

Practical Guide
on Biocidal Products Regulation

ABC

LEGAL NOTICE

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.

Practical guide on Biocidal Products Regulation

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Approval of active substance

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 substances².

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 substance³ 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

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).

eligible for inclusion into the Review Programme⁴.

For active substances contained in certain products not covered by Directive 98/8/EC but falling under the BPR⁵ available on the market before 1 September 2013, there is a deadline of 1 September 2016 for the submission of the applications for the relevant AS in those products. Where such an application is not made by the deadline, the product must be removed from the market by 1 September 2017.

BPs that contain only existing active substances⁶ 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: active substances*, 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 enquire from ECHA about 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 in spite of every effort of the applicant, ECHA can grant permission to the applicant to refer to the data. For more information see Practical Guide chapter on data sharing.
- 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

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. (Note that the new Review Programme Regulation is likely to be published in autumn 2014.)

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).

HOW



status of the applicant, before submitting an application for active substance approval. For more information on the recognition of an SME status and on how to submit relevant documentation see [ECHA's website](#)⁷.

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: using IUCLID*, available on ECHA's website;
- *BSM Technical guide: using R4BP 3* 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 substitution⁸, a public consultation will be launched in parallel with the peer review. On the basis of 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.

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:

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.

BSM Technical guide: using R4BP 3 BSM Application instructions: active substances

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 explains their obligations regarding confidentiality 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 in the process also at other stages of the process as described in the *Working Procedure*¹¹ available on ECHA's website. The document describes the process and timelines in detail. In accordance with the working procedure, the applicant:

- Should review, where a public consultation is required, the text proposal for the public 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

¹⁰ http://echa.europa.eu/documents/10162/4221979/bpc_conduct_code_applicants_en.pdf

¹¹ Biocidal active substance approval: working procedure for the BPC, http://echa.europa.eu/documents/10162/4221979/bpc_working_procedure_active_substance_en.pdf

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*¹² 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).

¹² <http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>

TO NOTE



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 [Practical Guide chapter on Article 95: List of active substances and suppliers].

EXCEPTIONS AND PARTICULAR CASES

Exclusion criteria

In the course of evaluation of applications for active substance approval, active substances will be assessed against the exclusion criteria¹³:

- carcinogens, mutagens and reprotoxic substances category 1A or 1B according to the CLP Regulation¹⁴;
- endocrine disruptors;
- persistent, bioaccumulative and toxic (PBT) substances;
- 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 public consultation during the approval process¹⁵. 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 use¹⁶.

Annex I to the BPR

¹³ Ref: Article 5(1) of the BPR.

¹⁴ 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

¹⁵ Ref: Article 10 of the BPR.

¹⁶ Ref: Article 23 of 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 88/2014¹⁷, 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].

Applicants seeking to include an active substance in **categories 1, 2, 3, 4 or 5** of Annex I to the BPR must submit an application 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: active substances*, 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.¹⁸

To prevent a market freeze, there are transitional provisions in place.¹⁹

If the active substance is either under examination in the Review Programme on 1 September 2016 or if an application for the active substance approval is received by that date and/or there is a combination of those active substances plus already approved active substances, then the treated article can stay on the market until the date of approval of the last active substance. If (one of) the active substances is/are not

¹⁷ 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.

¹⁸ Ref: Article 58 of the BPR.

¹⁹ Ref: Article 94 of the BPR.

approved (decision adopted) after 1 September 2016, then the active substance must be off the market within 180 days of that decision.

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

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) in order to continue placing it on the market after 1 September 2016, the company will need 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 is not approved (decision adopted before 1 September 2016) for the relevant PT, the relevant treated articles should no longer be 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 are transitional provisions in place²⁰. 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 is made by 1 September 2016. If such an application is not made by that date, the BP should be removed from the market by 1 September 2017 (phase out date).

²⁰ 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*²¹.

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://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>

²¹ <http://www.echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr>

The Biocidal Products Committee

» <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee>

Treated articles

» <http://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles>

Relevant Biocides competent authorities meetings documents

» <https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942>

Guidance on Biocides legislation

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

Submission

• Submission instructions

Active substance

» <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>

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 Application instructions: active substances

» http://www.echa.europa.eu/documents/10162/14938692/bsm_04_active_substances_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>

Renewal of an approval of active substance

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

Active substances should be regularly examined to take account of developments in science and technology. Therefore, an active substance is approved for a maximum of 10 years. The active substance is approved for less than 10 years in particular when it meets the exclusion or substitution criteria set out under the Biocidal Products Regulation ((EU) No 528/2012) (BPR). An application to renew the approval of an active substance/product-type (PT) combination must be made before the initial approval period expires. Chapter III of the BPR addresses the procedure of renewal including conditions, which have to be met for a renewal to be granted.

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Usually, the applicant is expected to be the same person who applied for the original active substance approval; however, a different company can also apply. The application can be made on behalf of a task force, including new or different members from the original applicant(s).

In particular, when several companies are seeking renewal of the same active substance/PT combination, they are encouraged to create a task force and make one submission. The applicant may have a person/entity handling the practical issues related to the application on its behalf (e.g. a consultant).

Note that the renewal process also has consequences for inclusion on the Article 95 list. See the Practical Guide chapter on *Article 95: List of active substances and suppliers*.

WHEN



TIMELINES RELATED TO THE OBLIGATION/PROCESS

The application for renewal of the active substance approval for a given PT should be submitted to the European Chemicals Agency (ECHA) at the latest 550 days before the expiry date of the approval of the active substance for this PT. If the application relates to more than one PT, it should be made at the latest 550 days before the earliest expiry date.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

An applicant is obliged to provide in all cases²²:

- the name of the competent authority (CA) that it proposes should evaluate the application for renewal and written confirmation that the CA agrees to do so;
- all data required under Article 20 of the BPR that has been generated since the initial approval or previous renewal has been granted i.e. new relevant data regarding requirements listed in Annexes II or III to the BPR (including data requested or answers to issues raised and left open at the time of the initial approval);
- an assessment of whether the conclusions of the initial or previous assessment of the active substance are still valid;
- any supporting information related to that assessment, if not already available in R4BP 3.

For active substances that meet the exclusion criteria set out under Article 5(1) of the BPR, it is also required to provide justifications that at least one of the conditions set out in Article 5(2) is met, to justify that the approval of the active substance may be renewed.

These justifications for derogation should be provided for each individual Member State (MS), unless the grounds for derogation are the same and valid for all MSs across the EU.

In addition, to make sure that the overall data package for the active substance is available for renewal or review, all studies that were assessed for the first approval of the active substance should be reported and attached in the IUCLID dossier.

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's website.

Issues to consider:

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 submitting an application for renewal. For more information on the recognition of an SME status and on how to

²² Ref: Article 13 of the BPR

HOW



submit relevant documentation see ECHA website²³.

PROCEDURE TO FOLLOW

Creation of a IUCLID dossier:

The applicant seeking renewal of an approval of an active substance needs to submit the data using an IUCLID format.

The following documents describe how to create a complete 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.

Submitting and processing an application:

The application for renewal of the active substance approval 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 evaluating CA (eCA) for evaluation.

At an early stage, the eCA decides whether a full evaluation of the application for renewal is necessary or not. Full evaluation takes 365 days and allows applicants to submit additional data requested by the eCA. If a full evaluation is not necessary, the evaluation has to be completed in 180 days.

Evaluation is followed by a peer review performed by ECHA through the Biocidal Products Committee (BPC) which issues an opinion. The duration of the peer review depends on the type of the evaluation: 270 days for a full evaluation and 90 days if the eCA evaluation is not a full one. On the basis of the BPC opinion, the European Commission (COM) takes a decision on the renewal of the approval of the active substance²⁴.

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, the application may be rejected.

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

- *BSM Technical guide: using R4BP 3*
- *BSM Application instructions: active substances*

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

²³ <http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr>

²⁴ Ref: Articles 13-14 of the BPR

RESULT



OUTCOME OF THE OBLIGATION/PROCESS

On the basis of the ECHA opinion, the COM shall decide whether or not to renew the approval of the active substance/PT²⁵.

The renewal of an approval of an active substance shall be for a maximum period of 15 years for all PTs to which the approval applies. If the active substance meets the substitution criteria, the approval will be renewed for a maximum of seven years with the exception of substances meeting exclusion criteria, which are renewed as long as they fulfil the criteria of Article 5(2) of the BPR. Such substances may be renewed for a maximum of five years.

If the outcome of the process is that the active substance approval is not renewed or if the conditions for approval are amended, the MSs or, in the case of a Union authorisation, the COM, shall cancel or, where appropriate, amend the authorisations of biocidal products (BPs) in the PTs concerned containing that active substance, and shall grant a period of grace for disposal, making available on the market and use of the BPs. The period of grace shall not exceed 180 days for the making available on the market, and an additional period of 180 days for the disposal and use of the BPs concerned. This is applicable unless continuing to use or make the BP available on the market constitutes an unacceptable risk to human health, animal health or the environment.

Where the approval of the active substance is likely to expire before a decision has been taken on its renewal, the COM may adopt a decision postponing the expiry date of approval for a period sufficient to enable it to examine the application.

COST



RELATED FEES

Both ECHA and national fees are applicable for this process.

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

Note that small or medium-sized enterprises (SMEs) may be entitled to a reduced fee, see ECHA's website²⁶.

National fees related to the application for renewal of 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.

²⁵ Ref: Article 12(1) of the BPR

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

HELP



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

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

» <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances>

Relevant Biocides competent authorities meetings documents

» <https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942>

CA-Sept14-Doc.5.2 – Final – Complementary guidance regarding the renewal of anticoagulant rodenticide active substances and biocidal products

Guidance on Biocides legislation

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

Submission

- Submission instructions

Renewal of an active substance approval

» <http://echa.europa.eu/support/dossier-submission-tools/r4bp/renewal-active-substance-approval>

- Biocides Submission Manuals

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

BSM Technical guide: using IUCLID

- » http://echa.europa.eu/documents/10162/14938692/bsm_01_using_iuclid_en.pdf

BSM Technical guide: using R4BP 3

- » http://echa.europa.eu/documents/10162/14938692/bsm_02_using_r4bp3_en.pdf

BSM Application instructions: active substances

- » http://echa.europa.eu/documents/10162/14938692/bsm_04_active_substances_en.pdf

BSM Process of invoicing in R4BP 3

- » http://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>

Review of an approval of an active substance

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

Where there are significant indications that the biocidal active substance no longer meets the conditions set in Article 4(1), or where relevant in Article 5(2), of the Biocidal Products Regulation ((EU) No 528/2012) (BPR), the European Commission (COM) may at any time review the approval of an active substance for one or more product-types (PTs)²⁷.

