ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on national authorisation of biocidal products

February 2024

Disclaimer

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V2.1	Amendments to section OUTCOME OF THE OBLIGATION/PROCESS	March 2022
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Practical guide on national authorisation of biocidal products

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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The basic principle in the Biocidal Products Regulation ((EU) No 528/2012 (BPR)) is that a biocidal product (BP) must be authorised before it can be made available on the market or used in the European Union (EU)/European Economic Area (EEA).[1] This takes place in two consecutive steps. As the first step, the active substance is evaluated and, provided the criteria are fulfilled, is then approved in a specified product-type (PT). The second step is the authorisation of each BP consisting of, containing or generating the approved active substance(s). This document concerns the second step, the authorisation of a BP.

The national authorisation (NA) of a BP is granted by the competent authority of the Member State (MSCA) where the BP will be made available on the market (receiving Competent Authority - receiving CA) and is only valid for the approved terms and conditions stated therein. To avoid duplication of the evaluation procedure, the product authorisation granted in one MS can be recognised in other MSs through the mutual recognition procedure[2]. For more details on mutual recognition see the Practical Guide chapter on Mutual recognition.

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

Certain BPs may be authorised at Union level, without the need to obtain single NAs. For more information see the Practical Guide chapter on Union authorisation.

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

An application for NA can be made by, or on behalf of, the prospective authorisation holder (AH). Accordingly, the prospective AH may have a person/entity handling the practical issues related to the application on its behalf (e.g., a consultant).

The AH is the person/entity established within the EU/EEA who is responsible for the placing on the market of a BP in a particular MS[4] and is specified in the authorisation.

[1] Ref: Article 17(1) of the BPR.
[2] Ref: Articles 33 and 34 of the BPR.
[3] Ref: Article 3(1)(s) of the BPR.
[4] Ref: Article 3(1)(p) of the BPR.

WHEN

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

Specific transitional rules apply to the timing of the application for NA with regards to existing BPs[5]:

- The BP authorisation application 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.[6] The use of existing stocks of that BP may continue until 365 days after the approval date. An NA application can also be made at a later date, but in such a case, until authorisation is granted the products must be removed from the market.

- Where that BP contains more than one active substance for the same PT, the application for NA 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 for NA when all the active substance(s) contained in it has/have been approved for all relevant PTs before the deadline of the last approved.

  See the Union list of approved active substances[7], available on the European Chemicals Agency's (ECHA) website.

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

- For an existing BP already on the market in more than one MS in accordance with national laws, to enable closer cooperation between MSs in the evaluation of this BP, it is necessary to apply for mutual recognition in parallel at the same time in all the MSs where the product is intended to be authorised. One of those MSs should act as reference MS (rMS).

It is recommended that NA 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.

[5] "Existing BPs" 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).
[6] Ref: Article 89(3) of the BPR.
[7] http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

Phasing-out periods also apply when the application for NA is rejected or the receiving MSCA decides not to grant the authorisation[8]. Existing products must be removed from the market within 180 days of the date of such rejection or decision. The use of existing stocks of that BP may continue until 365 days after the date of the rejection or decision.

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

If a BP contains only existing active substances which have not been approved yet, an application for authorisation can be submitted according to the national rules of the MS in which authorisation is sought.

WHAT

INFORMATION REQUIREMENTS AND SOURCES

Article 20(1)(a) and (2) of the BPR lists the requirements for an application for NA of a BP. *BSM Application instructions: How to submit an application for National Authorisation* available on ECHA's website explains what types of information files should be prepared and included in an application for NA.

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

The applicant must consider a number of important elements before preparing an application for NA:

- If the applicant is not the data owner of the dossier(s) of the approved active substance(s) contained in the BP, then the applicant needs to provide information to demonstrate access to the relevant data of each of the active substance(s) to fulfil the requirements set out in Annex II to the BPR. This may be achieved by:

[8] Ref: Article 89(4) of the BPR.
[9] "New BPs" 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 contained therein.

