ECHA
EUROPEAN CHEMICALS AGENCY

Practical guide on the approval of biocidal active substances

December 2021

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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WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The basic principle in the Biocidal Products Regulation ((EU) No 528/2012 (BPR)) is that a biocidal product (BP) must be authorised before it can be made available on the market or used in the European Union (EU)/European Economic Area (EEA)[1]. This takes place in two consecutive steps. As the first step, the active substance is evaluated and, provided the criteria are fulfilled, is then approved in a specified product-type (PT). The second step is the authorisation of each BP consisting of, containing or generating the approved active substance(s). This document concerns the first step, approval of active substances[2].

WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Any person may apply for the approval of an active substance. Normally, the application is expected to be made by a person who is placing the active substance on the market within the EU.

The applicant may have a person/entity handling the practical issues related to the application on behalf of the applicant (e.g. a consultant).

WHEN

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

An application for approval of a new active substance[3] can be submitted at any time.

An application for active substance approval may also need to be submitted within a specified timeframe where active substances are eligible for inclusion into the Review Programme[4].

[1] Ref: Article 17(1) of the BPR.
[2] Ref: Chapter II of the BPR.
[3] A “new active substance” is a substance which was not on the market on 14 May 2000, as an active substance of a BP for purposes other than scientific or product and process-orientated research and development (Article 3(1)(e) of the BPR).
[4] The Review Programme is a Commission work programme for reviewing all existing biocidal active substances. The programme was set up under the Biocidal Products Directive and continues under the BPR.

For active substances contained in certain products not covered by Directive 98/8/EC but falling under the BPR[5] available on the market before 1 September 2013, there was a deadline of 1 September 2016 for the submission of the applications for the relevant AS in those products. Where such an application was not made by the deadline, the product had to be removed from the market by 1 September 2017.

BPs that contain only existing active substances[6] that are included in the Review Programme may be permitted to be made available on the market or used before the approval date of the active substance, subject to national laws of the relevant Member State (MS).

WHAT

INFORMATION REQUIREMENTS AND SOURCES

Information requirements

Article 6 of the BPR lists the requirements for an application for active substance approval. *BSM Application instructions: How to submit an application for active substance*, available on the European Chemicals Agency's (ECHA) website, explains what types of information files should be prepared and included in the application for active substance approval.

ECHA provides more advice on information requirements as given by Annexes II and III to the BPR and the assessment of the information in the *Guidance on information requirements for Biocides,* available on ECHA's website.

Issues to consider

- To avoid duplication of testing on vertebrates, owners of existing data and prospective applicants must share data involving tests on vertebrates for biocidal active substances and products already submitted to ECHA or the MSCAs under the BPR or Directive 98/8/EC. First, the prospective applicants should submit an inquiry to ECHA through R4BP 3 to obtain the contact details of the data submitters. While sharing of vertebrate data is mandatory, the prospective applicant may also request to share non-vertebrate data. Where an enquiry has been made, and then negotiations fail despite every effort of the applicant, ECHA can grant permission to the applicant to refer to the data. For more information see the Practical Guide chapter on data sharing.

[5] Ref: Article 93 of the BPR.
[6] An "existing active substance" is a substance which was on the market on 14 May 2000 as an active substance of a BP for purposes other than scientific or product and process-orientated research and development (Article 3(1)(d) of the BPR).

- If the applicant is a small or medium-sized enterprise (SME), it may be entitled to a reduced fee. Note that ECHA needs to recognise the SME status of the applicant, before an application for active substance approval is submitted. For more information on the recognition of an SME status and on how to submit relevant documentation see ECHA's website[7].