The COM may also review the approval of an active substance at the request of a Member State (MS) if there are indications that the use of the active substance in biocidal products (BPs) or treated articles raises significant concerns about the safety of such BPs or treated articles.

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

The review of the approval of active substance is started by the COM on its own initiative or at the request of an MS. The initial applicants for the approval will be given an opportunity to comment (see below).

WHEN



TIMELINES RELATED TO THE OBLIGATION/PROCESS

The review of an active substance approval may be initiated at any time.

²⁷ Ref: Article 15 of the BPR

WHAT**INFORMATION REQUIREMENTS AND SOURCES**

On a case-by-case basis, the COM, an MS or the European Chemicals Agency (ECHA) may use any available information related to the active substance under review.

HOW**PROCEDURE TO FOLLOW**

The COM or an MS indicates the need for a review of an approved active substance. The COM will then make the information that it is carrying out a review publicly available.

The COM will give an opportunity for the initial applicant to submit comments which are taken into account in its review. The COM may consult ECHA on any questions of a scientific or technical nature related to the review of approval of the active substance in question.

When such a consultation is made, ECHA will prepare an opinion within 270 days (through the Biocidal Products Committee (BPC)) and submit it to the COM. The COM will decide whether there is a need to amend or cancel the approval of the active substance.

There is no deadline given in the BPR for the length of the process.

The COM may decide to cancel or amend the approval of an active substance for one or more PTs.

RESULT**OUTCOME OF THE OBLIGATION/PROCESS**

Where the COM cancels the approval or amends the conditions for approval it will adopt an implementing regulation. Where the approval is cancelled, the active substance will be removed from the Union list of approved active substances.

MSs or, in the case of a Union authorisation, the COM shall cancel or amend the authorisations of BPs in the PTs concerned containing that active substance, and shall grant a period of grace for the disposal, making available on the market and use of the BPs²⁸. The period of grace shall not exceed 180 days for the making available on the market, and an additional period of 180 days for the disposal and use of the BPs concerned. This is applicable unless continuing to use or make the BP available on the market constitutes an unacceptable risk to human health, animal health or the environment.

²⁸ Ref: Article 15(3) of the BPR

COST



RELATED FEES

No fees are applicable for this process.

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://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances>

Annex I amendment

» <http://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>

Treated articles

» <http://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles>

Relevant Biocides competent authorities meetings documents

» <https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942>

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>

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

Q&As

» <http://echa.europa.eu/support/qas-support>

Article 95: List of active substances and suppliers

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

Article 95 of the Biocidal Products Regulation (EU) No 528/2012 (BPR) aims to ensure the equal treatment of persons placing active substances on the market and to establish a level playing field as quickly as possible on the market for existing active substances. To achieve this, the European Chemicals Agency (ECHA) ECHA publishes a list of relevant active substances and suppliers (substance and product).

Since 1 September 2015, a BP (consisting of, containing, or generating a relevant substance) cannot be made available on the EU market if the substance supplier or product supplier is not included in the Article 95 list (for the product-type (PT) to which the product belongs).

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Article 95 creates an obligation on persons making available BPs on the market to make sure that either the “substance supplier” or “product supplier” is included in the list published by ECHA under Article 95 (for the PT to which the product belongs).

A **substance supplier** is defined as a person established in the EU who manufactures or imports a relevant substance, on its own or in biocidal products⁵.

A **product supplier** is defined as a person established in the EU who manufactures or makes available on the market a biocidal product consisting of, containing or generating a relevant substance.

- Those who are placed automatically on the list and do not have to make a submission to ECHA under Article 95, namely:

- Participants in the Review Programme²⁹.
 - Supporters of new active substances (those who have submitted a dossier under Article 11 of Directive 98/8/EC (BPD) or under Article 7 of the BPR).
 - Submitters of third party dossiers (alternative active substance dossiers submitted as part of a product authorization application).
- Alternative suppliers who must make a submission to ECHA under Article 95 to be included on the list. Such entities would normally include:
 - Manufacturers of active substances in the Review Programme who were not participants in the Review Programme.
 - Importers of active substances (on their own or in BPs) in the Review Programme who were not participants in the Review Programme.
 - Manufacturers of new active substances who did not support the approval of the active substance.
 - Importers of new active substances (on their own or in BPs) who did not support the approval of the active substance.
 - Manufacturers of BPs, if the supplier of the active substance(s) used in their products is not on the list.
 - Entities which make BPs available on the market if the supplier of the active substance(s) used in their products is not on the list.

Not all companies requires being included on the Article 95 list. It is sufficient that one company in the supply chain is listed.

The Article 95 list is structured per active substance. The names of the suppliers (and their country) are listed and their role as “substance supplier” and/or “product supplier” is indicated. The relevant PT and the date of inclusion of the entity in the list are also indicated.

WHEN



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

Since 1 September 2015, a BP (consisting of, containing, or generating a relevant substance) cannot be made available on the EU market if the substance supplier or product supplier is not included in the list for the PT to which the product belongs.

The concerned companies (alternative suppliers) need to submit an

²⁹ Review Programme is the term used for the work programme established by the Commission under Article 16(2) of the BPD for the assessment of existing active substances established, which is continued under Article 89(1) of the BPR, and implemented under Commission Delegated Regulation (EU) No 1062/2014

application that is compliant with Article 95 to ECHA well ahead of making available BPs on the market to accommodate for the time needed for the processing of the applications.

Not all active substances are at present “relevant substances” for the purpose of Article 95. It is only when the evaluating competent authority has validated (completeness check) the active substance approval application that the substance is added to the Article 95 list. This may not be until late 2016 in the case of Article 93 applications or later in the case of applications further to a notification under Commission Delegated Regulation (EU) No 1062/2014.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

Companies can submit to ECHA a complete substance dossier³⁰, a LoA, a combination of a dossier and a LoA or a reference to an existing dossier for which all data protection periods have expired. ECHA verifies whether the dossier, or the LoA, is adequate.

A template LoA can be found in the Practical Guide Special Series on Data Sharing – Letters of Access.

BSM Application instructions: active substances explains what types of information files should be prepared and included in the application for inclusion on the Article 95 list. For further information on information requirements companies are recommended to consult the *Guidance on active substance suppliers*³¹ as well as Annex II to the BPR and the *Guidance for information requirements for Biocides*, available on ECHA's website.

Issues to consider:

The duplication of tests on vertebrates for the purposes of the BPR is prohibited. Any person intending to perform such tests should make an inquiry to ECHA to find out if the tests have already been submitted to ECHA or the MSCAs under the BPD or the BPR. If the relevant studies have already been submitted, ECHA will give the inquiring company the contact details of the data submitter.

Owners of existing data and prospective applicants are obliged to make every effort to share data involving tests on vertebrates. Furthermore, for the submissions under Article 95 relating to substances listed in the Review Programme,³² the respective parties are also obliged to make every effort to share all toxicological, ecotoxicological and environmental

³⁰ In accordance with Article 95(1) of the BPR, a dossier is deemed “complete” when it fulfils the information requirements set out in Annex II to the BPR or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive.

³¹ Under revision (September 2014)

³² Ref: Annex II to Regulation (EC) No 1451/2007

HOW



fate and behaviour studies (including those not on vertebrates).

For more information see the Practical Guide Special Series on Data Sharing.

PROCEDURE TO FOLLOW

Creation of a IUCLID dossier:

The entity seeking inclusion on the Article 95 list is required to submit the required information 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.

For a submission based on a LoA to a complete substance dossier, no IUCLID dossier is required.

Submission and processing of an application using R4BP 3:

The application for inclusion on the Article 95 list must be submitted through R4BP 3. Following confirmation that the submission has passed the initial checks by ECHA, the application will be verified by the Agency. ECHA will send a draft decision to the applicant for comments, and at this time it is also possible for the applicant to submit missing information. ECHA then takes a decision on the inclusion of the supplier in the Article 95 list.

Applicants need to monitor the status of their submission and receive/react to requests from ECHA in R4BP 3. If the applicant fails to meet a deadline, e.g. for payment of fees or to comment or submit additional information further to a draft decision, the application may be rejected. Only one update of the dossier is permitted. Updates of the dossier on the initiative of the applicant are not possible.

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: using R4BP 3;
- BSM Application instructions: active substances

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

RESULT



OUTCOME OF THE OBLIGATION/PROCESS

If a positive decision is made to include a company in the Article 95 list, it will be included on the Article 95 list as a substance and/or product supplier (as appropriate) for the relevant active substance and PT. The related entry is published by ECHA in its regular update of the Article 95 list.

If a negative decision is made, the company will not be included on the list, and may consider submitting a new application.

Since 1 September 2015, a BP (consisting of, containing, or generating a relevant substance) cannot be placed on the EU market if the substance supplier or product supplier is not included in the list for the PT to which the product belongs.

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

Relation with the technical equivalence process

The assessment of technical equivalence for Article 95 purposes is not mandatory under the BPR and inclusion of a supplier in the Article 95 list does not automatically indicate the technical equivalence of their active substance.

Nevertheless, a company can request a technical equivalence assessment under Article 54 of the BPR (or a chemical similarity check, if a decision to approve the active substance has not yet been adopted) from ECHA before applying to be listed in the Article 95 list to make sure that the data they are about to obtain from an already listed company are relevant for its active substance.

For more information see the Practical Guide chapter on technical equivalence.

Annex I to the BPR

Except for the substances listed in category 6, all other active substances listed in Annex I are not within the scope of Article 95. As a consequence, BPs containing such active substances can be made available on the market after 1 September 2015, provided they are authorised.

For substances listed in category 6 of Annex I, companies which make available on the market BPs which consist of, contain, or generate those substances will have to comply with the provisions of Article 95. Therefore, the same rules apply as for other active substances.

Treated articles

Producers or importers of treated articles are not subject to the

COST

requirements of Article 95.

