

Practical guide on Union authorisation of biocidal products

September 2023

ABC

Disclaimer

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Version	Changes	
V1		October 2016
V2	Editorial improvements	December 2021
V3	Clarifications introduced in the Section 'Related Fees' concerning the annual fees of Union authorisations	September 2023

Practical guide on Union authorisation of biocidal products

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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. The second step is the authorisation of each BP consisting of, containing, or generating the approved active substance(s). This document concerns the second step, the authorisation of a BP.

The BPR introduces the possibility to have certain BPs authorised at the Union level. UA allows companies to place their BPs on the market throughout the entire EU/EEA, without the need to obtain single national authorisations. The Union authorisation (UA) will give the same rights and obligations in all the Members States (MSs) as those provided by national authorisations.

UA can be granted for products with similar conditions of use across the EU. Some BPs are precluded from UA, namely: BPs that contain active substances that meet the exclusion criteria (Article 5 of the BPR) and BPs of product-types (PTs) 14, 15, 17, 20 and 21². It is possible to apply for UA of both BPs and biocidal product families (BPFs)³. The relevant provisions regarding UA are set out in Chapter VIII of the BPR.

UA may be viewed as an alternative to applying for national authorisation followed by mutual recognition(s) provided that the products belong to eligible PTs. See the Practical Guide chapter on national authorisation and Practical Guide chapter on mutual recognition.

¹ Ref: Article 17(1) of the BPR.

² Ref: Article 42(1) of the BPR.

³ 'Biocidal product family' means a group of BPs with similar uses, the same active substances, similar composition with specified variations and similar levels of risk and efficacy (ref. Article 3(s) of the BPR).

WHO**WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?**

An application for UA shall 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).

The AH is the person/entity established within the EU and is responsible for the placing on the market of a BP in a particular MS.⁴

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

For the categories of BPs eligible for UA, a pre-defined schedule has been identified which depends on whether the product contains new⁵ or existing⁶ active substances.

A product of a PT eligible for UA containing new active substances, also in combination with existing active substances, may be authorised by UA from 1 September 2013.

For BPs containing only existing active substances, UA could be granted in three different stages, depending on the PT of the product:

- from 1 September 2013 for PTs 1, 3, 4, 5, 18 and 19;
- from 1 January 2017 for PTs 2, 6 and 13;
- from 1 January 2020 onwards for the remaining PTs 7, 8, 9, 10, 11, 12, 16 and 22.

Specific transitional rules apply to the timing of the application for UA as regards existing BPs⁷:

⁴ Ref: Article 3(1)(p) of the BPR.

⁵ 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).

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).

⁷ "Existing BPs" refers in the context of this Practical Guide, to those products which have already been placed on the market of the relevant Member State (as opposed to the EU market as a whole) at the date of approval of the active substance. This concerns biocidal products containing only active substances included in the Review Programme (Article 89(2) of the BPR).

- The UA 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 date⁸. 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 UA must be submitted no later than the 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 UA 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 substances⁹ available on ECHA's website.
- In practice, there is around a two-year time to submit an application for UA for an existing BP from the date on which the decision was taken to approve the last of the product's active substances. The approval date is included in the Annex to the approval decision (Commission Regulation).

It is recommended that UA applications are made well ahead of the deadline to accommodate for possible rejection due to submission or payment failures before the applications are accepted for processing.

Phasing-out periods apply also when the application for UA is rejected or the Commission (COM) decides not to grant the authorisation¹⁰. Existing products must be removed from the market within 180 days of the date of such rejection or decision. The use of existing stocks of that BP may continue until 365 days after the date of rejection or decision.

The applications for UA of new BPs¹¹ are not subject to any deadlines and the application can be made at any point after the decision on the approval of the (last) active substance is adopted. Making available on the market and use of such a new BP can start after the UA is granted.

⁸ Ref: Article 89(3) of the BPR.

⁹ <http://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

¹⁰ Ref: Article 89(4) of the BPR.

¹¹ "New BPs" refers in the context of this Practical Guide, to those products which have not already been placed on the market of any Member State at the date of the approval of the (last) active substance therein.

Make pre-submission six months in advance

A prospective applicant for UA should make a pre-submission to ECHA as soon as possible and at the latest six months before the intended date of submission of a UA application. The pre-submission serves to confirm whether:

- the product falls within the scope of BPR;
- the product has similar conditions of use across the EU; and
- that the appropriate PT has been identified.

WHAT

INFORMATION REQUIREMENTS AND SOURCES



Information requirements

BSM Application instructions: How to submit an application for Union Authorisation outlines the different types of information files that should be prepared and included for the purposes of pre-submission and in an application for UA.

