

Changes of biocidal products

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

National authorisations (NAs) of biocidal products (BPs) issued by competent authorities of the Member States (MSCAs) or for Union authorisations (UAs) by the European Commission (COM) are only valid for the approved terms and conditions stated therein.

The relevant provisions on amendments of NAs and UAs on request of the authorisation holder (AH) can be found in Article 50 of the Biocidal Products Regulation ((EU) No 528/2012 (BPR)) and the detailed rules for notifications/applications and procedures for changes of these authorisations in the Commission Implementing Regulation ((EU) No 354/2013) on changes of biocidal products authorised in accordance with the Changes Regulation (CR) ((EU) No 528/2012).

Three types of changes can be distinguished ¹²⁹:

- administrative changes¹³⁰;
- minor changes, which should not affect the conclusion with regard to the fulfilment of the conditions for authorisation¹³¹; and
- major changes, when a need for reassessment of the risk and the efficacy can be expected to fulfil the conditions for authorisation¹³².

The MSCAs for NA, or the European Chemicals Agency (ECHA) for UA, must be informed of all intended changes to an authorised BP. All amendments to the terms and conditions of an authorisation of a BP are handled only by the MSCAs for NA or by COM for UA.

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

129 See the non-exhaustive list in the Annex to CR.

130 Ref: Article 3(1)(aa) of the BPR.

131 Ref: Article 3(1)(ab) of the BPR.

132 Ref: Article 3(1)(ac) of the BPR.

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

The AH or its representative (e.g. a consultant) may apply for amendments to any of the information included in the authorisation of a BP/BPF.

WHEN



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

The applicant can apply for changes at any time. For certain administrative changes, the applicant may only be required to notify the relevant MSCA for NA or ECHA for UA within 12 months following the implementation of such a change¹³³.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

The information requirements are listed in Article 5 of the CR. *BSM Application instructions: national authorisations*, explains what types of information files should be prepared and included in the application/notification. For the time-being the manual covers only the request for changes in relation to NA.

Issues to consider:

Classification of changes:

Taking into account the extent to which the change requires a reassessment of the risk and efficacy of the BP/BPF, changes to the authorisations are classified into three different categories¹³⁴:

- administrative change. Administrative changes are further divided into two types:
 - changes which have to be notified before implementation; and
 - changes which can be notified within 12 months after implementation;
- minor changes;
- major changes.

The Annex to the CR helps to determine the category of the sought change.

An administrative change to the authorisation is sought by a notification procedure and a minor or major change by an application procedure.

Grouping of changes:

As a general rule, a separate notification/application must be submitted

¹³³ Ref: Annex, title 1, section 2 to CR.

¹³⁴ Ref: Article 3(1)(aa), (ab) and (ac) of the BPR.

HOW



for each change. Under certain conditions, the changes can be grouped. Some examples are given in the *BSM Application instructions: national authorisations*, available on ECHA's website.

Even when changes are grouped for NA, a notification/application has to be submitted simultaneously to each MS concerned.

PROCEDURE TO FOLLOW

Request ECHA to classify a change where relevant

If the applicant is unable to determine the category to which the intended change belongs (it is not listed in one of the tables in the Annex to the CR), the applicant may request ECHA to issue an opinion on the classification of the change. For this purpose, the applicant has to submit an application for classification of the change. A separate application for an opinion must be submitted for each change sought through R4BP 3.

More details concerning information requirements and how to submit an application for classification of change are given in the *BSM Application instructions: national authorisations*, available in the support section of ECHA's website.

More information related to invoicing and R4PB 3 can be found in the *BSM Process of invoicing in R4BP 3*.

Submit a notification for administrative change/application for a minor/major change

Creation of a IUCLID dossier:

Where relevant, the applicant should 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 a notification/application using R4BP 3:

The applicant needs to submit a notification/application through R4BP 3:

- to all MSs concerned, which have issued the authorisation and where the change is intended – for NA, or
- to ECHA – for UA.

Where a change of BP (NA) has already been agreed in one or more MS, and the AH wants to apply for the same change in an additional MS concerned, a notification/application has to be submitted to the additional MS.