RELATED FEES

Fees related to this process are described in the fifth entry of Annex III to *Commission Implementing Regulation (EU) No 564/2013*.

HELP**TO CONTACT FOR FURTHER INFORMATION****ECHA Helpdesk**

» <http://echa.europa.eu/contact/helpdesk-contact-form>

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

Active substances and suppliers

» <http://echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers>

Guidance on biocides legislation

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

Submission

- **Submission instructions**

Active substances

» <http://www.echa.europa.eu/support/dossier-submission-tools/r4bp/active-substances>

- Inclusion on the list of active substances and suppliers (Art. 95)

- **Biocides Submission Manuals**

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

BSM Technical guide: using R4BP 3

» <http://www.echa.europa.eu/documents/10162/14938692/>

[bsm_02_using_r4bp3_en.pdf](#)

BSM Application instructions: active substances

» http://www.echa.europa.eu/documents/10162/14938692/bsm_04_active_substances_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

» [Questions and Answers on Active substances and suppliers](#)

Technical equivalence

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The intention of the provision of Article 54 of the Biocidal Products Regulation EU No 528/2012 BPR is to enable the European Chemicals Agency ECHA to determine the similarity of the chemical composition and hazard profile of active substances that may differ from the one that was evaluated for the purpose of approval (reference source).

The assessment of technical equivalence (TE) is required when the active substance to be used in a biocidal product (BP) differs from the reference source of the approved active substance by having a different manufacturing process, a different manufacturing location or a different manufacturer.

A positive decision on the TE of the active substance issued by ECHA is a required element in the application for a BP authorisation (Commission Delegated Regulation (EU) No 837/2013 amending Annex III to the BPR).

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Manufacturers or suppliers of alternative sources of active substances (including the Review Programme³³ participants and supporters of new active substances following a change in the reference source) who wish to sell their actives to product formulators. Formulators may also apply for TE in particular when the manufacturers or suppliers of their active substance do not have an interest to apply for TE.

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

³³ 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 Biocidal Products Regulation. (Note that the new Review Programme Regulation is likely to be published in autumn 2014.)

WHEN



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

Companies may request the assessment of the TE of their active substance once the decision on the approval of the active substance has been adopted. Since ECHA's decision on TE has to be included in an application for a BP authorisation, the deadlines relevant for BP authorisation applications (where applicable) need to be taken into account when submitting an application for TE.

For BPs containing existing active substances, and already on the market under national laws, the BP authorisation application must be made by the date of approval of the active substance, as explained in the Practical Guide chapters on national authorisation and Union Authorisation, otherwise the products must be removed from the market within 180 days of the active substance approval date. (A product authorisation application can also be made at a later date but until it is granted the products must be removed from the market).

For BPs containing new active substances, and therefore not already available on the market, there is no deadline for the product authorisation application.

In all cases, however, TE applications should be made well ahead of the foreseen submission date of the respective product authorisation application to accommodate for the time needed for the processing of the TE applications.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

BSM Application instructions: technical equivalence and chemical similarity, available on ECHA's website, explains what types of information files should be prepared and included in an application for TE.

Section 3.3 in the *Guidance on applications for technical equivalence*, available on ECHA's website, provides more advice on information requirements of the TE application and provides suggestions for further reading. For further details on the relevant information requirements, applicants should refer to Annex II to the BPR and the *Guidance for information requirements for Biocides*, available on ECHA's website.

Applicants should be aware when compiling their dossiers that the information requirements differ if they choose to apply for Tier I or Tier II TE assessment. Tier I assessment focuses on the substance identity and the impurity profile. In addition to these requirements, for Tier II toxicological and ecotoxicological data are also evaluated.

It should be noted that a five-batch analysis is always requested and that the spectral data is used to confirm the identity of the active substance. The methods of analysis should also be validated.

HOW

**Issues to consider:**

The fee for the application for assessment of the TE will be based on the type of the application, Tier I or Tier II. It is in the responsibility of the applicants to assess which tier is appropriate for their case.

When applying for a Tier II assessment, a self-assessment of TE with the relevant toxicological and ecotoxicological data needs to be included in the application. The list of endpoints for the approved reference active substances is available from the CA Biocides [CIRCABC website](#).³⁴

The applicants should be aware that each dossier can only refer to one alternative source. If several alternative sources need assessment, for example, if the company obtains their active substance from more than one source which differ in the manufacturing process, the company needs to submit separate applications for each alternative source of the active substance.

PROCEDURE TO FOLLOW**Creation of a IUCLID dossier:**

The applicant seeking assessment of TE is required to submit the data using an IUCLID format.

For more detailed instructions, see section 2.5 of the *BSM Application instructions: technical equivalence and chemical similarity* on how to include all required information in an IUCLID dataset.

The following documents describe in further detail how to create and complete an 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:

The application for TE should be submitted through R4BP 3. Following confirmation that the submission has passed the initial checks by ECHA, the application will be evaluated by ECHA (90 days unless additional information requested). ECHA takes a decision on the TE.

Applicants need to monitor the status of their submission and receive/react to requests from ECHA 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. Only one update of the dossier is permitted in relation to a particular request. Updates of the dossier on the initiative of the applicant are not possible.

Applicants will find the relevant information and instructions for

³⁴ <https://circabc.europa.eu/w/browse/c8291b94-5b48-440b-ba6d-f03fa3777109>

submitting and following up the application for TE through R4BP 3 in the following submission manuals available on ECHA's website:

- *BSM Technical guide: using R4BP 3.*
- *BSM Application instructions: technical equivalence and chemical similarity.*

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

RESULTS



OUTCOME OF THE OBLIGATION/PROCESS

On the basis of the assessment made by ECHA, applicants will receive a decision through R4BP 3 that:

- 1) For Tier I: either the TE cannot be concluded upon and the applicant should proceed to Tier II OR that the alternative and reference sources are equivalent.
- 2) For Tier II: the alternative and reference sources are/are not equivalent.

The decision must be attached to the application for product authorisation or where relevant to the application for an administrative change to an existing authorisation to be submitted under Implementing Regulation (EU) No 354/2013.

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

Chemical similarity check

If the active substance is not yet approved, companies can request ECHA to check the chemical similarity of the relevant sources of the active substances. Two types of applications can be submitted: individual applications and joint applications. The chemical similarity check does not replace the TE assessment obligation when the active substance is eventually approved.

The principles that apply for the chemical similarity check service are similar to those applied for TE.

More information about the chemical similarity check service and the different application types can be found on ECHA's website and in the *BSM Application instructions: technical equivalence and chemical similarity*.

Relation with Article 95

It should be noted that the assessment of TE is not required for Article 95 purposes. The listing in the active substances and suppliers list (Article 95 list) does not automatically imply the TE to an active substance. For more information on inclusion on the Article 95 list [see Practical Guide chapter Article 95: List of active substances and suppliers](#).

Nevertheless, a company may benefit from requesting a TE assessment from ECHA before applying to be listed in the Article 95 list. This is relevant where the company intends to acquire rights to data used to establish the reference source during the active substance approval for the purposes of inclusion on the Article 95 list. It will provide some assurances to the company that the data they are about to acquire rights to are relevant for their active substance.

Where the active substance is not yet approved, applying for the chemical similarity check by an alternative supplier before applying for inclusion on the Article 95 list may provide similar benefits. The fact that, in this case, the reference source is temporary and the active substance may not eventually be approved brings its own risks.

COST



RELATED FEES

Fees related to this process are described in the first entry of Annex III to *Commission Implementing Regulation (EU) No 564/2013*.

HELP



TO CONTACT FOR FURTHER INFORMATION

ECHA Helpdesk

» <http://echa.europa.eu/contact/helpdesk-contact-form>

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

Technical equivalence

» <http://echa.europa.eu/regulations/biocidal-products-regulation/technical-equivalence>

Chemical similarity check service

» <http://echa.europa.eu/regulations/biocidal-products-regulation/chemical-similarity-check-service>

Guidance on Biocides legislation

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

Submission

• Submission instructions

Technical equivalence and chemical similarity

- » <http://echa.europa.eu/web/guest/support/dossier-submission-tools/r4bp/technical-equivalence-and-chemical-similarity>

- Assessment of technical equivalence
- Chemical similarity check service

• 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 Application instructions: technical equivalence and chemical similarity

- » http://www.echa.europa.eu/documents/10162/14938692/bsm_05_technical_equivalence_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>

National authorisation

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).³⁵ 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 second step, the authorisation of a BP³⁶.

The national authorisation (NA) of a BP is granted by the competent authority of the Member State (MSCA) where the BP will be made available on the market (receiving MS) and is only valid for the approved terms and conditions stated therein. To avoid duplication of the evaluation procedure, the product authorisation granted in one MS can be recognised in other MS through the mutual recognition procedure³⁷. For more details on mutual recognition see [Practical Guide chapter on Mutual recognition](#).

The same rules as for a single BP apply also for a biocidal product family (BPF)³⁸.

Certain BPs may be authorised at Union level, without the need to obtain single NAs. For more information see [the Practical Guide chapter on Union authorisation](#).

³⁵ Ref: Article 17(1) of the BPR.

³⁶ Ref: Chapter IV of the BPR.

³⁷ Ref: Articles 33 and 34 of the BPR.

³⁸ '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 NA can be made by, or on behalf of, the prospective authorisation holder (AH). Accordingly, the prospective AH may have a person/entity handling the practical issues related to the application on its behalf (e.g. a consultant).

The AH is the person/entity established within the EU/EEA who is responsible for the placing on the market of a BP in a particular MS³⁹.

WHEN



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

The application for NA can, in general, be made at any time after the decision to approve the active substance has been adopted.

Specific transitional rules apply to the timing of the application for NA with regards to existing BPs⁴⁰:

- The BP authorisation 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.⁴¹ 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 at a later date 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 NA 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 NA 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](#)⁴², available on the European Chemicals Agency's (ECHA) website.
- In practice, there is around a two-year time period to submit an application for NA for an existing BP from the date on which the decision was taken to approve the product's active substances. The approval date is included in the Annex to the approval decision (Commission Regulation).
- For an existing BP already on the market in more than one MS in accordance with national laws, to enable closer cooperation between MSs in the evaluation of this BP, it is necessary to apply for mutual recognition in parallel at the same time in all the MSs where the product is intended to be authorised. One of those MSs should act as

³⁹ Ref: Article 3(1)(p) of the BPR.