- providing evidence of access to the information submitted for the purposes of the BPD or the BPR through a Letter of Access (LoA)[10]; or
- declaring that the relevant data protection period for the information on the active substance has expired. The right to refer to that data by the subsequent applicant is subject to an agreement of the receiving CA in so far as the applicant can provide evidence that the active substance is technically equivalent to the reference source[11]; or
- waiving of information requirements[12] by providing justifications why specific data of a complete dossier are not relevant to the uses which are claimed to be supported; or
- providing alternative and equivalent studies, including published studies, instead of those protected[13]. Note that some data is mandatory to share. For more information see the Practical Guide chapter on data sharing.

- If the active substance(s) contained in the BP has/have a different source (e.g., a different manufacturer or the same manufacturer, but manufactured by a different process) than the reference source(s) used for approval of the active substance(s), the applicant needs to provide a proof of technical equivalence with the application for NA. See the Practical Guide chapter on technical equivalence.

- If the applicant is the owner of the data on the active substance contained in the dossier used to support the approval of the active substance, but the data was not originally submitted in IUCLID format, the applicant may submit a complete IUCLID file or submit a reference to its own active substance(s) dossier(s).

- The applicant can also refer to data related to BPs where the data protection period relevant to them has expired. The use of the data by the subsequent applicant is subject to an agreement of the receiving CA. In such a case, the subsequent applicant has to provide evidence that the BP is the same as the one already authorised or an explanation that the differences between them are not significant in relation to the risk assessment and the active substance(s) contained in the BP are technically equivalent to those in the BP already authorised.[14]

[10] Ref. Articles 20(1)(a)(iii) and 59(1)(a) of the BPR.
[11] Ref. first subparagraph of Article 64(1), and Article 59(1)(b) of the BPR.
[12] Ref: Article 21(1) and (2) of the BPR.
[13] Ref: Article 20(1)(a)(iii) of the BPR.
[14] Ref: subparagraph 2 of Article 64(1) of the BPR.

- An NA for a BP may cover various PTs. The applicant should make sure that the PT(s) is/are relevant to the use purpose and pattern of the BP.

  If there are any doubts as to whether a product is falling within the scope of the BPR or not[15], or to which PT(s) it belongs, the applicants are invited to contact the future receiving CA.

- Special attention should be given to the use instructions (e.g., use patterns, application rates, categories of users, or, if applicable, risk mitigation measures) and label claims as they are also used for the purpose of the risk and efficacy assessment.

- The efficacy data requirements are more elaborate at the product authorisation stage than for the active substance approval.

- Careful consideration needs to be given to the design of the summary of the product characteristics (SPC) as it is critical for the BP label information[16].

HOW

PROCEDURE TO FOLLOW

Creation of a IUCLID dossier

The applicant seeking to obtain NA needs to submit the data using a IUCLID format.

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

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

[15] Ref: Article 3(3) of the BPR.
[16] CA-May14-Doc.5.6 – Final

Submission and processing of an application

The application for NA should be submitted through R4BP 3. 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.

Following confirmation that the submission has passed the initial checks by ECHA, the application will be forwarded to the relevant receiving CA for acceptance[17], validation[18] and evaluation[19].

During the evaluation (365 days, unless additional information is requested) of a BP containing active substances that are considered as candidates for substitution, a comparative assessment will be performed[20]. This will assess whether less harmful alternative products are available for the same use. The receiving CA takes a decision on the authorisation.

Applicants are however free to choose the CA where they want to apply for the initial NA; subsequently, they can apply either for mutual recognition in sequence or in parallel of this BP in other MSs.

Applicants will find the relevant information and instructions for submitting and following up 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.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

After finalising the assessment, the MSCA will update all necessary information related to the BP (assessment report and, if applicable, SPC) in R4BP 3 and either grant, or not grant, an NA. To grant the authorisation, the conditions summarised in Article 19 of the BPR must be met. NA for a BP can be granted for a maximum period of 10 years, which is renewable.