Following confirmation that the submission has passed the initial checks by ECHA, the notification/application will be forwarded to the relevant authority, i.e.:

- to all MSs concerned, which have issued the authorisation and where the change is intended – for NA, or
- to ECHA – for administrative and minor changes to UA, or
- to the evaluating competent authority (eCA) – for major changes to UA.

Depending on the category of the intended change, different procedures apply¹³⁵.

The requests for minor and major changes to BPs authorised by NA are validated and evaluated by a reference MS. Requests for major changes to BPs authorised by UA are validated and evaluated by the eCA. The reference/evaluating CA should be the same that evaluated the initial NA/UA application. Only when the change of the BP authorised by NA/UA is not sought in that MS, can the applicant choose another MS. ECHA validates and evaluates the requests for minor changes to BPs authorised through UA.

The processing of the notifications/applications for changes in relation to BPs authorised through UA involves the opinion of ECHA (through the Biocidal Products Committee (BPC)).

The decision to agree or reject the change is taken by the MSCAs concerned for NA or by the COM for UA. The decision concerning NAs has to be taken in every MS individually. For some requests for a change concerning NA submitted to more than one MS, the decision by COM or an agreement by the Coordination Group (CG) may also be necessary (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 the payment of fees, or, at a later stage, requests 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.

The applicants will find more information and instructions for submitting and following up their notification/application through R4BP 3 in the submission manuals on ECHA's website:

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

One of the administrative changes listed in the CR¹³⁶ is the possibility to transfer an NA to a new AH. It must be made through the application procedure 'transferring a national authorisation' outlined in *BSM*,

¹³⁵ For the notification procedure for administrative changes of BP, see Article 6 for NA or Article 11 for UA of the CR. For the application procedure for minor changes of BP, see Article 7 for NA or Article 12 for UA of the CR. For the application procedure for major changes of BP, see Article 8 for NA or Article 13 for UA of the CR.

¹³⁶ Section 1, item 3 of title 1 of the Annex to the CR.

Application instructions: National authorisations available on ECHA's website. See also the section on Exceptions and particular cases below.

The possibility to transform a frame formulation (FF) into a BPF is also listed as an administrative change in the CR¹³⁷, however, it must be made through the application procedure 'Merge of a product authorisation(s) in a family' outlined in *BSM, Application instructions: National authorisations* available on ECHA's website. See also the section on Exceptions and particular cases below.

More information related to invoicing and R4PB 3 can be found in the *BSM Process of invoicing in R4BP 3* available on ECHA's website.

Derogations - NA

Any of the MSs concerned may disagree with the proposed change to an NA and propose to refuse to adjust the terms and conditions of the authorisation based on the following grounds¹³⁸:

- 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 being a candidate for substitution¹³⁹.

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 BPC) in order to conclude on its decision¹⁴⁰.

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.

Settlement of disagreements - NA

When, for requests of a change, the MS concerned disagrees with the conclusions of the assessment report, with the summary of the product characteristics (SPC) or with the notified change, it must send a detailed explanation of the reasons for such a position to the reference MS, all

137 Section 1, item 6 of title 1 of the Annex to the CR.

138 Ref: Article 10(1) of the CR.

139 Ref: Article 37(1) of the BPR.

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

RESULT



other MSs concerned and the applicant. The points of disagreement must be referred to the CG¹⁴¹ without delay by the reference MS where the MSs use their best endeavours to reach an agreement. The applicant is allowed to present its point of view. When the 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 in order to conclude on its decision. The settlement of disagreements through the CG is not relevant for UA.

OUTCOME OF THE OBLIGATION/PROCESS

Administrative changes for NA and UA, which can be notified within 12 months after implementation¹⁴² may be implemented any time before completion of the procedures laid down in Articles 6 and 11 of the CR.

Administrative changes, which have to be notified before implementation¹⁴³ may be implemented at the earliest on the date when the MSCA (for NA) or the COM (for UA) agree with the change, or 45 days following receipt of the notification by the MSCA (for NA) or ECHA (for UA), whichever is first.

Minor changes concerning NA may be implemented any time after the reference MS has recorded the agreement on the conclusions of the assessment report, and the SPC where relevant, in R4BP 3, or for UA, any time after ECHA's positive opinion has been made available in R4BP 3.

