

National authorisation

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).³⁵ 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 BP³⁶.

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 MS) 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 MS through the mutual recognition procedure³⁷. For more details on mutual recognition [see Practical Guide chapter on Mutual recognition](#).

The same rules as for a single BP apply also for a biocidal product family (BPF)³⁸.

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](#).

³⁵ Ref: Article 17(1) of the BPR.

³⁶ Ref: Chapter IV of the BPR.

³⁷ Ref: Articles 33 and 34 of the BPR.

³⁸ 'Biocidal product family' means a group of BPs with 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).

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 MS³⁹.

WHEN



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

The application for NA can, in general, be made at any time after the decision to approve the active substance has been adopted.

Specific transitional rules apply to the timing of the application for NA with regards to existing BPs⁴⁰:

- 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.⁴¹ 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 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 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](#)⁴², 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

³⁹ Ref: Article 3(1)(p) of the BPR.

⁴⁰ "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).

⁴¹ Ref: Article 89(3) of the BPR.

⁴² <http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>

reference MS.

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.

Phasing-out periods also apply when the application for NA is rejected or the receiving MSCA decides not to grant the authorisation⁴³. 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 BP⁴⁴ 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.

Products not covered by Directive 98/8/EC (BPD), but as BPs now falling within the scope of the BPR

The BPR includes transitional measures to facilitate the transition from the BPD system to the new provisions of the BPR. There are products which, since 1 September 2013, fall within the scope of the BPR⁴⁵.

If such BPs were available on the market before 1 September 2013, then the legal provisions cited above contain timelines and deadlines (1 September 2016) for the submission of the applications for the relevant AS in those products. Where such an application is not made by the deadline, the product must be removed from the market by 1 September 2017.

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: national authorisations* 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.

⁴³ Ref: Article 89(4) of the BPR.

⁴⁴ "New BPs" 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 contained therein.

⁴⁵ Ref: Article 93 of the BPR or the Regulation (EU) No 613/2013.

Issues to consider:

The applicant has to 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 to fulfil the requirements set out in Annex II to the BPR. This may be achieved by:
 - providing evidence of access to the information submitted for the purposes of the BPD or the BPR through a Letter of Access (LoA)⁴⁶; 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 competent authority (CA) in so far as the applicant can provide evidence that the active substance is technically equivalent to the reference source⁴⁷; or
 - waiving of information requirements⁴⁸ 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 protected⁴⁹. Note that some data is mandatory to share. For more information see [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.⁵⁰
- 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

46 Ref. Article 20(a)(a)(iii) and Article 59(1)(a) of the BPR.

47 Ref. Article 64(1), first subparagraph, and Article 59(1)(b) of the BPR.

48 Ref: Article 21(1) and (2) of the BPR.

49 Ref: Article 20(1)(a)(iii) of the BPR.

50 Ref: Article 64(1), subparagraph 2, of the BPR.

HOW



scope of the BPR or not, or to which PT(s) it belongs, the applicants are invited to contact the future receiving CA.⁵¹

- Special attention should be given to the use instructions (e.g. use patterns, application rates, categories of users, risk mitigation measures if applicable) and label claims as they are also used for the purpose of the risk and efficacy assessment.
- For any uses not evaluated earlier during the active substance approval, a risk assessment has to be conducted and included in the product authorisation application.
- 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 also critical for the BP label information.⁵²

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: 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 NA 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 receiving CA for validation and evaluation. 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. This will assess whether less harmful alternative products are available for the same use. The receiving CA takes a decision on the authorisation⁵³.

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.

To facilitate the evaluation of the application, it would be preferable that the applicant submits the application for NA to the CA in that MS, which

⁵¹ Ref: Article 3(3) of the BPR.

⁵² CA-May14-Doc.5.6 – Final

⁵³ Ref: Articles 29-30 of the BPR.

evaluated the dossier of the active substance contained in the product, if the BP is already placed or is intended to be placed on the market of that MS.

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: using R4BP 3*
- *BSM Application instructions: national authorisations*

ECHA's website provides further details on the processing of the applications.

RESULTS



OUTCOME OF THE OBLIGATION/PROCESS

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

For BPs containing an active substance that is a candidate for substitution, NA may be granted for a period not exceeding five years. The authorisation cannot be granted for longer than the approval period of the active substance(s) contained therein.

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 market, except where a particular BP is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes.⁵⁴

More information and instructions for submitting the notification through R4BP 3 are given in the *BSM Application instructions: national authorisations*.

