

Practical guide on mutual recognition of biocidal products

March 2022

ABC

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Version	Changes	
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

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Reference: ECHA-22-H-06-EN

ISBN: 978-92-9468-117-1

Cat. Number: ED-09-22-107-EN-N

DOI: 10.2823/769963

Publ.date: March 2022

Language: EN

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Cover page © European Chemicals Agency

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WHY**PRINCIPLES BEHIND THE OBLIGATION/PROCESS**

The authorisation of a biocidal product (BP) can be recognised in other Member States (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 authorisation¹, and mutual recognition in parallel (MRP) which is relevant where the initial application for national authorisation (NA) and the applications for MR are submitted at the same time².

Authorisation according to MRS/MRP should be granted under the same terms and conditions as the (initial) NA; however, in certain cases³, the MSs concerned 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) in the reference MS. Accordingly, the applicants 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/concerned MSs⁵.

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 'Biocidal product family' means a group of BPs having similar uses, the same active substances, similar composition with specified variations, and similar levels of risk and efficacy (ref. Article 3(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 MR, just like in the case of NA, can be made only after the decision to approve the active substance is adopted.

An application for MRP is made after the decision to approve the active substance is adopted and at the same time as the initial NA application. An application for MRS can be made at any point after the NA is granted in the reference MS, on the condition that it is still valid.

Specific transitional rules apply to the timing of the application for MRP in regards to existing BPs⁶:

- The application(s) for MRP in the MSs concerned 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. A product authorisation application can also be made at a later date but, until it is granted, the products must be removed from the market.
- 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 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 substances⁸ 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 BP⁹ 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 authorisation¹⁰. 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: national authorisations 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 MSs concerned, 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.

⁹ "New biocidal products" refers in the context of this Practical Guide, to those products which have not already been placed on the market of any 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 validation and evaluation:

- for MRS, to the MSs concerned;
- for MRP, to the reference MSCA (the initial application) and at the same time to all MSs concerned (MRP).

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). 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 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 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 R4BP 3 can be found in the *BSM process of invoicing* available on ECHA's website.

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 a NA through MRS/MRP or to adjust its terms and conditions based on the following grounds¹¹:

- 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 ECHA for an opinion on scientific and technical issues (through the Biocidal Products Committee (BPC)) to conclude on its decision¹².

Besides the reasons for derogations listed above, authorisations of BPs of PTs 15, 17 and 20 may be refused from MRP/MRS by an MSCA on the grounds of animal welfare¹³. 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 MS concerned 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.

¹¹ Ref: Article 37(1) of the BPR.

¹² Ref: Article 37(2) and (3) of the BPR.

¹³ Ref: Article 37(4) of the BPR.

Settlement of disagreements

When any of the MSs concerned disagree with the conclusions of the product assessment report or with the 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 CG¹⁴ without delay by the concerned MS where the 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 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 (30 days) to conclude on its decision.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS



After finalising the evaluation and reaching an agreement between the reference MS and MS(s) concerned, 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). For MRS, the validity of the product authorisation should also be the same as for the initial authorisation granted by the reference MS, unless the active substance is a candidate for substitution (i.e. maximum of four or five years).

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 same BP with the same use and the same conditions of use as in the MS already authorised provided that¹⁵:
- no application for authorisation has been submitted to that MSCA for such a BP already authorised in the other MS, and

¹⁴ Ref: Article 35(1) of the BPR.

¹⁵ Ref: Article 39 of the BPR.

- the AH of this BP has agreed to such an application.

When the authorisation is given by that MSCA, 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 same biocidal product processes.
- It is possible to mutually recognise a product family starting from a product family or a single product starting from a single product but not only part of a family or a single product starting from 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 MRS/MRP in accordance with the third entry of Annex III to *Commission Implementing Regulation ((EU) No 564/2013)*.

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

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 – Final: Guidance note on the biocidal products family concept;

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

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 Technical guide: using SPC
- BSM Application instructions: national authorisations
- BSM Process of invoicing in R4BP 3

- **IUCLID Manuals**

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

Q&As

<https://echa.europa.eu/it/support/qas-support/browse>