HOW

PROCEDURE TO FOLLOW

Creation of a IUCLID dossier

The applicant seeking an approval of an active substance needs to submit the data using an 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 R4BP3* available on ECHA's website

Submission and processing of an application

The application for active substance approval should be submitted using R4BP 3. Following confirmation that the submission has passed the initial checks by ECHA, the application will be forwarded to the relevant evaluating competent authority (eCA) for validation and evaluation. Evaluation (365 days unless additional information is requested) is followed by a peer review (270 days) performed by ECHA through the Biocidal Products Committee (BPC) which issues an opinion. During the evaluation, if active substances are identified as candidates for substitution[8], a consultation will be launched in parallel with the peer review. Based on the BPC opinion, the Commission takes a decision on the approval of the active substance.[9] The total time from submitting an application to having a formal active substance approval decision is approximately two and a half years as a minimum. The approval process will take longer if the data package needs to be complemented during the evaluation.

[7] http://www.echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr
[8] Ref: Article 10 of the BPR.
[9] Ref: Articles 7-9 of the BPR.

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 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 provided after the deadline. Details on the applicants' input during the peer review are given below.

Applicants will find the relevant information and instructions for submitting and following up their application through R4BP 3 in the submission manuals on ECHA's website:
BSM Technical guide: How to use R4BP 3 and BSM Application instructions: How to submit an application for Active Substance.
More information related to invoicing and R4PB 3 can be found in the *BSM Process of invoicing in R4BP 3*.

Applicants input to the peer review

The peer review process entails a scientific and technical review by the BPC working groups (WGs) before eventual adoption of the opinion by the BPC. During the peer review, ECHA permits the participation of applicants to clarify any discussion items and to make sure that all aspects are properly addressed and understood when the BPC and the BPC WGs consider their application.

The role and responsibilities of applicants participating in the peer review phase is explained in the ECHA Code of conduct for applicants participating in the Biocidal Products Committee and its Working Groups[10] available on ECHA's website. The Code of conduct sets out general rules and responsibilities for applicants and explains the mechanism to the applicants that may participate in meetings. Furthermore, it explains their obligations regarding confidentiality[11] and the rules that apply to documentation from applicants.

To participate in the BPC or BPC WG meetings, after the draft agenda for the meeting has been published on ECHA's website, applicants need to contact the BPC or BPC WG Secretariat no later than 14 days before the meeting. Accredited stakeholder organisations (ASO) can be present at WG meetings, but do not have access to confidential substance documents.

Applicants are given the opportunity to participate also at other stages of the process as described in the Working Procedure[12] available on ECHA's website. The document describes the process and timelines in detail. In accordance with the working procedure, the applicant:

[10] https://echa.europa.eu/documents/10162/763823/bpc_conduct_code_applicants_en.pdf
[11] See also "Guidelines for assessing confidentiality claims "
https://echa.europa.eu/documents/10162/992289/guidelines_assess_bpr_conf_claims_en.pdf
[12] Biocidal active substance approval: working procedure for the BPC,
https://echa.europa.eu/documents/10162/763823/bpc_working_procedure_active_substance_en.pdf

- Should review, where a consultation is required, the text proposal for the consultation to make sure that no confidential information is placed in the public domain;
- May provide comments on the Competent Authority Report (CAR) during the commenting period by which the peer review stage is launched. Where the applicant makes comments it should discuss these with the eCA with the aim of reaching an agreement that will then be recorded in the commenting table. The applicant may discuss any remaining open points trilaterally with the eCA and ECHA;
- May review the updated commenting table, once the results of all trilateral discussions are included by the eCA, to make sure that all points have been addressed correctly. If there is disagreement, the applicant can request re-opening a point for a discussion in the BPC or WG meeting;
- Should monitor ECHA's website to find out when their application is scheduled to be discussed in the WG or BPC meeting. The applicant may register and attend the discussions on their application if they have previously registered;
- Should review the discussion table to be discussed at the relevant WG meeting. If the applicant wishes to discuss an issue that is not in the discussion table, they should immediately contact the Secretariat. ECHA will include such additional issues in the discussion table before the WG meeting only when they are critical for the approval and/or for fulfilling the exclusion or substitution criteria;
- Where an agreement is not reached during the WG meeting, the WG convenes an ad hoc follow-up group coordinated by ECHA. The intention is to reach an agreement for all remaining open points from the WG meeting. The applicant may be invited to participate as an observer;
- Can review and send comments on the minutes of the WG meeting to the Secretariat;
- Receives the draft BPC opinion and updated assessment report before the BPC meeting. After the meeting, the eCA together with the applicant, will prepare a non-confidential version of the assessment report and the study summaries for the active substance (doc IIIA).