⁴⁰ "Existing BPs" 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).

⁴¹ Ref: Article 89(3) of the BPR.

⁴² <http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>

reference MS.

It is recommended that NA 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 also apply when the application for NA is rejected or the receiving MSCA decides not to grant the authorisation⁴³. 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 the rejection or decision.

The application for NA of a new BP⁴⁴ can be submitted at any time after the decision on the approval of the (last) active substance contained therein is adopted. Such a new BP can be placed on the market of the relevant MS for the first time only when the NA has been granted.

If a BP contains only existing active substances which have not been approved yet, an application for authorisation can be submitted according to the national rules of the MS in which authorisation is sought.

Products not covered by Directive 98/8/EC (BPD), but as BPs now falling within the scope of the BPR

The BPR includes transitional measures to facilitate the transition from the BPD system to the new provisions of the BPR. There are products which, since 1 September 2013, fall within the scope of the BPR⁴⁵.

If such BPs were available on the market before 1 September 2013, then the legal provisions cited above contain timelines and deadlines (1 September 2016) for the submission of the applications for the relevant AS in those products. Where such an application is not made by the deadline, the product must be removed from the market by 1 September 2017.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Article 20(1)(a) and (2) of the BPR lists the requirements for an application for NA of a BP. *BSM Application instructions: national authorisations* available on ECHA's website explains what types of information files should be prepared and included in an application for NA.

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's website.

⁴³ Ref: Article 89(4) of the BPR.

⁴⁴ "New BPs" refers in the context of this Practical Guide, to those products which have not already been placed on the market of any MS at the date of the approval of the (last) active substance contained therein.

⁴⁵ Ref: Article 93 of the BPR or the Regulation (EU) No 613/2013.

Issues to consider:

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

- If the applicant is not the data owner of the dossier(s) of the approved active substance(s) contained in the BP, then the applicant needs to provide information to demonstrate access to the relevant data of each of the active substance to fulfil the requirements set out in Annex II to the BPR. This may be achieved by:
 - providing evidence of access to the information submitted for the purposes of the BPD or the BPR through a Letter of Access (LoA)⁴⁶; 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 the receiving competent authority (CA) in so far as the applicant can provide evidence that the active substance is technically equivalent to the reference source⁴⁷; or
 - waiving of information requirements⁴⁸ 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 protected⁴⁹. 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 NA. [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 the receiving CA. In such a case, the subsequent applicant has to 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.⁵⁰
- An NA 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 of the BP. If there are any doubts as to whether a product is falling within the

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

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

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

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

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

HOW



scope of the BPR or not, or to which PT(s) it belongs, the applicants are invited to contact the future receiving CA.⁵¹

- 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 information.⁵²

PROCEDURE TO FOLLOW

Creation of a IUCLID dossier:

The applicant seeking to obtain NA 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: using IUCLID available on ECHA's website;
- BSM Technical guide: using R4BP 3 available on ECHA's website.

Submission and processing of an application:

The application for NA 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 receiving CA 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 alternative products are available for the same use. The receiving CA takes a decision on the authorisation⁵³.

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 NA to the CA in that MS, which

⁵¹ Ref: Article 3(3) of the BPR.

⁵² CA-May14-Doc.5.6 – Final

⁵³ Ref: Articles 29-30 of the BPR.

evaluated the dossier of the active substance contained in the product, if the BP is already placed or is intended to be placed on the market of that MS.

Applicants are however free to choose the CA where they want to apply for the initial NA; subsequently, they can apply either for mutual recognition in sequence or in parallel of this BP in other MSs.

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

- *BSM Technical guide: using R4BP 3*
- *BSM Application instructions: national authorisations*

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

RESULTS



OUTCOME OF THE OBLIGATION/PROCESS

After finalising the assessment, the MSCA will update all necessary information related to the BP (assessment report and SPC) in R4BP 3 and either grant, or not grant, a NA. To grant the authorisation, the conditions summarised in Article 19 of the BPR have to be met. NA for a BP can be granted for a maximum period of 10 years, which is renewable.

For BPs containing an active substance that is a candidate for substitution, NA 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.

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

Authorisation of same biocidal products

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

National authorisation granted for a BPF

If an NA 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.⁵⁴

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

⁵⁴ Ref: Article 17(6) of the BPR.

National authorisation of BPs containing only active substance(s) from Annex I of 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 because the BP does not fulfil Article 25(b), (c) or (e) of the BPR it remains a possibility to apply for NA.⁵⁵

Permit for parallel trade

BPs can be also made available on the market using a parallel trade permit⁵⁶. A parallel trade permit is relevant when a company is interested in purchasing an authorised BP in a specific MS (MS of origin) and making it available on the market in another MS (MS of introduction-MSI), where an identical product has already been authorised. The applicant does not need to be the BP authorisation holder.

The applicant for a parallel trade permit does not need to submit data to show that the BP it wishes to make available on the market in the MSI is safe and efficacious, only that it is identical to the BP already authorised in the MS of introduction (the reference BP)⁵⁷. Additional information such as example labels are also required as part of the application⁵⁸. If the application is successful, the MSI shall grant the permit within 60 days of receipt of the applicable fees from the applicant (this may take longer where additional information is required from the MS of origin).

A parallel trade permit should be granted under the same terms and conditions as the authorisation for the reference BP. Furthermore, its expiry date is the same as the expiry date of authorisation of the reference BP.

A parallel trade permit may be cancelled independently of the authorisation related to the reference BP. At the same time, cancellation of authorisation of the reference BP on request of the AH does not affect the parallel trade permit, if the requirements of Article 19 are still fulfilled. However, the MSCA in the MSI may withdraw the parallel trade permit if the authorisation of the introduced product is withdrawn in the MS of origin due to safety or efficacy reasons.

More information and instructions for submitting the application for parallel trade permit through R4BP 3 are given in the *BSM Application instructions: national authorisations*.

Derogations from the requirements

Under certain conditions, derogations from authorisation requirements are possible, namely:

- Provisional authorisation

For a BP containing a new active substance not yet approved, a provisional authorisation can be granted by the MSCA for a period

⁵⁵ Ref: Article 19(1) of the BPR.

⁵⁶ Ref: Article 53 of the BPR.

⁵⁷ Ref: Article 53(3) of the BPR.

⁵⁸ Ref: Article 53(4) of the BPR.

not exceeding three years, renewable for one year⁵⁹.

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 the MSCAs 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) taking into account the factors set out in Article 19(2) of the BPR.

More information and instructions for submitting the application for provisional national authorisation through R4BP 3 are given in the *BSM Application instructions: national authorisations*.

- **Permission for a limited and controlled use**
An MSCA can permit the making available on the market or use of a BP, which is not authorised if there is an unforeseen danger to public or animal health or the environment which cannot be contained by other means⁶⁰. Such BPs can be placed on the market for a limited and controlled use only and under the supervision of that MSCA for a period not exceeding 180 days. Only with a justified request of the MSCA, can the European Commission (COM) extend that period by no more than 550 days.
- **Authorisation given to protect the cultural heritage**
A BP, which contains a non-approved active substance can be authorised by the MSCA if this active substance is essential for the protection of cultural heritage and there are no appropriate alternatives on the market. An application⁶¹ containing due justification shall be submitted by the MSCA to the COM and the authorisation can be given only with the consent of the COM.

Applications for NA submitted under the BPD

Wherean application for NA was submitted under the BPD and the evaluation was not completed by 1 September 2013, the relevant CA continues the evaluation in accordance with that directive. However, if the risk assessment on the active substance indicates that one or more of the exclusion criteria is met⁶², the BP shall be authorised in accordance with Articles 19 and 23 of the BPR. If the risk assessment of the active substance shows that one or more of the substitution criteria⁶³ is met but not any of the exclusion criteria, the conditions for authorisations are those laid down in Article 5 of the BPD and Article 23 of the BPR (and the principles of Annex VI to the BPD should be taken into account to evaluate the product). If neither the exclusion or substitution criteria are met, the conditions for authorisations are those laid down in Article 5 of the BPD (and the principles of Annex VI to the BPD should be taken into account to evaluate the product). Nevertheless, the legal basis for the product authorisation will be Article 19 and 91 of the BPR. Where the evaluation

⁵⁹ Ref: Article 55(2) of the BPR.

⁶⁰ Ref: Article 55(1) of the BPR.

⁶¹ Ref: Article 55(3) of the BPR.

⁶² Ref: Article 5(1) of the BPR.

⁶³ Ref: Article 10 of the BPR.

identifies concerns arising from the application of provisions of the BPR which were not included in the BPD, the applicant shall be given the opportunity to provide additional information.

Notification of unexpected or adverse effects

An AH is obliged to notify the MSCA that has granted the NA 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 authorisation⁶⁴. 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 NA⁶⁵. MSCAs, which have mutually recognised that NA shall examine whether these authorisations need also to be amended or cancelled.

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: national authorisations*.

COST



RELATED FEES

The national fees related to the application for NA may vary between the 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 MSCAs' fees, the applicant should contact the designated national MSCA or its helpdesk.

There is no fee charged by ECHA for an NA, but if together with an application for NA also applications for MRP are submitted to one or more concerned MS, the Mutual Recognition Submission Fee for them should be paid to ECHA in accordance with the third entry of Annex III to *Commission Implementing Regulation (EU) No 564/2013*.

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>

⁶⁴ Ref: Article 47 of the BPR.

⁶⁵ Ref: Article 48 of the BPR.

MORE



authorities

National authorities providing support

» <http://echa.europa.eu/support/helpdesks/national-helpdesks/list-of-national-helpdesks>

INFORMATION

Legislation relevant to biocides

» <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

Regulatory aspects

National authorisation and mutual recognition

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

Relevant Biocides competent authorities meetings documents

» <https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942>

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

CA-Sept13-Doc.5.1.g - Final.Rev.1: 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.5.1: Transition between national schemes and BPR-authorisations following active substance approvals;

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-Sept14-Doc.5.7: Harmonised approach to the consideration of the expiry dates of new product authorisations linked to other authorisations through certain authorisation procedures;

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;

CA-Nov14-Doc.5.8 – Final: Implementing the new concept of biocidal product families.

