ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on same biocidal product authorisation

February 2024

Disclaimer

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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The following are the basic principles of the Same Biocidal Product Regulation 414/2013 (SBP regulation) as amended by Regulation No 2016/1802:

- a subsequent authorisation of a same biocidal product (SBP) can be granted based on the evaluation of a biocidal product already authorised or registered under the Biocidal Product Directive 98/8/EC (BPD)[1], or
- already authorised under the Biocidal Product Regulation No 528/2012 (BPR)[2], or

Applications can be requested for authorisations of same biocidal products where there is already an identical product authorised or where the identical product is under evaluation and not yet authorised. The biocidal product already authorised or under evaluation to be authorised is called the 'related reference product' (or the reference BP).

The precondition for authorisation of same biocidal products is that these products are identical within the limited variations of an administrative change[3].

The terms and conditions for the SBP authorisation will be based on the evaluation made on the reference BP.

The same rules mentioned above for a single biocidal product apply also for a biocidal product family (BPF). Same product authorisation can also be granted for an individual product of a biocidal product family.

The SBP regulation covers national, simplified and Union authorisation procedures.

[1] Ref: Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

[2] Ref: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

[3] Ref Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

WHO

WHO IS CONCERNED BY THIS PROCESS?

An application for SBP authorisation can be made by the prospective authorisation holder (AH), who can be the same or a different enterprise than the AH of the reference BP. It can also be made on behalf of the AH by a person/entity handling the practical issues related to the application on their behalf (e.g. a consultant).

The AH is the person/entity established within the European Union (EU)/European Economic Area (EEA)[4] who is responsible for placing a BP on the market in a particular MS or within the Union and specified in the authorisation.

WHEN

TIMELINES AND DEADLINES RELATED TO THE PROCESS

An application for SBP authorisation can, in general, be made at any time after the decision to approve the active substance has been adopted, and where:

- A Union, national or simplified authorisation for the reference biocidal product has been issued and is still valid (UA-BBS, NA-BBS, SA-BBS), or
- an application for Union, national or simplified authorisation has been submitted and is still pending (UA-BBP, NA-BBP, SA-BBP).

The same transitional rules apply to the timing of the application for SBP as for the related reference product where they are existing BPs[5]:

- The SBP 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. A product authorisation application can also be made later 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 SBP must be submitted no later than the

[4] An authorisation holder may, under the revised mutual recognition agreement be domiciled or have a registered office in Switzerland. For further information please visit the following webpage http://www.bag.admin.ch/anmeldestelle/13604/13869/15343/index.html?lang=en

[5] "Existing BPs" refers in the context of this Practical Guide, to those products which were already 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 or a combination of such substances and new active substances approved in accordance with the BPR (Article 89(2) of the BPR).

[6] Ref: Article 89(3) of the BPR.

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 SBP 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, available on the European Chemicals Agency's (ECHA) website:

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

In practice, it means that an application for UA-BBP, NA-BBP or SA-BBP for SBP must be submitted by the applicable deadline in case existing BP is sought to be kept on the market.

Phasing-out periods also apply when the application for NA-BBP is rejected or the receiving MSCA decides not to grant the authorisation[7]. Existing products must be removed from the market within 180 days of the date of such 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 SBP of a new BP[8] can be submitted at any time after the decision on the approval of the (last) active substance contained therein is adopted and where respective authorisation for the reference product has been issued and is still valid, or relevant application has been submitted and is still pending.

WHAT

INFORMATION REQUIREMENTS AND SOURCES

Article 2 of the SBP regulation lists the requirements for an application for SBP. In addition *Biocides Submission Manuals; Application instructions* available on ECHA website explain what types of information should be prepared and included in an application.

Issues to consider

The applicant has to consider a number of important elements before preparing an application for SBP:

- If you intend to apply for authorisation of SBP where the related reference product has already been authorised or registered in accordance with the BPR or BPD (UA-BBS, NA-BBS or SA-BBS) and you are not the authorisation holder (asset owner) of the related reference product, the initial asset owner should make an active

[7] Ref: Article 89(4) of the BPR.
[8] "New BPs" refers in the context of this Practical Guide, to those products which were not on the market of any MS at the date of the approval of the (last) active substance contained therein.

delegation in R4BP 3 for your company. Otherwise, the system will not let you to complete the application.

- If you intend to apply for authorisation of SBP where an application for the related reference product has been submitted (UA-BBP, NA-BBP or SA-BBP) and you are not the case owner of the related application, you will need to contact the case owner of the application for authorisation of the related reference product to obtain the relevant 'reference case number' used in R4BP 3.

HOW

PROCEDURE TO FOLLOW

The type of SBP you can apply for depend on the type of reference authorisation:

1. When the related reference product is authorised/subject of an application for Union authorisation (UA) you can apply for either UA or NA (new possibility introduced by regulation No 2016/1802).