Major changes may only be implemented after the MSs concerned for NA or, COM for UA have agreed with the change and, where relevant, amended the decision granting the existing authorisation.

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

Transferring a NA

A transfer usually occurs as a result of a merger or acquisition of a company and is the process by which the authorisation is transferred from the current AH to a new one, which is a different legal entity. A change of name and/or address of the AH does not fall under an authorisation transfer if the holder remains the same legal entity. Other changes, e.g. change of the name of the BP are also not a part of a transfer application and should be submitted separately.

More information and instructions for submitting the notification through R4BP 3 are given in the *BSM, Application instructions: National authorisations* available on ECHA's website.

141 Ref: Article 35(1) of the BPR.

142 Section 2 of title 1 of the Annex to the CR.

143 Section 1 of title 1 of the Annex to the CR.

Merge of product authorisation(s) into a BPF

In general, the AH should apply for a merge of authorisations into a BPF before making a notification of a product in a BPF or submitting any other type of application related to the authorisations covered by the FF and well before the deadline for application for renewal of product authorisation.

More information and instructions for submitting the notification through R4BP 3 are given in the *BSM, Application instructions: National authorisations* available on ECHA's website.

BP authorised through simplified authorisation procedure¹⁴⁴

To notify of/apply for changes to authorisations granted through a simplified procedure, applicants should submit a respective notification/application through R4BP 3 as outlined in the *BSM Application instructions: Simplified authorisations* available on ECHA's website. To transfer a simplified authorisation to a new AH, the notification must be made through the procedure 'transfer of a simplified authorisation'.

Where the authorisation has been granted in accordance with the simplified authorisation procedure¹⁴⁵, the applicant is obliged to notify each MS on the territory of which this BP is made available, of each notification/application for the change(s) made to the reference MS (under implementation). Where a revised version of the SPC has been accepted by the reference MS, the applicant has to submit this revised version to each MSCA in the official language(s) of that MS.

COST**RELATED FEES**

The national fees related to notification/application of changes may vary between MSs and are established in the national legal acts of each MS.

For more information about the MS fees, the applicant should contact the designated MSs.

Fees related to notification/application for change(s) of UA as well as classification of changes payable to ECHA are listed in Annex II to *Commission Implementing Regulation ((EU) No 564/2013)*.

The fee applicable to the classification of a change applies to both NA and UA. The fee is deducted from a subsequent notification/application for administrative or minor change in the context of UA.

¹⁴⁴ Ref: Article 9 of the CR.

¹⁴⁵ Ref: Article 26 of the BPR.

HELP



TO CONTACT FOR FURTHER INFORMATION

ECHA Helpdesk

» <http://echa.europa.eu/contact/helpdesk-contact-form>

MSCAs contact details

» <http://echa.europa.eu/contacts-of-the-member-state-competent-authorities>

National authorities providing support

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

MORE



INFORMATION

Legislation relevant to biocides

» <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

Regulatory aspects

Authorisation of biocidal products

» <http://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products>

The Biocidal Products Committee

» <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee>

Relevant Biocides competent authorities meetings documents

» <https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942>

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

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>

- Classification of a change to a product authorisation
- Administrative change on request
- Minor or major change on request

- Merge of product authorisation(s) in one product family
- Transfer of authorisation

Simplified authorisations

» <http://echa.europa.eu/support/dossier-submission-tools/r4bp/simplified-authorisations>

- Administrative change on request
- Minor or major change on request
- Transfer of authorisation

• Biocides Submission Manuals

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

BSM Technical guide: using IUCLID

» http://echa.europa.eu/documents/10162/14938692/bsm_01_using_iuclid_en.pdf

BSM Technical guide: using R4BP 3

» http://echa.europa.eu/documents/10162/14938692/bsm_02_using_r4bp3_en.pdf

BSM Technical guide: using SPC

» http://echa.europa.eu/documents/10162/14938692/bsm_03_using_spc_en.pdf

BSM Application instructions: national authorisations

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

BSM Application instructions: simplified authorisations

» http://echa.europa.eu/documents/10162/14938692/bsm_07_simplified_authorisation_en.pdf

BSM Process of invoicing in R4BP 3

» http://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>