Guidance on Biocides legislation

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

Submission

- **Submission instructions**

National authorisation

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

- Authorisation of biocidal products
- Authorisation of a same biocidal product (authorised and pending)
- Parallel trade
- Notification for a product in a product family
- Notification of unexpected or adverse effect

- **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: national authorisations

- » http://www.echa.europa.eu/documents/10162/14938692/bsm_06_national_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>

Mutual recognition

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The authorisation of a biocidal product (BP) can be recognised in other Member States (MSs) in accordance with the mutual recognition (MR) procedures to avoid duplication of the evaluation. There are two procedures: mutual recognition in sequence (MRS) which is relevant where there is an existing authorisation⁶⁶, and mutual recognition in parallel (MRP) which is relevant where the initial application for national authorisation (NA) and the applications for MR are submitted at the same time⁶⁷.

Authorisation according to MRS/MRP should be granted under the same terms and conditions as the (initial) NA; however, in certain cases⁶⁸, the MSs concerned may propose to refuse to grant the authorisation or to adjust its terms and conditions.

The same rules as for a single BP also apply for a biocidal product family (BPF)⁶⁹.

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

For MRS, the application can be made by, or on behalf of, the authorisation holder (AH) in the reference MS. 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 established within the European Union (EU)/European Economic Area (EEA) who is responsible for the placing on the market of the BP in the reference/concerned MSs.⁷⁰

If the prospective AH in the concerned MS is a separate person/entity than the AH of the reference NA, they can also make the application, provided they obtain the necessary rights to the required data.

⁶⁶ Ref: Article 33 of the BPR.

⁶⁷ Ref: Article 34 of the BPR.

⁶⁸ Ref: 35(2) and 37(1) of the BPR.

⁶⁹ 'Biocidal product family' means a group of BPs having 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).

⁷⁰ Ref: Article 3(1)(p) of the BPR

WHEN



For MRP, the application for the initial NA must be made by, or on behalf of, the prospective AH. If the prospective AH in the concerned MSs is a separate person/entity than the AH of the initial NA, they can also make the application, if they obtain the necessary rights to the required data on the active substance and BP.

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

An application for MR, just like in the case of NA, can be made only after the decision to approve the active substance is adopted.

An application for MRP is made after the decision to approve the active substance is adopted and at the same time as the initial NA application. An application for MRS can be made at any point after the NA is granted in the reference MS, on the condition that it is still valid.

Specific transitional rules apply to the timing of the application for MRP in regards to existing BPs⁷¹:

- The application(s) for MRP in the MSs concerned together with an application in the reference MS for an initial NA 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 date⁷². 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 at a later date 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 product-type (PT), the applications 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 when the active substance(s) contained in it has/have been approved for all relevant PTs before the deadline of the last approved.
The [Union list of approved active substances](#)⁷³ is available on the European Chemicals Agency's (ECHA) website.
- In practice, there is around a two-year time period to submit an application for MRP from the date on which the decision was taken to include all of the product's active substances. The approval date is included in the Annex to the approval decision (Commission Regulation).

The application for MRP of a new BP⁷⁴ can be submitted at any time after

⁷¹ "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).

⁷² Ref: Article 89(3) of the BPR.

⁷³ <http://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

⁷⁴ "New biocidal products" refers in the context of this Practical Guide, to those products which have not already been placed on the market of any MS at the date of the approval of the (last) active substance.

the decision on the approval of the (last) active substance is adopted. Such a new BP can be placed on the market of the relevant MS for the first time only when the NA from that MS has been granted.

It is recommended that MRP 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 when the application for MRP is rejected or the reference MS decides not to grant the authorisation⁷⁵. Existing products must be removed from the market within 180 days of the date of the rejection or decision. The use of existing stocks of that BP may continue until 365 days after the date of rejection or decision.

For MRS, the BP can only be placed on the market in the concerned MS once the authorisation is granted by this MS.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

BSM Application instructions: national authorisations available on ECHA's website outlines the different types of information files that should be prepared and included in an application for MRP or MRS.

HOW



PROCEDURE TO FOLLOW

For an application for MRS and for MRP in the MSs concerned, an IUCLID dossier is not required. Nevertheless, an IUCLID dossier must be submitted with the initial NA application to the reference MS as explained in the [Practical Guide chapter on national authorisation](#).

Submission and processing of an application:

The application for MRP/MRS 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 MSCA for validation and evaluation:

- for MRS, to the MSs concerned;
- for MRP, to the reference MSCA (the initial application) and at the same time to all MSs concerned (MRP).

The respective MSCA takes a decision on the authorisation. NA will be granted in the concerned MSs within 30 days of agreement being reached on the summary of the product characteristics (SPC). In the case of MRP, this takes place only after the reference MSCA has evaluated the application (365 days). In some cases, granting the authorisation through an MRS/MRP procedure requires a decision by the European Commission

⁷⁵ Ref: Article 89(4) of the BPR.

(COM) or an agreement by the Coordination Group (CG) (see below).

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.

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

- *BSM Technical guide: using R4BP 3*
- *BSM Application instructions: national authorisations.*

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

More information related to invoicing and R4PB 3 can be found in the *BSM Technical guide: using R4BP 3* available on ECHA's website.

Derogations

By way of derogation from authorising a BP under the same terms and conditions through an MRS/MRP procedure, any of the concerned MSs may propose to refuse to grant a NA through MRS/MRP or to adjust its terms and conditions based on the following grounds⁷⁶:

- the protection of the environment;
- public policy or public security;
- the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;
- the protection of national treasures possessing artistic, historic or archaeological value;
- the target organisms not being present in harmful quantities; or
- an active substance is a candidate for substitution.

In each case, a detailed justification is required to be communicated from the MS concerned to the applicant. The MS concerned seeks to reach agreement with the applicant on the proposed derogation.

If an agreement between the two is not reached, the MS concerned informs COM who takes a final decision on the derogation. COM may ask ECHA for an opinion on scientific and technical issues (through the Biocidal Products Committee (BPC)) in order to conclude on its decision.⁷⁷

Besides the reasons for derogations listed above, authorisations of BPs of PTs 15, 17 and 20 may be refused from MRP/MRS by an MSCA on the

⁷⁶ Ref: Article 37(1) of the BPR.

⁷⁷ Ref: Article 37(2) and (3) of the BPR.

grounds of animal welfare⁷⁸. Such a refusal must be justified and the other MSs and COM informed.

This procedure can also apply when additional/different restrictions are proposed by the MS concerned which, in the case of the BP containing an active substance that is a candidate for substitution, has made a supplementary comparative assessment to the comparative assessment carried out by the reference MS.

Settlement of disagreements

When any of the MSs concerned disagree with the conclusions of the product assessment report or with the SPC, it must send a detailed explanation of the reasons for such a position to the reference MS, all other MSs concerned and the applicant. The points of disagreement must be referred to the CG⁷⁹ without delay by the reference MS where the MSs use their best endeavours to reach an agreement. The applicant is allowed to present its point of view. When an agreement is not reached by the CG within 60 days, the reference MS informs COM which takes a final decision by means of an implementing act. COM may either ask ECHA for an opinion on scientific and technical issues (through the BPC) or give an opportunity to the applicant to comment (30 days) in order to conclude on its decision.

RESULT



OUTCOME OF THE OBLIGATION/PROCESS

After finalising the evaluation and reaching an agreement between the reference MS and MS(s) concerned, each of the MSCAs update the information in R4BP 3 relating to this BP and grant an NA of the BP.

Authorisation according to MRP should be granted for the same number of years in all MSs (e.g. up to 10 years). For MRS, the validity of the product authorisation should also be the same as for the initial authorisation granted by the reference MS, unless the active substance is a candidate for substitution (i.e. maximum of four or five years).

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

Application for MR made by official or scientific bodies

If there is a general interest in the use of a BP, which is not on that MS's market, official or scientific bodies involved in pest control activities or the protection of public health may apply for MRS of the same BP with the same use and the same conditions of use as in the MS already authorised provided that⁸⁰:

- no application for authorisation has been submitted to that MSCA for such a BP already authorised in the other MS, and
- the AH of this BP has agreed to such an application.

⁷⁸ Ref: Article 37(4) of the BPR.

⁷⁹ Ref: Article 35(1) of the BPR.

⁸⁰ Ref: Article 39 of the BPR.

When the authorisation is given by that MSCA, the body that made the application has the same rights and obligations as other AHs.

- It is possible to start a MR in sequence from an authorisation already obtained via a same biocidal product processes.
- It is possible to mutually recognise a product family starting from a product family or a single product starting from a single product but not only part of a family or a single product starting from a product family.

COST



RELATED FEES

The national fees related to an application for MRS/MRP 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 MSCA.

For more information about the MSs fees, the applicant should contact the designated national competent authorities or helpdesk.

An MR Submission Fee will be charged by ECHA in relation to applications for NA of a BP through MRS/MRP in accordance with the third entry of Annex III to *Commission Implementing Regulation ((EU) No 564/2013)*.

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>

MORE



INFORMATION

Legislation relevant to biocides

- » <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

Regulatory aspects

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

CA-Sept13-Doc.5.1.g - Final.Rev.1: 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 sensitiser 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-Sept13-Doc.6.2.d - Final: Submission in EN of the proposed SPC in applications for mutual recognition in parallel and other regulatory procedures;

CA-March14-Doc.5.1: Transition between national schemes and BPR-authorisations following active substance approvals;

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

CA-Sept14-Doc.5.7: Harmonised approach to the consideration of the expiry dates of new product authorisations linked to other authorisations through certain authorisation procedures;

CA-Nov14-Doc.5.8 - Final: Implementing the new concept of biocidal product families.

Guidance on Biocides legislation

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

Submission

- **Submission instructions**

National authorisations

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

- Mutual recognition in sequence
- Mutual recognition in parallel

- **Biocides Submission Manuals**

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

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: national authorisations

» http://echa.europa.eu/documents/10162/14938692/bsm_06_national_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>

Renewal of national authorisation and authorisations subject to mutual recognition

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The Biocidal Products Regulation ((EU) No 528/2012 (BPR)) states that an authorisation of a biocidal product (BP) can be granted for a maximum period of 10 years⁸¹. Article 31 of the BPR sets out the procedure for the renewal of a single national authorisation granted by the Member State competent authority (MSCA).