RESULT

OUTCOME OF THE OBLIGATION/PROCESS

The European Commission (COM) takes a decision on the AS approval through an implementing regulation or non-approval through an implementing decision, which will be published in the Official Journal of the European Union. The COM implementing regulation will include the approval and expiry date. The approved active substances will be included in a Union list of approved active substances[13] available on ECHA's website. The approval of an active substance will concern only the product types applied for. The approval of the active substance is not specific to any company (unlike in the case of the BP authorisation which is specific to the company which is responsible for placing the product on the market).

Approval for an active substance can be granted for a maximum period of 10 years (renewable).

Approval for an active substance that meets the substitution criteria (see below) can be granted for a maximum period of seven years (renewable).

Approval for an active substance that meets the exclusion criteria will not be granted unless the substance meets the derogation conditions of Article 5(2) of the BPR (see below). In such cases, approval may be granted for a maximum period of five years (renewable).

The applicant will be included also in the list of active substances and suppliers (Article 95 list) after the validation of the application by the evaluating CA. In the case of an eventual non-approval decision, the entry will be taken off the list. For more information see the Practical Guide chapter on Article 95: List of active substances and suppliers.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES

Exclusion criteria

During the evaluation of applications for active substance approval, active substances will be assessed against the exclusion criteria[14]:

- carcinogens, mutagens and reprotoxic substances category 1A or 1B according to the CLP Regulation[15];
- endocrine disruptors;
- persistent, bioaccumulative and toxic (PBT) substances;

[13] http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances
[14] Ref: Article 5(1) of the BPR.
[15] Regulation (EC) no 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

- very persistent and very bioaccumulative (vPvB) substances.

Such active substances shall not be approved unless conditions set out under Article 5(2) are met: if exposure to them is negligible, they are essential in controlling a serious danger, or where the consequences of not using them are disproportional to the risk avoided.

Substitution criteria

Active substances meeting the substitution criteria are considered as potential candidates for substitution and they will undergo a consultation during the approval process[16]. The criteria are based on the intrinsic hazardous properties in combination with the use and potential exposure and include:

- meeting at least one of the exclusion criteria;
- classification as a respiratory sensitiser;
- toxicological reference values significantly lower than those of the majority of approved active substances for the same PT and use;
- meeting two of the criteria to be considered as PBT;
- causing concerns for human or animal health and for the environment even with very restrictive risk management measures;
- containing a significant proportion of non-active isomers or impurities.

During the evaluation of a BP containing active substances considered as candidates for substitution, a comparative assessment will be performed to assess whether less harmful products are available for the same use[17].

Annex I to the BPR

It is also possible to apply for the active substance to be included in Annex I to the BPR. This annex lists active substances which do not give rise to concern. The process is set out in Regulation (EU) No 88/2014[18], and largely follows that for active substance approval.

BPs containing one or more active substance(s) included on Annex I to the BPR are eligible for a simplified authorisation procedure (where certain conditions are met), as well as the regular product authorisation procedure. More details on the former can be found in the [Practical Guide chapter on simplified authorisation].

[16] Ref: Article 10 of the BPR.
[17] Ref: Article 23 of the BPR.
[18] Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the amendment of Annex I to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

Applicants seeking to include an active substance in **categories 1, 2, 3, 4 or 5** of Annex I to the BPR must apply through R4BP 3 in line with the data requirements listed in Regulation (EU) No 88/2014. Where there is no conclusive evidence of a robust consensus of expert opinion regarding one or more endpoints, an application must contain all additional data necessary to show that the substance does not give rise to the concern.

Applicants seeking to include an active substance in **category 6** of Annex I to the BPR must submit a dossier containing a data package through R4BP 3, equivalent to those submitted for active substance approvals, allowing a full risk assessment for the intended use.