[17] Ref: Article 29(1) of the BPR.
[18] Ref: Article 29(2-5) of the BPR.
[19] Ref: Article 30 of the BPR.
[20] Ref: Article 23 of the BPR.

For BPs containing an active substance that is a candidate for substitution, NA may be granted for a period not exceeding five years.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES

Authorisation of same biocidal products

Please refer to the same biocidal product chapter of the practical guide.

National authorisation granted for a BPF

If an NA is granted for a BPF, a notification through R4BP 3 is required for each BP within this family before placing it on that MS's market, except where a particular BP is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations[21].

More information and instructions for submitting the notification through R4BP 3 are given in the *BSM Application instructions: How to submit an application for National Authorisation*.

National authorisation of BPs containing only active substance(s) from Annex I of the BPR

Normally when an active substance is on Annex I to the BPR, the simplified authorisation is appropriate. However, if the BP does not fulfil Article 25 of the BPR and therefore it is not eligible for simplified authorisation, it remains a possibility to apply for NA.[22]

Permit for parallel trade

BPs can be also made available on the market using a parallel trade permit[23]. A parallel trade permit is relevant when a company is interested in purchasing an authorised BP in a specific MS (MS of origin) and making it available on the market in another MS (MS of introduction-MSI), where an identical product has already been authorised. The applicant does not need to be the BP AH.

[21] Ref: Article 17(6) of the BPR.
[22] Ref: Article 19(1) of the BPR.
[23] Ref: Article 53 of the BPR.

The applicant for a parallel trade permit does not need to submit data to show that the BP it wishes to make available on the market in the MSI is safe and efficacious, only that it is identical to the BP already authorised in the MSI (the reference BP)[24]. Additional information, such as example labels, are also required as part of the application[25]. If the application is successful, the MSI shall grant the permit within 60 days of receipt of the applicable fees from the applicant (this may take longer where additional information is required from the MS of origin).

A parallel trade permit should be granted under the same terms and conditions as the authorisation for the reference BP. Furthermore, its expiry date is the same as the expiry date of authorisation of the reference BP.

A parallel trade permit may be cancelled independently of the authorisation of the reference BP. At the same time, cancellation of authorisation of the reference BP on request of the AH does not affect the parallel trade permit, if the requirements of Article 19 of the BPR are still fulfilled[26]. However, the MSCA in the MSI may withdraw the parallel trade permit if the authorisation of the introduced product is withdrawn in the MS of origin due to safety or efficacy reasons[27].

More information and instructions for submitting the application for parallel trade permit through R4BP 3 are given in the *BSM Application instructions: How to submit an application for National Authorisation*.

Derogations from the requirements

Under certain conditions, derogations from authorisation requirements are possible, namely:

- Provisional authorisation

  For a BP containing a new active substance not yet approved, a provisional authorisation can be granted by the MSCA for a period not exceeding three years, renewable for one year[28].

  Such a provisional authorisation may be granted only after the MSCA, which evaluated the new active substance, has submitted a recommendation for approval of this substance and the MSCAs which received the application for the provisional authorisation consider that the BP complies with the provisions laid down in Article 19(1)(b), (c) and (d) considering the factors set out in Article 19(2) of the BPR.

[24] Ref: Article 53(3) of the BPR.
[25] Ref: Article 53(4) of the BPR.
[26] Ref: Article 53(6) of the BPR.
[27] Ref: Article 53(7) of the BPR.
[28] Ref: Article 55(2) of the BPR.

More information and instructions for submitting the application for provisional national authorisation through R4BP 3 are given in the *BSM Application instructions: How to submit an application for National Authorisation.*

- Permission for a limited and controlled use

  An MSCA can permit the making available on the market or use of a BP, which is not authorised, if there is an unforeseen danger to public or animal health or the environment which cannot be contained by other means[29]. Such BPs can be placed on the market for a limited and controlled use only and under the supervision of that MSCA for a period not exceeding 180 days. Only with a justified request of the MSCA, can the European Commission (COM) extend that period by no more than 550 days.