Supplementary rules for the renewal of authorisations subject to mutual recognition (MR) procedures and having the same terms and conditions with limited exceptions⁸² (grouped renewal), in all the Member States (MSs) where renewal is sought, are laid down in the MR Renewal Regulation (Commission Delegated Regulation (EU) No 492/2014).

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

An application for the renewal of national authorisation (NA) can be made by, or on behalf of, the authorisation holder(s) (AH) of the original authorisation(s). Accordingly, the applicant may have a person/entity handling the practical issues related to the application and renewal procedure on behalf of the AH.

The AH is the person/entity established within the European Union (EU)/ European Economic Area (EEA), who is responsible for placing the BP on the market in a particular MS⁸³.

WHEN



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

An application for the renewal of NA including those subject to MR shall be submitted at least 550 days before the expiry date of the NA. In the case of the applications for renewal of NA, subject to or granted through

⁸¹ Ref: Article 17(4) of the BPR.

⁸² Ref: Article 1(3) of the MR Renewal Regulation.

⁸³ Ref: Article 3(1)(p) of the BPR.

MR, the applications need to be made to the reference MS and the MSs concerned at the same time.

Phasing-out period for BPs

If an application for renewal has not been submitted, or is rejected, or additional information on the request of the MS has not been submitted by the applicant, the BPs shall be taken off the market within 180 days after the expiry date of the initial authorisation. An additional maximum period of 180 days can be granted for the use of existing stocks⁸⁴.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

BSM Application instructions: national authorisations, available on the European Chemical Agency's (ECHA) website, outlines the different types of information files that should be prepared and included in an application for renewal.

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's website.

HOW



PROCEDURE TO FOLLOW

Creation of a IUCLID dossier:

An application must always include a IUCLID dossier with, at minimum, the information on the product composition. Where relevant, the technical and scientific data also have to be included in the IUCLID file.

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:

The application for renewal of NA should be submitted through R4BP 3:

- for renewal of a single NA, to the receiving MS. Any authorisation can be treated as a single NA, including an authorisation granted through mutual recognition, which does not meet anymore the conditions laid down in Article 1(2)(3) of the MR Renewal Regulation;
- for grouped renewal of NAs, subject to or granted through mutual MR, to the reference MS and all MS(s) concerned. In case of several NAs linked together by mutual recognition, which have different AHs and for which there is an agreement that they will be renewed together, the AHs may agree who will make the grouped application on their behalf and nominate the company in charge of submitting the renewal using

⁸⁴ Ref: Article 52 of the BPR.

the “Nomination” functionality in R4BP 3.

Following confirmation that the submission has passed the initial checks by ECHA, the application will be forwarded to the relevant MS(s) for validation and evaluation. At a very early stage, the receiving/reference MSCA decides whether a full evaluation of the application for renewal is necessary or not. Full evaluation takes 365 days. If a full evaluation is not necessary, the evaluation has to be completed in 180 days. The receiving/reference MSCA may request the applicant to submit additional data.

The respective competent authority(s) (CA) take(s) a decision on the renewal of an authorisation. In the context of renewal, subject to or granted through MR, in some cases granting the renewal of an authorisation requires a decision by the European Commission (COM) or an agreement by the Coordination Group (CG) (see below).

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.

Applicants will find the relevant information and instructions for submitting and following up the application for renewal through R4BP 3 in the [BSM Application instructions: national authorisations](#) available on ECHA's website.

ECHA's website gives details on the assessment procedure in relation to this process.

Derogations

For renewal, subject to or granted through MR, any of the MSs concerned may propose to refuse to renew an authorisation or to adjust its terms and conditions based on the following grounds⁸⁵:

- the protection of the environment;
- public policy or public security;
- the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;
- the protection of national treasures possessing artistic, historic or archaeological value;
- the target organisms not being present in harmful quantities; or
- an active substance is a candidate for substitution.

In each case, a detailed justification is required to be communicated from the MS concerned to the applicant. The MS concerned seeks to reach agreement with the applicant on the proposed derogation.

If an agreement between the two is not reached, the MS concerned informs COM who takes a final decision on the derogation. COM may ask

⁸⁵ Ref: Article 37(1) of the BPR.

the ECHA for an opinion on scientific and technical issues (through the Biocidal Products Committee (BPC)) in order to conclude on its decision⁸⁶.

This procedure can also apply when additional/different restrictions are proposed by the MS concerned, which for BPs containing an active substance which is a candidate for substitution, has made a supplementary comparative assessment to the comparative assessment carried out by the reference MS.

Settlement of disagreements

In the case of renewal subject to, or granted through MR, when any of the MSs concerned disagrees with the conclusions of the product assessment report or with the summary of the product characteristics (SPC) it must send a detailed explanation of the reasons for such a position to the reference MS, all other MSs concerned and the applicant. The points of disagreement must be referred to the CG⁸⁷ without delay by the reference MS where the MS use their best endeavours to reach an agreement. The applicant is allowed to present its point of view.

When an agreement is not reached by the CG within 60 days, the reference MS informs COM, which takes a final decision by means of an implementing act. COM may either ask ECHA for an opinion on scientific and technical issues (through the BPC) or give an opportunity to the applicant to comment in order to conclude on its decision.

RESULT



OUTCOME OF THE OBLIGATION/PROCESS

After finalising the evaluation and, in the case of MR, after reaching an agreement between reference MS and MS(s) concerned, the authorisation shall be renewed for a maximum period of 10 years, unless the active substance is a candidate for substitution (i.e. maximum of five years).

For authorisations granted through MR, the maximum validity of the renewed authorisations should be the same in all the MSs where the product is renewed.

For reasons beyond the control of the AH where no decision is taken on the renewal before the expiry date of the initial authorisation, the relevant MSCA must grant a renewal for the period necessary to complete the evaluation.

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

Renewals of authorisations of anticoagulant rodenticides

For already authorised BPs containing anticoagulant rodenticides⁸⁸, which are candidates for substitution, a comparative assessment has to be done

⁸⁶ Ref: Article 37(2) and (3) of the BPR.

⁸⁷ Ref: Article 35(1) of the BPR.

⁸⁸ Difenacoum, difethialone, chlorophacinone, bromadiolone, coumatetralyl, flocoumafen, brodifacoum, warfarin and warfarin sodium.

before their authorisations will be renewed. Applications for renewal of such products have to be submitted within the usual 550-day deadline but then the assessment will be put on hold by the MSs until decisions on the renewal of the relevant active substance approvals are taken.

So far, the applicants have been requested to submit only an application form for renewal of product authorisation generated from R4BP 3 and relevant supporting document. Provided that an application for renewal of BP authorisation has been submitted, MSs should grant a renewal of the existing authorisation for a period necessary to complete the evaluation.

When the approval of the active substance is renewed, the applicants will have to submit all data generated since the initial authorisation was granted and potentially other information.

COST



RELATED FEES

The national fees related to the application for renewals of NA 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 MSs fees, the applicant should contact the designated national CA or its helpdesk.

There is no fee charged by ECHA for a renewal of NA or authorisations subject to or granted through MR.

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>

MORE



INFORMATION

Legislation relevant to biocides

- » <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

Regulatory aspects

Renewal of National authorisation and authorisations subject to Mutual recognition

- » <http://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/national-authorisation-renewal>

Relevant Biocides competent authorities meetings documents

- » <https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942>

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.5.2.b - Final: Substance approval and product authorisation renewals of the anticoagulant rodenticides

CA-July13-Doc.11.3 - Final: Application of Art. 23(4) of the BPR to anticoagulant rodenticides for which the authorisation decision will be taken after 1st September 2013

Guidance on Biocides legislation

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

Submission

• **Submission instructions**

National authorisations

- » <http://echa.europa.eu/support/dossier-submission-tools/r4bp/renewal-national-authorisation>

Renewal of authorisation(s) (including authorisations subject to mutual recognition)

- » <http://echa.europa.eu/support/dossier-submission-tools/r4bp/renewal-of-authorisations-subject-to-mutual-recognition>

• **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: national authorisations

» http://www.echa.europa.eu/documents/10162/14938692/bsm_06_national_authorisation_en.pdf

- **IUCLID Manuals**

» <http://iuclid6.echa.europa.eu/support>

Q&As

» <http://echa.europa.eu/support/qas-support>

Union authorisation

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).⁸⁹ 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 21⁹⁰. It is possible to apply for UA of both BPs and biocidal product families (BPFs)⁹¹. 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](#).

⁸⁹ Ref: Article 17(1) of the BPR.

⁹⁰ Ref: Article 42(1) of the BPR.

⁹¹ '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/EEA, who is responsible for the placing on the market of a BP in a particular MS.⁹²

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 new⁹³ or existing⁹⁴ 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 can 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 BPs⁹⁵:

- 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 date⁹⁶. 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 at a later date 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

⁹² Ref: Article 3(1)(p) of the BPR.

⁹³ 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).

⁹⁴ 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).

⁹⁵ “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).

⁹⁶ Ref: Article 89(3) of the BPR.

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 substances](#)⁹⁷ available on ECHA's website.

- In practice, there is around a two-year time period 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 authorisation⁹⁸. 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 BPs⁹⁹ 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.

Products not covered by the Directive 98/8/EC (BPD), but as BPs now falling within the scope of the BPR

The BPR includes transitional measures to facilitate the transition from the BPD system to the new provisions of the BPR. There are products which fall, only since 1 September 2013, as BPs within the scope of the BPR¹⁰⁰.

If such BPs were made available on the market before 1 September 2013, then the legal provisions cited above contain timelines and deadlines (1 September 2016) for the submission of the applications for the relevant active substance in those products including those for UA apply. Where such an application is not made by the deadline, the product must be removed from the market by 1 September 2017.

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:

⁹⁷ <http://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

⁹⁸ Ref: Article 89(4) of the BPR.

⁹⁹ "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.

¹⁰⁰ Ref: Article 93 or 94 of the BPR or the Regulation (EU) No 613/2013.

WHAT



- 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.

INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

BSM Application instructions: Union authorisations 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 has to consider a number of important elements before preparing an application for UA:

- BPs should have similar conditions of use across the EU¹⁰¹. 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:
 - providing evidence of access to the information submitted for the purposes of the BPD or the BPR through a Letter of Access (LoA)¹⁰²; 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 source¹⁰³; or
 - waiving of information requirements¹⁰⁴ 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 protected¹⁰⁵. 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

101 CA-Feb13-Doc.5.1.e - Final.

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

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

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

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

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 has to 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.¹⁰⁶
- 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 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 information¹⁰⁷.
- 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 submitting an application for UA. For more information on the recognition of an SME status and on how to submit relevant documentation see [ECHA's website](#).¹⁰⁸

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.

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

107 CA-May14-Doc.5.6 – Final

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

On the basis of 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: Union authorisations*.

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: using IUCLID*, available on ECHA's website;
- *BSM Technical guide: using 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. On the basis of the BPC opinion, COM takes a decision on the authorisation.¹⁰⁹

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 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:

¹⁰⁹ Ref: Articles 43-44 of the BPR.

BSM Application instructions: Union authorisations.

More information related to invoicing and R4PB 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 Groups](#)¹¹⁰ 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.

Applicants are also given an opportunity to participate at other stages of the process as described in the [Working Procedure](#)¹¹¹ 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 have to 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

¹¹⁰ http://echa.europa.eu/documents/10162/4221979/bpc_conduct_code_applicants_en.pdf

¹¹¹ Union authorisation applications: working procedure for the BPC, http://echa.europa.eu/documents/10162/4221979/bpc_working_procedure_union_authorisation_en.pdf

TO NOTE



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.

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 dyes.¹¹²

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 because the BP does not fulfil Article 25(b), (c) or (e) of the BPR, it remains a possibility to apply for UA.¹¹³

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 year.¹¹⁴

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) taking into account 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: Union authorisations*, available on ECHA's website.

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

113 Ref: Article 19(1) of the BPR.

114 Ref: Article 55(2) of the BPR.

COST



RELATED FEES

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

Note that **SMEs** may be entitled to a reduced fee, see [ECHA's website](#).¹¹⁵

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.

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>

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

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

¹¹⁵ <http://www.echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr>

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

CA-Nov14-Doc.5.8-Final.rev.1: Implementing the new concept of biocidal product families

Guidance on Biocides legislation

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

Submission

• Submission instructions

» <http://echa.europa.eu/support/dossier-submission-tools/r4bp/union-authorisation>

- 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: 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: Union authorisations

» http://www.echa.europa.eu/documents/10162/14938692/bsm_08_union_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>

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).

WHEN



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.

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 eCA¹¹⁷.

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 data¹¹⁸, 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 requirements¹²⁰ 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 authority¹²¹.

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 authorisation¹²².

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 MS¹²⁴. 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.

RESULT

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

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 BPD¹²⁵.

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 dyes¹²⁶.

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 authorisation¹²⁷. 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 SA¹²⁸.

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>

Changes of biocidal products

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

National authorisations (NAs) of biocidal products (BPs) issued by competent authorities of the Member States (MSCAs) or for Union authorisations (UAs) by the European Commission (COM) are only valid for the approved terms and conditions stated therein.

The relevant provisions on amendments of NAs and UAs on request of the authorisation holder (AH) can be found in Article 50 of the Biocidal Products Regulation ((EU) No 528/2012 (BPR)) and the detailed rules for notifications/applications and procedures for changes of these authorisations in the Commission Implementing Regulation ((EU) No 354/2013) on changes of biocidal products authorised in accordance with the Changes Regulation (CR) ((EU) No 528/2012).

Three types of changes can be distinguished ¹²⁹:

- administrative changes¹³⁰;
- minor changes, which should not affect the conclusion with regard to the fulfilment of the conditions for authorisation¹³¹; and
- major changes, when a need for reassessment of the risk and the efficacy can be expected to fulfil the conditions for authorisation¹³².

The MSCAs for NA, or the European Chemicals Agency (ECHA) for UA, must be informed of all intended changes to an authorised BP. All amendments to the terms and conditions of an authorisation of a BP are handled only by the MSCAs for NA or by COM for UA.

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

129 See the non-exhaustive list in the Annex to CR.

130 Ref: Article 3(1)(aa) of the BPR.

131 Ref: Article 3(1)(ab) of the BPR.

132 Ref: Article 3(1)(ac) of the BPR.

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

The AH or its representative (e.g. a consultant) may apply for amendments to any of the information included in the authorisation of a BP/BPF.

WHEN



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

The applicant can apply for changes at any time. For certain administrative changes, the applicant may only be required to notify the relevant MSCA for NA or ECHA for UA within 12 months following the implementation of such a change¹³³.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

The information requirements are listed in Article 5 of the CR. *BSM Application instructions: national authorisations*, explains what types of information files should be prepared and included in the application/notification. For the time-being the manual covers only the request for changes in relation to NA.

Issues to consider:

Classification of changes:

Taking into account the extent to which the change requires a reassessment of the risk and efficacy of the BP/BPF, changes to the authorisations are classified into three different categories¹³⁴:

- administrative change. Administrative changes are further divided into two types:
 - changes which have to be notified before implementation; and
 - changes which can be notified within 12 months after implementation;
- minor changes;
- major changes.

The Annex to the CR helps to determine the category of the sought change.

An administrative change to the authorisation is sought by a notification procedure and a minor or major change by an application procedure.

Grouping of changes:

As a general rule, a separate notification/application must be submitted

¹³³ Ref: Annex, title 1, section 2 to CR.

¹³⁴ Ref: Article 3(1)(aa), (ab) and (ac) of the BPR.

HOW



for each change. Under certain conditions, the changes can be grouped. Some examples are given in the *BSM Application instructions: national authorisations*, available on ECHA's website.

Even when changes are grouped for NA, a notification/application has to be submitted simultaneously to each MS concerned.

PROCEDURE TO FOLLOW

Request ECHA to classify a change where relevant

If the applicant is unable to determine the category to which the intended change belongs (it is not listed in one of the tables in the Annex to the CR), the applicant may request ECHA to issue an opinion on the classification of the change. For this purpose, the applicant has to submit an application for classification of the change. A separate application for an opinion must be submitted for each change sought through R4BP 3.

More details concerning information requirements and how to submit an application for classification of change are given in the *BSM Application instructions: national authorisations*, available in the support section of ECHA's website.

More information related to invoicing and R4PB 3 can be found in the *BSM Process of invoicing in R4BP 3*.

Submit a notification for administrative change/application for a minor/major change

Creation of a IUCLID dossier:

Where relevant, the applicant should 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 a notification/application using R4BP 3:

The applicant needs to submit a notification/application through R4BP 3:

- to all MSs concerned, which have issued the authorisation and where the change is intended – for NA, or
- to ECHA – for UA.

Where a change of BP (NA) has already been agreed in one or more MS, and the AH wants to apply for the same change in an additional MS concerned, a notification/application has to be submitted to the additional MS.

Following confirmation that the submission has passed the initial checks by ECHA, the notification/application will be forwarded to the relevant authority, i.e.:

- to all MSs concerned, which have issued the authorisation and where the change is intended – for NA, or
- to ECHA – for administrative and minor changes to UA, or
- to the evaluating competent authority (eCA) – for major changes to UA.

Depending on the category of the intended change, different procedures apply¹³⁵.

The requests for minor and major changes to BPs authorised by NA are validated and evaluated by a reference MS. Requests for major changes to BPs authorised by UA are validated and evaluated by the eCA. The reference/evaluating CA should be the same that evaluated the initial NA/UA application. Only when the change of the BP authorised by NA/UA is not sought in that MS, can the applicant choose another MS. ECHA validates and evaluates the requests for minor changes to BPs authorised through UA.

The processing of the notifications/applications for changes in relation to BPs authorised through UA involves the opinion of ECHA (through the Biocidal Products Committee (BPC)).

The decision to agree or reject the change is taken by the MSCAs concerned for NA or by the COM for UA. The decision concerning NAs has to be taken in every MS individually. For some requests for a change concerning NA submitted to more than one MS, the decision by COM or an agreement by the Coordination Group (CG) may also be necessary (see below).

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 the payment of fees, or, at a later stage, requests 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.

The applicants will find more information and instructions for submitting and following up their notification/application through R4BP 3 in the submission manuals on ECHA's website:

- *BSM Technical guide: using R4BP 3*
- *BSM Application instructions: national authorisations*

One of the administrative changes listed in the CR¹³⁶ is the possibility to transfer an NA to a new AH. It must be made through the application procedure 'transferring a national authorisation' outlined in *BSM*,

¹³⁵ For the notification procedure for administrative changes of BP, see Article 6 for NA or Article 11 for UA of the CR. For the application procedure for minor changes of BP, see Article 7 for NA or Article 12 for UA of the CR. For the application procedure for major changes of BP, see Article 8 for NA or Article 13 for UA of the CR.

¹³⁶ Section 1, item 3 of title 1 of the Annex to the CR.

Application instructions: National authorisations available on ECHA's website. See also the section on Exceptions and particular cases below.

The possibility to transform a frame formulation (FF) into a BPF is also listed as an administrative change in the CR¹³⁷, however, it must be made through the application procedure 'Merge of a product authorisation(s) in a family' outlined in *BSM, Application instructions: National authorisations* available on ECHA's website. See also the section on Exceptions and particular cases below.

More information related to invoicing and R4PB 3 can be found in the *BSM Process of invoicing in R4BP 3* available on ECHA's website.

Derogations - NA

Any of the MSs concerned may disagree with the proposed change to an NA and propose to refuse to adjust the terms and conditions of the authorisation based on the following grounds¹³⁸:

- the protection of the environment;
- public policy or public security;
- the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;
- the protection of national treasures possessing artistic, historic or archaeological value;
- the target organisms not being present in harmful quantities; or
- an active substance being a candidate for substitution¹³⁹.

In each case, a detailed justification is required to be communicated from the MS concerned to the applicant. The MS concerned seeks to reach agreement with the applicant on the proposed derogation.

If an agreement between the two is not reached, the MS concerned informs COM who takes a final decision on the derogation. COM may ask ECHA for an opinion on scientific and technical issues (through the BPC) in order to conclude on its decision¹⁴⁰.

This procedure can also apply when additional/different restrictions are proposed by the MS concerned which, in the case of the BP containing an active substance that is a candidate for substitution, has made a supplementary comparative assessment to the comparative assessment carried out by the reference MS.