For the time being, the COM has not specified the information requirements and procedure to amend **category 7** of Annex I to the BPR.

More information and instructions for submitting the application for the inclusion on Annex I are given in the *BSM Application instructions: How to submit an application for Active Substance,* available on ECHA's website. ECHA's website also gives further details on the process.

Implications for approval of active substances used in treated articles

The BPR introduces the principle that a treated article cannot be placed on the market unless the active substance contained in the BPs that it is treated with or incorporates is approved for the relevant product types or is included in Annex I[19].

To prevent a market freeze, there were transitional provisions in place.[20]

If the active substance was either under examination in the Review Programme on 1 September 2016 or if an application for the active substance approval was received by that date and/or there was a combination of those active substances plus already approved active substances, then the treated article could stay on the market until the date of approval of the last active substance. If (one of) the active substances is/are not approved (decision adopted) after 1 September 2016, then the active substance had to be off the market within 180 days of that decision.

Where the active substance was not under evaluation on 1 September 2016 (Review Programme or new application) or was the subject of a non-approval decision *before* 1 September 2016, then the treated article could stay on the market until 1 March 2017 (phase-out period).

[19] Ref: Article 58 of the BPR.
[20] Ref: Article 94 of the BPR.

Therefore, where a treated article contains an active substance which is not already approved, or for which an application for approval has not already been made (in the Review Programme or Article 7 of Directive 98/8/EC or Article 11 of the BPR) to continue placing it on the market after 1 September 2016, the company would have needed to submit a complete application dossier on the active substance by 1 September 2016. The active substance dossier must include data on the relevant PT.

If the active substance is not approved (decision adopted after 1 September 2016) for the relevant PT, treated articles which were treated with or incorporated a BP containing this active substance should no longer be placed on the market as from 180 days from the decision of non-approval on the active substance.

If the active substance was not approved (decision adopted before 1 September 2016) for the relevant PT, the relevant treated articles could no longer have been placed on the market as from 1 March 2017.

Precursors of *in situ* generated substances

Precursors placed on the market with the intention to generate active substances *in situ* must be covered under the approved active substance. The *in situ* generated active substance precursor system will require to be approved and product authorisation granted before they can be made available on the market.

Furthermore, for precursors and the *in situ* generated active substances which are not part of the Review Programme, and where the BP did not fall within the scope of Directive 98/8/EC, there were transitional provisions in place[21]. The BP may be made available on the market or used, subject to national laws of the MSs, where an application for the relevant active substance/product type combination was made by 1 September 2016. If such an application was not made by that date, the BP should have been removed from the market by 1 September 2017 (phase out date).

[21] Ref: Article 93 of the BPR.

COST

RELATED FEES

Both ECHA and national fees are applicable for this process.

ECHA fees related to this process are described in the Annex I to *Commission Implementing Regulation (EU) No 564/2013*. Additional fees may be applicable for additional product types and if the substance is a candidate for substitution.

Note that **small or medium-sized enterprise (SME)** may be entitled to a reduced fee, see ECHA's website[22].

National fees related to the application for active substance approval may vary between CAs 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.

For more information about the CA 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
Approval of active substances
http://www.echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances

Annex I amendment
http://www.echa.europa.eu/regulations/biocidal-products-regulation/annex-i-amendment

The Biocidal Products Committee
http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

[22] http://www.echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr

Treated articles
http://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles

Relevant Biocides competent authorities meetings documents
https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a

Guidance on Biocides legislation

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

Submission

- Submission instructions

  Active substances
  http://echa.europa.eu/support/dossier-submission-tools/r4bp/active-substances

  - Approval of an active substance
  - Approval of an active substance in an additional product type
  - Amendment to the conditions of an approved active substance
  - Amendment of Annex I to the BPR (first inclusion of an active substance or amendment of restrictions)

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

- IUCLID Manuals

http://iuclid6.echa.europa.eu/support

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