ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on changes to biocidal products

February 2024

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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[1]:

- administrative changes[2];
- minor changes, which should not affect the conclusion regarding the fulfilment of the conditions for authorisation[3]; and
- major changes, when a need for reassessment of the risk and the efficacy can be expected to fulfil the conditions for authorisation[4].

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).

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.

[1] See the non-exhaustive list in the Annex to CR.
[2] Ref: Article 3(1)(aa) of the BPR.
[3] Ref: Article 3(1)(ab) of the BPR.
[4] Ref: Article 3(1)(ac) of the BPR.

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 change[5].

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

Considering 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 categories[6]:

- administrative change. Administrative changes are further divided into two types:
  - changes which must 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.

[5] Ref: Annex, title 1, section 2 to CR.
[6] Ref: Article 3(1)(aa), (ab) and (ac) of the BPR.

Grouping of changes:

Generally, a separate notification/application must be submitted 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 must be submitted simultaneously to each MS concerned.

HOW

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: How to prepare a biocides dossier*, available on ECHA's website;

- *BSM Technical guide: How to use 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 apply[7].

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.

7 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.

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: How to use R4BP 3*
> *BSM Application instructions: How to submit an application for national authorisation*

One of the administrative changes listed in the CR[8] 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, 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 CR[9], 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.

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

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

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 grounds[10]:

- 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 substitution[11].

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) to conclude on its decision.[12]

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 other MSs concerned and the applicant. The points of disagreement must be referred to the CG[13] 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.

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

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

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

13 Ref: Article 10(2) of the CR

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 to conclude on its decision.

The settlement of disagreements through the CG is not relevant for UA.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

Administrative changes for NA and UA, which can be notified within 12 months after implementation[14] 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 implementation[15] 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.

[14] Section 2 of title 1 of the Annex to the CR.
[15] Section 1 of title 1 of the Annex to the CR.

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 authorisations* available on ECHA's website.

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: How to submit an application for National authorisations* available on ECHA's website.

BP authorised through simplified authorisation procedure[16]

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: How to submit an application for 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 procedure[17], 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.

[16] Ref: Article 9 of the CR.
[17] Ref: Article 26 of the BPR.

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.

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

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/386abfea-55ce-4764-8a31-f9d4f6ceaf0a

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 or 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: How to prepare a biocides dossier
  - BSM Technical guide: How to use R4BP 3
  - BSM Application instructions: How to submit an application for national authorisations
  - BSM Application instructions: How to submit an application for simplified authorisation
  - *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