Simplified authorisation

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 substance 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 (CA) of the evaluating Member State (MS) and is only valid for the approved terms and conditions stated therein.

Mutual recognition by other MSs is not needed for an SA. A notification to the relevant MS(s) before actually placing the product on its territory is sufficient (derogations may apply)[116].

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 authorisation holder (AH). Accordingly, the applicants may have a person/entity handling the practical issues related to the application on their behalf (e.g. a consultant).

116 Ref: Article 27 of the BPR.

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.

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[117].

To place the BP on the market of another MS after the initial 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 each MS through R4BP 3 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) (see Practical Guide on Changes of biocidal products).

WHAT

INFORMATION REQUIREMENTS AND SOURCES

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: simplified authorisations* 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[118], 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)[119].

117 If the active substance is included in the Review Programme, the BP it contains may be made available on the market and used without an authorisation under the BPR, as per Article 89 of the BPR.
118 Ref: Article 20(1)(b)(ii) of the BPR.
119 Ref: Article 60(3) of the BPR, as amended by Regulation (EU) No 334/2014.

It may also be possible to waive certain information requirements[120] 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 so far in Annex I (except category 6), 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, or to which PT it belongs, the applicants are invited to contact the future receiving competent authority[121].

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:* using IUCLID available on ECHA's website;
- *BSM Technical guide: using 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 relevant evaluating CA (eCA) for acceptance and evaluation (90 days unless additional information requested). The eCA takes a decision on the authorisation[122].

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 evaluation may be completed disregarding the information that has been

120 Ref: Article 21(1) and (2) of the BPR.
121 Ref: Article 3(3) of the BPR.
122 Ref: Article 26 of the BPR.

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

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

Notification for placing on the market

Submission and processing of an 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 relevant CAs (30 days). 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). [123]

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

From October 2016 it is possible to notify to each relevant MS through R4BP 3 a whole family, part of it or a single product belonging to that family.

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: simplified authorisations* available on ECHA's website.

Settlement of disagreements through CG

When any of the MSs concerned disagree on whether the BP meets the criteria for SA or consider that it has not been notified or labelled correctly, the CG has to be addressed by that MS[124]. A detailed explanation of the reasons for such a position has to be made by the MS to the evaluating MS, all other MSs concerned and the applicant. The CG shall within 60 days reach an agreement and the applicant is allowed to present its point of view. When an agreement is not reached by the CG, COM takes a final decision by means of an implementing act. COM may either ask the Agency for an opinion on scientific and technical issues (through the

123 Ref: Article 27 of the BPR.
124 Ref. Article 27(2) of the BPR.

Biocidal Products Committee) or give an opportunity to the applicant to comment (30 days) in order to conclude on its decision.

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 as long as the SA of the BP granted by the eCA is valid.

In the context of the notification on the market, where the respective 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.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES

Authorisation under the BPD

Where the relevant low risk product registration has been made under Directive 98/8/EC (BPD (close to the concept of the SA procedure under the BPR)), it is valid under the BPR until expiry, but no notification for placing on the market can be made.

Please refer to the 'CA Notes for Guidance' regarding the placing on the market of a product not authorised according to Article 26 of the BPR but for which a biocidal product registration application was submitted and/or granted according to the BPD[125] .

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 market, except where a particular BP is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes[126].

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

Notification of unexpected or adverse effects

125 The Notes for Guidance on 'Handling of applications for product registration submitted under the BPD for which the evaluation has not been completed by 1st September 2013' should be followed (CA-Sept13-Doc.6.2.e).

126 Ref: Article 17(6) of the BPR.

An AH is obliged to notify the MSCA that has granted the SA 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[127]. 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 SA[128].

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: simplified authorisations.*

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 of fees to the chosen eCA.

The notification to the concerned 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

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

127 Ref: Article 47 of the BPR.
128 Ref: Article 48 of the BPR.

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/85cf24d4-e4d3-4b34-b59d-7a69394d0942

CA-Sept13-Doc.6.2.e – Final: Handling of applications for product registration submitted under the BPD for which the evaluation has not been completed by 1st September 2013

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

Guidance on Biocides legislation
» http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

Submission

- **Submission instructions**
  Simplified authorisation
  » 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: 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: simplified authorisations
» http://www.echa.europa.eu/documents/10162/14938692/bsm_07_simplified_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/qas