ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on simplified authorisation of biocidal products

February 2024

Disclaimer

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

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V3	Editorial improvements and clarifications throughout the document; Alignment of the section 'settlement of disagreements' with the updated *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; Update of relevant documents and guides.	February 2024

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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The simplified authorisation (SA) procedure aims to encourage the use of biocidal products (BPs) that have a more favourable environmental or human and animal health profile.

The application procedure for SA of a BP is similar to the procedure for national authorisation except that there are fewer information requirements.

To apply for the SA procedure, the BP must be eligible according to Article 25 of the Biocidal Products Regulation ((EU) No 528/2012 (BPR)):

- all the active substances contained in the BP appear in Annex I to the BPR and comply with the specified restrictions;
- the BP does not contain any substances of concern;
- the BP does not contain any nanomaterials;
- the BP is sufficiently effective;
- the handling of the BP and its intended use do not require personal protective equipment.

The SA of a BP is granted by the competent authority of the evaluating Member State (MS), i.e., evaluating Competent Authority (eCA), and is only valid for the approved terms and conditions stated therein.

The same rules as for a single BP also apply for a biocidal product family (BPF)[1].

Instead of mutual recognition by other Member States (MSs) , a notification to the relevant MS(s) (i.e., notified MSs) needs to be done for a product authorised with the SA procedure, before placing the product on the market of the notified MS(s)[2].

There is no renewal procedure for SAs. Therefore, if the authorisation holder (AH) wants to continue to make available on the market its product beyond the expiry date of the SA, a new SA application must be submitted sufficiently in advance so that the new authorisation can be granted by the eCA, and the company can submit the notifications in the other MSs where the product is made available on the market, before the previous authorisation expires. It is recommended that

[1] Ref. Article 3(1)(s) of the BPR.
[2] Ref: Article 27 of the BPR.

such an application is submitted at the latest 550 days year before the expiry of the SA[3].

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

An application for SA (and notification for placing on the market) can be made by, or on behalf of, the prospective AH. Accordingly, the prospective AH may have 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) who is responsible for the placing a BP on the market in a particular MS[4] and is specified in the authorisation.

WHEN

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

An application for SA can be submitted at any time where all the conditions in Article 25 of the BPR are met. The BP can only be made available on the market in a given MS when the SA is granted by the relevant eCA.

The application for SA in the eCA and notifications in the notified MSs must be made by the date of approval of the active substance; otherwise the existing BPs[5] 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 SA and notification applications can also be made at a later date but, in such a case, until authorisation/notification (as applicable) is granted, the products must be removed from the market.

To place the BP on the market of another MS after the SA is granted, a notification must be made to the MS in whose territory the BP will be made available no later than 30 days before placing the BP on the market in the territory of that MS. This may be done only once the SA has been granted by the eCA. The AH is obliged to re-notify the BP in each notified MS through R4BP 3 when a change of the SA is authorised by the eCA (see Practical Guide on Changes of biocidal products).

[3] CA-March16-Doc.4.6
[4] Ref: Article 3(1)(p) of the BPR.
[5] "Existing biocidal products" 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.

WHAT

INFORMATION REQUIREMENTS AND SOURCES

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

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 website.

Issues to consider:

- As for the requirement to provide efficacy data[7], the information requirements in section 6 on efficacy in Annex III to the BPR are relevant in full for this type of application. This data requirement can be fulfilled by providing the relevant studies, a letter of access (LoA) to such studies, or declaring that the relevant data protection period has expired (upon agreement of the receiving competent authority)[8]. It may also be possible to waive certain information requirements[9] by providing justifications why specific data are not relevant to the uses which are claimed to be supported, why it is not scientifically necessary to supply the data, or why it is not technically possible to generate the data.

- Technical equivalence is only a requirement for active substances in category 6 of Annex I (also regarded as "approved"). Therefore, where the BP contains an AS in category 6 of Annex I, proof of technical equivalence should be submitted with the application for SA. See the (Practical Guide chapter on technical equivalence). For substances listed in categories 1 to 5, and 7, the establishment of technical equivalence is not relevant since no reference source has been established.

- For all substances listed in Annex I, no limitation is indicated regarding product-type (PT). Accordingly, BPs that contain them and that are eligible for the SA procedure can be placed on the market within any PT.

  If there are any doubts as to whether a product falls within the scope of the BPR or not[10], or to which PT it belongs, the

[7] Ref: Article 20(1)(b)(ii) of the BPR.
[8] Ref: Article 60(3) of the BPR.
[9] Ref: Article 21(1) and (2) of the BPR.
[10] Ref: Article 3(3) of the BPR.

applicant is invited to contact the future eCA.

HOW

PROCEDURE TO FOLLOW

Application for simplified authorisation

Creation of a IUCLID dossier

The applicant seeking to obtain SA is required 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* available on ECHA's website;
- *BSM Technical guide: How to use R4BP 3* available on ECHA's website.

Submission and processing of an application

Applicants seeking SA should submit their application through R4BP 3. Following confirmation that the submission has passed the initial checks by ECHA, the application will be forwarded to the eCA for acceptance[11] and evaluation[12] (90 days unless additional information is requested). The eCA takes a decision on the authorisation.

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, 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.

Applicants will find the relevant information and instructions for submitting and following up the application for SA 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 Simplified Authorisation*

[11] Ref: Article 26(2) of the BPR.
[12] Ref: Article 26(3) and (4) of the BPR.

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

Notification for placing on the market

Submission and processing of a notification:

The applicant should submit a notification for placing on the market to each relevant MS through R4BP 3. Following confirmation that the submission has passed the initial checks by ECHA, the notification will be forwarded to the notified MSs.