   The SBP application for UA has to be submitted to ECHA. A confirmation that the BP/BPF would have similar conditions of use across the Union or a reference to an evaluating Competent Authority (eCA) is not required for such type of application.

   The same BP/BPF application for NA has to be submitted to that MSCA on which market the same BP/BPF is intended to be placed.
2. When the related reference product is authorised/subject of an application for NA you can only apply for NA.

   The same BP/BPF application has to be submitted to the same CA that has granted/is requested to grant the NA for the related reference product.
3. When the related reference product/BPF is authorised/subject of an application for Simplified authorisation (SA) you can only apply for SA.

   The same BP/BPF application has to be submitted to the same CA that has granted/is requested to grant the SA for the related reference product.

The amendment of the SBP regulation by regulation No 2016/1802 has also introduced new possibilities when the reference product is a biocidal product family. The SBP can be an identical family, a reduced family (i.e. reduced number of meta SPCs or reduced number of products for certain meta-SPCs) or even a single product (family member).

Application for same biocidal product authorisation

For an application for SBP authorisation a IUCLID dossier is not required.

Submission and processing of an application:

Applicants seeking SBP authorisation should submit their application through R4BP 3.

For SBP applications for NA or SA, following confirmation that the submission has passed the initial checks by ECHA, the application will be forwarded to the receiving CA for validation. The receiving CA will take a decision on the authorisation[9].

For SBP applications for UA, following confirmation that the submission has passed the initial check by ECHA, the application will be validated by ECHA and an ECHA's opinion will be submitted to the Commission within 30 days of validation. Based on the BPC opinion, COM will take a decision on the authorisation[10].

The validation performed by the receiving CA or by ECHA is to check among others that the proposed differences between SBP and the related reference biocidal product concern merely information which can be the subject of an administrative change.

The applicant needs to monitor the status of its 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 decision may be taken disregarding the information that has been provided after the deadline.

Applicants will find the relevant information and instructions for submitting and following up the application for SBP authorisation through R4BP 3 in the following submission manuals available on ECHA's website:

- *BSM Application instructions: How to submit an application for national authorisation*
- *BSM Application instructions: How to submit an application for simplified authorisation*

[9] Ref: Article 26 and Articles 29-30 of the BPR respectively.
[10] Ref: Articles 43-44 of the BPR.

- *BSM Application instructions: How to submit an application for Union authorisation*

ECHA's website provides further details on the processing of the applications (see Submission instructions in the "More Information" section).

RESULT

OUTCOME OF THE PROCESS

The content of SBP authorisation shall be identical with that of the reference biocidal product (family), except for the administrative changes that have been applied for.

The authorisation of SBP will have a different authorisation number and may be changed, renewed or cancelled independently of authorisation related to the reference product. However, in some cases the appropriateness of cancelling or amending the authorisation of other products to which the product is linked in the R4BP 3 may be considered[11].

SBP authorisation can be granted for a maximum period of 10 years, which is renewable. It will have the same expiry date as the authorisation of the reference BP.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES

When a national authorisation for the SBP is issued an applicant interested to place biocidal product on the market in another country may apply for mutual recognition of SBP in the MS in question.

For SBP authorised under the simplified procedure, as for the related reference product, a product may be made available on the market in all Member States without the need for mutual recognition. Instead, a notification must be made to each Member State no later than 30 days before placing the biocidal product on the market.[12]

COST

[11] Ref: Article 7(2) of the SBP regulation
[12] Ref: Article 6a(3) of the SBP regulation

RELATED FEES

The national fees related to the application for NA and SA of SBP may vary between 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 MSCA fees, the applicant should contact the respective CA or its helpdesk.

The fee related to the application for UA of SBP payable to ECHA is listed in in the fourth entry of Annex II to *Commission Implementing Regulation (EU) No 564/2013*.

The **annual fees** payable for each biocidal product or product family authorised by the Union are listed in Annex III to *Commission Implementing Regulation (EU) No 564/2013*. The fees are due on the first and each subsequent anniversary of the entry into force of the authorisation and are related to the preceding year. Non-payment of the annual fees by the due date may lead to **cancellation** of the authorisation.

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

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-March15-Doc.4.7-Final: Applications for a same biocidal product of an individual product of a biocidal product family

Guidance on biocides legislation

http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation

Submission

- Submission instructions

  http://www.echa.europa.eu/support/dossier-submission-tools/r4bp/submit-applications-for-national-authorisation

  http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/r4bp/union-authorisations

  http://www.echa.europa.eu/support/dossier-submission-tools/r4bp/simplified-authorisations

- Biocides Submission Manuals

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

  - *BSM Application instructions: How to submit an application for national authorisation*
  - *BSM Application instructions: How to submit an application for simplified authorisation*
  - *BSM Application instructions: How to submit an application for Union authorisation*
  - *BSM Technical guide: How to use R4BP3*
  - *BSM Process of invoicing in R4BP 3*

Q&As

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