MRP procedure, any of the concerned MSs may propose to refuse to grant an NA through MRS/MRP or to adjust its terms and conditions based on the following grounds[15]:

- 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.

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. The COM may ask ECHA for an opinion on scientific and technical issues (through the Biocidal Products Committee (BPC)) to conclude on its decision[16]. If the COM has not adapted a decision within 90 days of being informed, then the concerned MS may implement their proposed derogation[17].

Besides the reasons for derogations listed above, authorisations of BPs of PTs 15, 17 and 20 may be refused in the MRP/MRS process by a concerned MS on the grounds of animal welfare[18]. Such a refusal must be justified and the other MSs and COM informed.

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

[15] Ref: Article 37(1) of the BPR.
[16] Ref: Articles 37(2) and 38(1) of the BPR.
[17] Ref: Article 37(3) of the BPR.
[18] Ref: Article 37(4) of the BPR.

Settlement of disagreements

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 Coordination Group (CG)[19] without delay by the concerned MS that expressed disagreement. 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[20]. In addition, each concerned MS that agreed on the SPC previously may authorise the product without prejudice to Articles 35, 36 and 37 of the BPR[21]. The COM takes a final decision by means of an implementing act[22] and may either ask ECHA for an opinion on scientific and technical issues (through the BPC)[23], or give an opportunity to the applicant to comment (30 days) to conclude on its decision[24]. 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[25].

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

After finalising the evaluation and reaching an agreement between the reference MS and concerned MS(s), each of the MSCAs update the information in R4BP 3 relating to this BP and grant an NA of the BP.

Authorisation according to MRP should be granted for the same number of years in all MSs (e.g., up to 10 years, unless the active substance is a candidate for substitution (i.e., maximum of four or five years)). For MRS, the validity of the product authorisation granted by the concerned MS should also be the same as for the initial authorisation granted by the reference MS.

[19] Ref: Article 35(2) of the BPR.
[20] Ref: Article 36(1) of the BPR.
[21] Ref. for MRS: Article 33(4) of the BPR. Ref. for MRP: Article 34(7) of the BPR.
[22] Ref: Article 36(3) and (4) of the BPR.
[23] Ref: Articles 36(2) and 38(1) of the BPR.
[24] Ref: Article 36(2) of the BPR.
[25] Ref: Article 36(4) of the BPR.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES

Application for MR made by official or scientific bodies

- If there is a general interest in the use of a BP, which is not on that MS's market, official or scientific bodies involved in pest control activities or the protection of public health may apply for MRS of the BP with the same use and the same conditions of use as in the MS where the BP is already authorised, provided that[26]:
  - no application for authorisation has been submitted to that MSCA for such a BP already authorised in the other MS, and
  - the AH of this BP has agreed to such an application.

When the authorisation is given by that concerned MS, the body that made the application has the same rights and obligations as other AHs.

- It is possible to start a MR in sequence from an authorisation already obtained via a MR[27] or same biocidal product process[28].
- In case of the MR of a product family, it is not possible to mutually recognise only part of the family (e.g., some products or a single product of a product family).

COST

RELATED FEES

The national fees related to an application for MRS/MRP may vary between MSs 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 competent authorities or helpdesk.

An MR Submission Fee will be charged by ECHA in relation to applications for NA of a BP through MRP in accordance with the third entry of Annex III to *Commission Implementing Regulation (EU) No 564/2013.*

[26] Ref: Article 39 of the BPR.
[27] CG-52-2022-14
[28] CA-Sept21-Doc.4.6

HELP

TO CONTACT FOR FURTHER INFORMATION

ECHA Helpdesk

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/authorisation-of-biocidal-products

Relevant Biocides competent authorities meetings documents

https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a

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-Sept13-Doc.5.1.g – Final.Rev.1: Application of BPR procedures to applications for product authorisation submitted under the BPD regime and on which a decision has not been taken by 1 September 2013;

CA-Sept13-Doc.6.2.a - Final.Rev.1: Authorisation of skin sensitiser biocidal products requiring PPE for non-professional users;

CA-Sept13-Doc.6.2.b Rev.1: Authorisation under the Biocidal Products Regulation of products containing more than one existing active substance or belonging to more than one product-type;

CA-Sept13-Doc.6.2.d – Final: Submission in EN of the proposed SPC in applications for mutual recognition in parallel and other regulatory procedures;

CA-March14-Doc.5.1: Transition between national schemes and BPR-authorisations following active substance approvals;

CA-March14-Doc.5.4 - Final: Comparative assessment of biocidal products

CA-Sept14-Doc.5.7: Harmonised approach to the consideration of the expiry dates of new product authorisations linked to other

authorisations through certain authorisation procedures;

CA-July19-Doc.4.2.Rev.3 – Final: Guidance note on the biocidal products family concept;

CA-July19-Doc.4.1 – Authorisation of products generating active substances in situ;

CA-May14-Doc.5.1 – Final: Composition of biocidal products and responsibilities of authorisation holders;

CA-June21-Doc.4.3 – Final: Categorisation of a biocidal product containing a non-active substance meeting the criteria for being PBT or vPvB;

CA-June22-Doc.4.8: Identification as a substance of concern of a non-active substance meeting the criteria for being endocrine disruptor;

CA-March21-Doc.4.3– Final: Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment;

CA-Sept21-Doc.4.6: Mutual Recognition of same biocidal product authorisations;

CA-Dec21-Doc.4.12: Non-authorisation decision in national authorisation, or major/minor changes applications that are subject to mutual recognition in parallel;

CA-June22-Doc.4.2: Consequences for biocidal products authorisations procedures of relevant information becoming available;

CA-June23-Doc.4.9-Final.rev1 – Misleading terms in trade names.

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 Inclusion of P-statements in SPC_Final: Outcomes of the e-consultation relating to the inclusion of precautionary statements (P statements) in section 5 of the SPC;

CG-51_e-c Guidance for first aid instructions_vf: Guidance for harmonisation of first aid instructions in the authorisation of biocidal products;

CG-44_e-c SoC and EUH labelling_Final;

CG-45-2021-03 Definitions and functions of co-formulants: Definitions and functions of co-formulants in biocidal products;

CG-50-2022-05 AP 16.6 ED assessment of co-formulants by applicants_vf: Practical information for applicants on how to perform the assessment of ED properties of a biocidal product;

CG-50-2022-07 AP 16.2 Dermal absorption value in PAs_vf: Dermal absorption value for the authorisation of biocidal products;

CG-53-2022-07 AP 14.1 Shelf-life setting during PA _vf: Shelf-life setting during the authorisation of biocidal products;

CG-56-2023-30 AP 14.1 Post-authorisation conditions for NA and SA_final: Post-authorisation conditions for national and simplified product authorisation: harmonising practices.

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
  - Mutual recognition in sequence
  - Mutual recognition in parallel

- **Biocides Submission Manuals**

  http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals
  - BSM Technical guide: using R4BP 3

- BSM Application instructions: How to submit an application for National Authorisation
- BSM Process of invoicing in R4BP 3

- **IUCLID Manuals**

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

Q&As

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