The notified MS informs the applicant when the submitted documentation is considered complete. If the notified MS has objections regarding the submitted application, it informs the applicant within 30 days (defined in Article 27(1) of the BPR) of the time when the submitted documentation is considered complete, that further discussions are needed with the eCA, so in line with Article 27(2) of the BPR the applicant cannot proceed to place the product on the market until the matter is resolved.[13] In some cases, processing of the notification requires an agreement by the Coordination Group (CG) or a decision by the European Commission (COM) (see below)[14].

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, for a request for comments, etc.), the notification may be rejected, or its processing may be completed disregarding the information that has been provided after the deadline.

It is only possible to notify to each notified MS through R4BP 3 an individual product. Thus, in case the applicant wants to notify the whole family, or part of it, a notification needs to be done for each product separately.

Applicants will find the relevant information and instructions for submitting and following up the notification for placing on the market through R4BP 3 in the *BSM Application instructions: How to submit an application for Simplified Authorisation* available on ECHA's website.

Settlement of disagreements through CG

[13] Working procedure for resolving of disagreements
[14] Ref: Article 27 of the BPR.

When any of the notified MSs disagree that the conditions laid down in Article 25 of the BPR are met, or consider that it has not been notified or labelled correctly, it may send a detailed explanation of the reasons for such a position to the eCA, all other notified MSs and the AH. The points of disagreement must be referred to the CG[15] without delay by the notified MS that expressed disagreement. In the CG the eCA and the notified MSs use their best endeavours to reach an agreement. The AH is allowed to present its point of view. When an agreement is not reached in the CG within 60 days, the disagreement procedure is closed, and the eCA informs COM of the matters where agreement was not reached[16]. The COM takes a final decision by means of an implementing act[17] and may either ask ECHA for an opinion on scientific and technical issues (through the Biocidal Products Committee)[18] or give an opportunity to the applicant to comment (30 days) to conclude on its decision[19]. Within 30 days of notification of this decision, the eCA and all notified MSs either grant, refuse to grant or cancel the authorisation/notification (as applicable), or vary its terms and conditions as necessary to comply with the decision[20].

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

The eCA shall authorise the BP in SA procedure if satisfied that the product meets the conditions laid down in Article 25 of the BPR for a defined number of years, not exceeding 10. A BP placed on the market through the SA/notification procedure may be on the market provided the SA of the BP granted by the eCA is valid and the notified MS did not inform the applicant that the product should not be placed on the market.

In the context of the notification on the market, where the respective notified MS has valid reasons to consider that a BP authorised in SA procedure does not meet the criteria laid down in Article 25 and a decision by the CG has not yet been taken, that MS may provisionally restrict or prohibit the product being available on the market or used in its territory[21].

TO NOTE

[15] Ref. Article 27(2) of the BPR.
[16] Ref: Article 36(1) of the BPR.
[17] Ref: Article 36(3) and (4) of the BPR.
[18] Ref: Articles 36(2) and 38(1) of the BPR.
[19] Ref: Articles 36(2) of the BPR.
[20] Ref: Article 36(4) of the BPR.
[21] Ref: Article 27(2) of the BPR.

EXCEPTIONS AND PARTICULAR CASES

Authorisation of same biocidal products

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

Simplified authorisation granted for a BPF

If an SA 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.

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

Notification of unexpected or adverse effects

An AH is obliged to notify the eCA 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[22]. 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 eCA 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 SA[23].

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 Simplified Authorisation.*

COST

RELATED FEES

National fees are applicable to the SAs.

The national fees related to an application for SA may vary between MSs and are established in national legal acts of each MS. The applicant is responsible for checking and paying the specified amount

[22] Ref: Article 47 of the BPR.
[23] Ref: Article 48 of the BPR.

of fees to the chosen eCA.

The notification to the notified MS(s) may be subject to fees.

For more information about the MSs' fees, the applicant should contact the designated national CA or its helpdesk.

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-March16-Doc.4.6.Rev.9 – Final: Q&A pairs concerning the practical implementation of the simplified authorisation procedure (SAP);

CA-Sept14-Doc.5.4 – Final: SPC template reviewed*;*

CA-May15-Doc.4.6.a – Final: Updated SPC template for BPF*;*

CA-July19-Doc.4.2.Rev.3 – Final: Guidance note on the biocidal products family concept*;*

CA-July19-Doc.4.1 – Authorisation of products generating active substances in situ*;*

CA-May14-Doc.5.5 – Final: Consideration of storage stability, stability and shelf-life data in the context of applications for product authorisation under the simplified procedure

CA-May14-Doc.5.1 – Final: Composition of biocidal products and responsibilities of authorisation holders;

CA-June22-Doc.4.2: Consequences for biocidal products authorisations procedures of relevant information becoming available;

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

Relevant CG meetings documents

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

CG-30-2018-11 AP 7.2_e-c Storage stability and simplified authorisations;

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

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-50-2022-07 AP 16.2 Dermal absorption value in PAs_vf: Dermal absorption value for the authorisation of biocidal products.

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/web/guest/guidance-documents/guidance-on-biocides-legislation

Submission

- Submission instructions

  Simplified authorisations
  http://echa.europa.eu/support/dossier-submission-tools/r4bp/simplified-authorisations
  - Authorisation of biocidal products
  - Authorisation of the same biocidal product (pending and authorised)
  - Notification for a product in a product family
  - Notification of unexpected or adverse effect
  - Notification for placing on the market
- 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 Simplified 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