⁵⁴ Ref: Article 17(6) of the BPR.

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 that is not available because the BP does not fulfil Article 25(b), (c) or (e) of the BPR it remains a possibility to apply for NA.⁵⁵

Permit for parallel trade

BPs can be also made available on the market using a parallel trade permit⁵⁶. 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 authorisation holder.

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 MS of introduction (the reference BP)⁵⁷. Additional information such as example labels are also required as part of the application⁵⁸. 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 related to 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 are still fulfilled. 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.

More information and instructions for submitting the application for parallel trade permit through R4BP 3 are given in the *BSM Application instructions: national authorisations*.

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

⁵⁵ Ref: Article 19(1) of the BPR.

⁵⁶ Ref: Article 53 of the BPR.

⁵⁷ Ref: Article 53(3) of the BPR.

⁵⁸ Ref: Article 53(4) of the BPR.

not exceeding three years, renewable for one year⁵⁹.

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) points (b), (c) and (d) taking into account the factors set out in Article 19(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: national authorisations*.

- **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 means⁶⁰. 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 application⁶¹ 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

Wherean 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 met⁶², 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 criteria⁶³ 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 taken into account 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 taken into account to evaluate the product). Nevertheless, the legal basis for the product authorisation will be Article 19 and 91 of the BPR. Where the evaluation

⁵⁹ Ref: Article 55(2) of the BPR.

⁶⁰ Ref: Article 55(1) of the BPR.

⁶¹ Ref: Article 55(3) of the BPR.

⁶² Ref: Article 5(1) of the BPR.

⁶³ Ref: Article 10 of the BPR.

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 authorisation⁶⁴. 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 decides if there is a need to amend or cancel the NA⁶⁵. MSCAs, which have mutually recognised that NA shall examine whether these authorisations need also 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: national authorisations*.

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 also applications for MRP are 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*.

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>

⁶⁴ Ref: Article 47 of the BPR.

⁶⁵ Ref: Article 48 of the BPR.

MORE



authorities

National authorities providing support

» <http://echa.europa.eu/support/helpdesks/national-helpdesks/list-of-national-helpdesks>

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/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-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-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-Sept14-Doc.5.9: Provisional authorisations granted or to be

granted in accordance with Article 55(2) of the BPR and conversion to definitive authorisations;

CA-Nov14-Doc.5.8 – Final: Implementing the new concept of biocidal product families.

Guidance on Biocides legislation

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

Submission

- **Submission instructions**

National authorisation

- » <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: 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

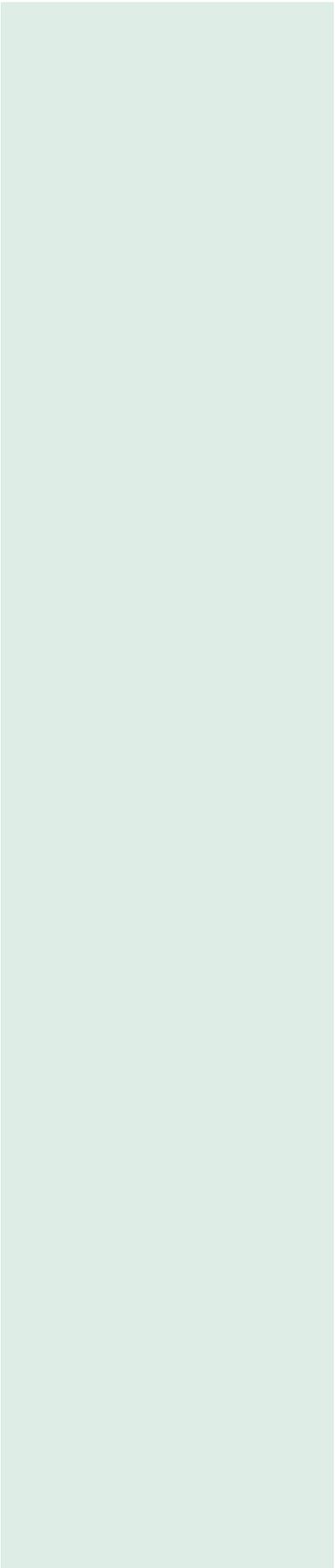
- » http://www.echa.europa.eu/documents/10162/14938692/bsm_06_national_authorisation_en.pdf

BSM Process of invoicing in R4BP 3

- » http://www.echa.europa.eu/documents/10162/14938692/bsm_09_invoicing_en.pdf

- **IUCLID Manuals**

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



Q&As

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