- Authorisation given to protect the cultural heritage

  A BP, which contains a non-approved active substance can be authorised by the MSCA if this active substance is essential for the protection of cultural heritage and there are no appropriate alternatives on the market. An application[30] containing due justification shall be submitted by the MSCA to the COM and the authorisation can be given only with the consent of the COM.

Applications for NA submitted under the BPD

Where an application for NA was submitted under the BPD and the evaluation was not completed by 1 September 2013, the relevant CA continues the evaluation in accordance with that directive. However, if the risk assessment on the active substance indicates that one or more of the exclusion criteria is met[31], the BP shall be authorised in accordance with Articles 19 and 23 of the BPR.

If the risk assessment of the active substance shows that one or more of the substitution criteria[32] is met, but not any of the exclusion criteria, the conditions for authorisations are those laid down in Article 5 of the BPD and Article 23 of the BPR (and the principles of Annex VI to the BPD should be considered to evaluate the product). If neither the exclusion or substitution criteria are met, the conditions for authorisations are those laid down in Article 5 of the BPD (and the principles of Annex VI to the BPD should be considered to evaluate the product). Nevertheless, the legal basis for the product authorisation will be Articles 19 and 91 of the BPR.

[29] Ref: Article 55(1) of the BPR.
[30] Ref: Article 55(3) of the BPR.
[31] Ref: Article 5(1) of the BPR.
[32] Ref: Article 10 of the BPR.

Where the evaluation identifies concerns arising from the application of provisions of the BPR which were not included in the BPD, the applicant shall be given the opportunity to provide additional information.

Notification of unexpected or adverse effects

An AH is obliged to notify the MSCA that has granted the NA on becoming aware of information or data concerning the authorised BP, or an active substance contained in it, which may affect the conditions laid down in the authorisation[33]. The notification shall be made through R4BP 3 immediately after obtaining the above information and particularly when it is related to adverse effects for vulnerable groups, animals or the environment, potential development of resistance of the active substance, or if the BP is not sufficiently effective.

The respective MSCA shall notify about such data or information other MSCAs and, when appropriate, also the COM without any delay and after the examination decide if there is a need to amend or cancel the NA[34]. MSCAs, which have mutually recognised that NA shall examine whether these authorisations also need to be amended or cancelled.

More information and instructions for submitting the notifications of unexpected or adverse effects of a biocidal product through R4BP 3 are given in the *BSM Application instructions: How to submit an application for National Authorisation.*

COST

RELATED FEES

The national fees related to the application for NA may vary between the 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 MSCAs' fees, the applicant should contact the designated national MSCA or its helpdesk.

There is no fee charged by ECHA for an NA, but if together with an application for NA, applications for MRP are also submitted to one or more concerned MS, the Mutual Recognition Submission Fee for them should be paid to ECHA in accordance with the third entry of Annex III to *Commission Implementing Regulation (EU) No 564/2013.*

[33] Ref: Article 47 of the BPR.
[34] Ref: Article 48 of the BPR.

HELP

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

National authorisation and mutual recognition

http://echa.europa.eu/web/guest/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/national-authorisation

Relevant Biocides competent authorities meetings documents

https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/386abfea-55ce-4764-8a31-f9d4f6ceaf0a/details

CA-July19-Doc.4.2 – Final.Rev.3: 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-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 sensitizer 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-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-May14-Doc.5.6 – Final: Discussion paper on the content of label of biocidal products with regard to the authorised uses in the SPC;

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

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-June22-Doc.4.2: Consequences for biocidal products authorisations procedures of relevant information becoming available;*CA-March23-Doc.4.13.rev1* – Implementation of the scientific criteria for the determination of endocrine disrupting properties in the context of biocidal product authorisation;.

Relevant CG meetings documents

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

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.

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
  - Authorisation of biocidal products
  - Authorisation of a same biocidal product (authorised and pending)
  - Parallel trade
  - Notification for a product in a product family
  - Notification of unexpected or adverse effect

- **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
- 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