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

The applicant must consider a number of important elements before preparing an application for UA:

- BPs should have similar conditions of use across the EU¹². Applicants are invited to contact ECHA to confirm these through a pre-submission consultation (see below).
- If the applicant is not the data owner of the dossier(s) of the approved active substance(s) contained in the BP, then they will need to provide information to demonstrate access to the relevant data of each of the active substances to fulfil the requirements set out in Annex II to the BPR. This may be achieved by:

¹² CA-Feb13-Doc.5.1.e – Final.

- providing evidence of access to the information submitted for the purposes of the BPD or the BPR through a Letter of Access (LoA) ¹³; or
 - declaring that the relevant data protection period for the information on the active substance has expired. The right to refer to that data by the subsequent applicant is subject to an agreement of ECHA in so far as the applicant can provide evidence that the active substance is technically equivalent to the reference source¹⁴; or
 - waiving of information requirements¹⁵ by providing justifications why specific data of a complete dossier are not relevant to the uses which are claimed to be supported; or
 - providing alternative and equivalent studies, including published studies, instead of those protected¹⁶. Note that some data is mandatory to share. For more information see Practical Guide chapter on data sharing.
- If the active substance(s) contained in the BP has/have a different source (e.g. a different manufacturer or the same manufacturer, but manufactured by a different process) than the reference source(s) used for approval of the active substance(s), the applicant needs to provide a proof of technical equivalence with the application for UA. See the Practical Guide chapter on technical equivalence.
 - If the applicant is the owner of the data on the active substance contained in the dossier used to support the approval of the active substance, but the data was not originally submitted in IUCLID format, the applicant may submit a complete IUCLID file or submit a reference to its own active substance(s) dossier(s).
 - The applicant can also refer to data related to BPs where the data protection period relevant to them has expired. The use of the data by the subsequent applicant is subject to an agreement of ECHA. In such a case, the subsequent applicant must provide evidence that the BP is the same as the one already authorised or an explanation that the differences between them are not significant in relation to the risk assessment and the active substance(s) contained in the BP are technically equivalent to those in the BP already authorised.¹⁷
 - A UA for a BP may cover various PTs. The applicant should make sure that the PT(s) is/are relevant to the use purpose and pattern

¹³ Ref: Article 20(a)(a)(iii) and Article 59(1)(a) of the BPR.

¹⁴ Ref: Article 64(1), first subparagraph, and Article 59(1)(b) of the BPR.

¹⁵ Ref: Article 21(1) and (2) of the BPR.

¹⁶ Ref: Article 20(1)(a)(iii) of the BPR.

¹⁷ Ref: Article 64(1), subparagraph 2, of the BPR.

of the BP.

- Special attention should be given to the use instructions (e.g. use patterns, application rates, categories of users, risk mitigation measures if applicable) and label claims as they are also used for the purpose of the risk and efficacy assessment.
- For any uses not evaluated earlier during the active substance approval, a risk assessment has to be conducted and included in the product authorisation application.
- The efficacy data requirements are more elaborate at the product authorisation stage than for the active substance approval.
- Careful consideration needs to be given to the design of the summary of the product characteristics (SPC) as it is also critical for the BP label information¹⁸.
- 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 applying for UA. For more information on the recognition of an SME status and on how to submit relevant documentation see [ECHA's website](http://www.echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr)¹⁹.

HOW

PROCEDURE TO FOLLOW



Pre-submission phase

To make a pre-submission for UA, the applicant should upload to the wizard "UP-APP – Pre-submission for Union authorisation" in R4BP 3, the supporting document for the pre-submission, together with a draft of the Summary of Product Characteristics (SPC) in .xml format.

Based on the pre-submission information, ECHA will launch a consultation of MSs and COM. ECHA will inform the prospective applicant of the outcome of the pre-submission consultation.

Applicants will find the relevant information and instructions in *BSM Application instructions: How to submit an application for Union Authorisation*.

¹⁸ CA-May14-Doc.5.6 – Final

¹⁹ <http://www.echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr>

Applications for Union authorisation

Creation of a IUCLID dossier

The applicant seeking to obtain UA needs 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

The application for UA should be submitted 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 validation and evaluation. During the evaluation (365 days unless additional information is requested) of a BP containing active substances that are considered as candidates for substitution, a comparative assessment will be performed. This will assess whether less harmful products are available for the same use. Evaluation is followed by a peer review (180 days) performed by ECHA through the Biocidal Products Committee (BPC) which issues an opinion. Based on the BPC opinion, COM takes a decision on the authorisation.²⁰

Within 30 days after the BPC opinion is sent to COM, the applicant has to submit the SPC in all official languages of the EU.

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.

To facilitate the evaluation of the application, it would be preferable that the applicant submits the application for UA to the CA which was

²⁰ Ref: Articles 43-44 of the BPR.

eCA for the approval of the active substance contained in the product. Applicants are however free to choose their eCA.

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

BSM Application instructions: How to submit an application for Union Authorisation.

More information related to invoicing and R4BP 3 can be found in the *BSM Process of invoicing in R4BP 3*.

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

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 Groups²¹ available on ECHA's website. The Code of conduct sets out general rules and responsibilities of applicants, explains the mechanism by which applicants may participate in meetings and explains their obligations regarding confidentiality and the rules regarding documentation from applicants.

To participate in 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.

²¹ https://echa.europa.eu/documents/10162/763823/bpc_conduct_code_applicants_en.pdf

Applicants are also given an opportunity to participate at other stages of the process as described in the Working Procedure²² available on ECHA's website. The document describes the process and timelines in detail.

RESULT

OUTCOME OF THE OBLIGATION/PROCESS



To grant the authorisation, the conditions summarised in Article 19 of the BPR must be met. If there is a positive decision, COM will adopt an Implementing Regulation including the conditions for the validity of authorisation, which will be published in the Official Journal of the European Union. UA for a BP can be granted for a maximum period of 10 years.

For BPs containing an active substance that is a candidate for substitution, UA may be granted for a period not exceeding five years. The authorisation cannot be granted for longer than the approval period of the active substance(s) contained therein. The list of BPs with UA will be published on ECHA's website.

TO NOTE

EXCEPTIONS AND PARTICULAR CASES



Authorisation of same biocidal products

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

Union authorisation granted for a BPF

If a UA is granted for a BPF, the AH shall notify ECHA and COM through R4BP 3 for each BP within this family before placing it on the EU market, except where a particular BP is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes²³.

Union authorisation of BPs containing only active substance(s) from Annex I to the BPR

Normally, when an active substance is on Annex I to the BPR, the simplified authorisation is appropriate. However, if that is not available

²² Union authorisation applications: working procedure for the BPC, https://echa.europa.eu/documents/10162/763823/bpc_working_procedure_union_authorisation_en.pdf

²³ Ref: Article 17(6) of the BPR.

because the BP does not fulfil Article 25(b), (c) or (e) of the BPR, it remains a possibility to apply for UA²⁴.

Provisional authorisation

For a BP containing a new active substance not yet approved, a provisional authorisation can be granted by COM for a period not exceeding three years, renewable for one year²⁵.

Such a provisional authorisation may be granted only after the MSCA, which evaluated the new active substance has submitted a recommendation for approval of this substance and ECHA which received the application for the provisional authorisation consider that the BP complies with the provisions laid down in Article 19(1) points (b), (c) and (d) considering the factors set out in Article 19(2) of the BPR.

More information and instructions for submitting the application for provisional Union authorisation through R4BP 3 are given in *BSM Application instructions: How to submit an application for Union Authorisation*, available on ECHA's website.

COST



RELATED FEES

The fees related to UA applications payable to ECHA are described in Annex II and Annex III to *Commission Implementing Regulation (EU) No 564/2013*.

Note that **SMEs** may be entitled to a reduced fee upon recognition by ECHA of the SME status of the applicant, see ECHA's website²⁶.

The **annual fees** for each biocidal product or product family authorised by the Union 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.

The fees related to UA applications payable to the eCA may vary between the CAs and are established in the 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 CA or its helpdesk.

²⁴ Ref: Article 19(1) of the BPR.

²⁵ Ref: Article 55(2) of the BPR.

²⁶ <http://www.echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr>

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**Union authorisation**

<http://echa.europa.eu/web/guest/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation>

Relevant Biocides competent authorities meetings documents

<https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a>

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

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

CA-Feb13-Doc.5.1.b.a – Final: Summary of the biocidal product characteristics for a biocidal product and biocidal product family;

CA-Feb13-Doc.5.1.e – Final: Note for Guidance on the Definition of Similar Conditions of Use across the Union

CA-Sept13-Doc.5.1.g – Final.Rev1: Application of BPR procedures to applications for product authorisation submitted under the BPD regime and on which a decision has not been taken by 1 September 2013

CA-Sept13-Doc.6.2.a – Final.Rev.1: Authorisation of skin sensitizer biocidal products requiring PPE for non-professional users;

CA-Sept13-Doc.6.2.b Rev.1: Authorisation under the Biocidal Products Regulation of products containing more than one existing active substance or belonging to more than one product-type.

CA-March14-Doc.5.4- Final: Comparative assessment of biocidal products

CA-May14-Doc.5.6 – Final: Discussion paper on the content of label of biocidal products with regard to the authorised uses in the SPC

CA-May14-Doc.5.6 – Final: Discussion paper on the content of label of biocidal products with regard to the authorised uses in the SPC

CA-Sept14-Doc.5.9: Provisional authorisations granted or to be granted in accordance with Article 55(2) of the BPR and conversion to definitive authorisations

Guidance on biocides legislation

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

Submission

- **Submission instructions**

Union authorisation

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

- Getting started – pre-submission
- Union authorisation
- Authorisation of the same biocidal product (pending)

- **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: using R4BP 3
- BSM Technical guide: using SPC
- BSM Application instructions: Union authorisations
- 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>