Settlement of disagreements - NA

When, for requests of a change, the MS concerned disagrees with the conclusions of the assessment report, with the summary of the product characteristics (SPC) or with the notified change, it must send a detailed explanation of the reasons for such a position to the reference MS, all

137 Section 1, item 6 of title 1 of the Annex to the CR.

138 Ref: Article 10(1) of the CR.

139 Ref: Article 37(1) of the BPR.

140 Ref: Article 37(2) and (3) of the BPR.

RESULT



other MSs concerned and the applicant. The points of disagreement must be referred to the CG¹⁴¹ without delay by the reference MS where the MSs use their best endeavours to reach an agreement. The applicant is allowed to present its point of view. When the agreement is not reached by the CG within 60 days, the reference MS informs COM which takes a final decision by means of an implementing act. COM may either ask ECHA for an opinion on scientific and technical issues (through the BPC) or give an opportunity to the applicant to comment in order to conclude on its decision. The settlement of disagreements through the CG is not relevant for UA.

OUTCOME OF THE OBLIGATION/PROCESS

Administrative changes for NA and UA, which can be notified within 12 months after implementation¹⁴² may be implemented any time before completion of the procedures laid down in Articles 6 and 11 of the CR.

Administrative changes, which have to be notified before implementation¹⁴³ may be implemented at the earliest on the date when the MSCA (for NA) or the COM (for UA) agree with the change, or 45 days following receipt of the notification by the MSCA (for NA) or ECHA (for UA), whichever is first.

Minor changes concerning NA may be implemented any time after the reference MS has recorded the agreement on the conclusions of the assessment report, and the SPC where relevant, in R4BP 3, or for UA, any time after ECHA's positive opinion has been made available in R4BP 3.

Major changes may only be implemented after the MSs concerned for NA or, COM for UA have agreed with the change and, where relevant, amended the decision granting the existing authorisation.

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

Transferring a NA

A transfer usually occurs as a result of a merger or acquisition of a company and is the process by which the authorisation is transferred from the current AH to a new one, which is a different legal entity. A change of name and/or address of the AH does not fall under an authorisation transfer if the holder remains the same legal entity. Other changes, e.g. change of the name of the BP are also not a part of a transfer application and should be submitted separately.

More information and instructions for submitting the notification through R4BP 3 are given in the *BSM, Application instructions: National authorisations* available on ECHA's website.

141 Ref: Article 35(1) of the BPR.

142 Section 2 of title 1 of the Annex to the CR.

143 Section 1 of title 1 of the Annex to the CR.

Merge of product authorisation(s) into a BPF

In general, the AH should apply for a merge of authorisations into a BPF before making a notification of a product in a BPF or submitting any other type of application related to the authorisations covered by the FF and well before the deadline for application for renewal of product authorisation.

More information and instructions for submitting the notification through R4BP 3 are given in the *BSM, Application instructions: National authorisations* available on ECHA's website.

BP authorised through simplified authorisation procedure¹⁴⁴

To notify of/apply for changes to authorisations granted through a simplified procedure, applicants should submit a respective notification/application through R4BP 3 as outlined in the *BSM Application instructions: Simplified authorisations* available on ECHA's website. To transfer a simplified authorisation to a new AH, the notification must be made through the procedure 'transfer of a simplified authorisation'.

Where the authorisation has been granted in accordance with the simplified authorisation procedure¹⁴⁵, the applicant is obliged to notify each MS 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). Where a revised version of the SPC has been accepted by the reference MS, the applicant has to submit this revised version to each MSCA in the official language(s) of that MS.

COST**RELATED FEES**

The national fees related to notification/application of changes may vary between MSs and are established in the national legal acts of each MS.

For more information about the MS fees, the applicant should contact the designated MSs.

Fees related to notification/application for change(s) of UA as well as classification of changes payable to ECHA are listed in Annex II to *Commission Implementing Regulation ((EU) No 564/2013)*.

The fee applicable to the classification of a change applies to both NA and UA. The fee is deducted from a subsequent notification/application for administrative or minor change in the context of UA.

¹⁴⁴ Ref: Article 9 of the CR.

¹⁴⁵ Ref: Article 26 of the BPR.

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>

MORE



INFORMATION

Legislation relevant to biocides

» <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

Regulatory aspects

Authorisation of biocidal products

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

The Biocidal Products Committee

» <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee>

Relevant Biocides competent authorities meetings documents

» <https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942>

CA-Sept13-Doc.6.2.d - Final: Submission in EN of the proposed SPC in applications for mutual recognition in parallel and other regulatory procedures

Guidance on Biocides legislation

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

Submission

• Submission instructions

National authorisations

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

- Classification of a change to a product authorisation
- Administrative change on request
- Minor or major change on request

- Merge of product authorisation(s) in one product family
- Transfer of authorisation

Simplified authorisations

» <http://echa.europa.eu/support/dossier-submission-tools/r4bp/simplified-authorisations>

- Administrative change on request
- Minor or major change on request
- Transfer of authorisation

• Biocides Submission Manuals

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

BSM Technical guide: using IUCLID

» http://echa.europa.eu/documents/10162/14938692/bsm_01_using_iuclid_en.pdf

BSM Technical guide: using R4BP 3

» http://echa.europa.eu/documents/10162/14938692/bsm_02_using_r4bp3_en.pdf

BSM Technical guide: using SPC

» http://echa.europa.eu/documents/10162/14938692/bsm_03_using_spc_en.pdf

BSM Application instructions: national authorisations

» http://echa.europa.eu/documents/10162/14938692/bsm_06_national_authorisation_en.pdf

BSM Application instructions: simplified authorisations

» http://echa.europa.eu/documents/10162/14938692/bsm_07_simplified_authorisation_en.pdf

BSM Process of invoicing in R4BP 3

» http://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>

Data Sharing

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The Biocidal Products Regulation ((EU) No 528/2012 (BPR)) prohibits repeating tests on vertebrates for the purposes of the BPR.¹⁴⁶

Owners of existing data and prospective applicants are obliged to share certain data from tests and studies on biocidal active substances and products submitted to relevant authorities under the BPR or the Biocidal Products Directive 98/8/EC.¹⁴⁷ The aim of this is to avoid unnecessary animal testing and to share costs.

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Before performing any new tests on vertebrate animals, the prospective applicant is obliged to make an inquiry to the European Chemicals Agency (ECHA); an inquiry about other tests and studies is optional. The inquiry serves to inform the prospective applicant about the contact details of the data submitters.

Where an inquiry is made, and there are available vertebrate tests, the prospective applicant is obliged to request from the data owner to share the data. For non-vertebrate tests, the data-sharing request is optional.¹⁴⁸ Where a request to share data is made, the data owner and the prospective applicant are required to make every effort to reach an agreement in a fair, transparent and non-discriminatory way.¹⁴⁹

WHEN



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

The prospective applicants are required to submit inquiries to share data:

146 Ref: Article 62(1) of the BPR.

147 Ref: Article 62 and 63 of the BPR.

148 Ref: Article 62(2) of the BPR

149 Ref: Article 63 of the BPR

WHAT



- For vertebrate tests, as soon as the need for such a test has been identified and before any test is performed;
- For non-vertebrate tests, at any time.

INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

To make an inquiry, you need to indicate during the submission:

- the name of the active substance when the inquiry relates to studies on active substances, or
- the relevant 'reference number' (asset number) of the biocidal product (BP) when the inquiry relates to studies on BPs.

More details on the information requirements:

- *BSM Application instructions: active substances*
- *BSM Application instructions: national authorisations*

It is also advised to consult the *Guidance on data sharing* available on ECHA's website. This document was originally created for REACH; therefore, an *explanatory note* has been added to clarify chapters that are particularly relevant to the BPR. The guidance helps the users to identify their obligations, the purpose of the inquiry process, how to conduct negotiations so as to prevent disputes and how to determine cost allocations and compensations.

Issues to consider:

Prior to submitting an inquiry to share data, prospective applicants may benefit from checking the [List of active substances and suppliers \(Article 95 list\)](#)¹⁵⁰ on ECHA's website to find out who manufactures or imports the same active substance or BP and contact the respective supplier to share these data. Note that the suppliers listed on the list are not always the data owners. The obligation to submit an inquiry discussed in this Practical Guide chapter are nevertheless not avoided by consulting the Article 95 list.

HOW



PROCEDURE TO FOLLOW

Inquiry to share data

The inquiry is submitted using R4BP 3. No IUCLID dossier is needed.

Following confirmation that the submission has passed the initial checks by ECHA, the inquiry will be processed by ECHA.

Applicants will find the relevant information and instructions for submitting and following-up their inquiry through R4BP 3 in the *BSM Technical guide: using R4BP 3*, available on ECHA's website.

¹⁵⁰ <http://echa.europa.eu/web/guest/information-on-chemicals/active-substance-suppliers>

RESULT



OUTCOME OF THE OBLIGATION/PROCESS

Following the inquiry to share data, ECHA provides the prospective applicants with the contact details of the data submitter to allow them to proceed with negotiations with the data owner on the sharing of the data. In parallel, ECHA informs the data submitter about an inquiry on their active substance or BP.

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

Article 95 obligation to share non-vertebrate data

For the purposes of making an application for inclusion on the Article 95 list, data sharing is mandatory for all toxicological, ecotoxicological and environmental fate and behaviour studies relating to Review Programme¹⁵¹ active substances, including any such studies not involving tests on vertebrates.¹⁵² For more information on the process of Inclusion on the Article 95 list, see [Practical Guide chapter on Article 95: List of active substances and suppliers](#).

Data-sharing dispute claims

Where the parties fail to reach an agreement, the prospective applicant may, as a last resort, initiate a data-sharing dispute procedure before ECHA which may result in ECHA granting a permission to refer to the data.¹⁵³

The inquiry is a formal pre-requisite for a data-sharing dispute claim. The dispute claim can be made at the earliest one month after the inquiry has been answered by ECHA.

A prospective applicant submitting a data-sharing dispute claim needs to provide documentary evidence demonstrating the efforts made by all parties compelled to reach an agreement on sharing data.

A data-sharing dispute claim must be submitted by the prospective applicant using the web form¹⁵⁴, available on ECHA's website. ECHA assesses the parties' respective efforts to reach such an agreement and takes a decision to grant or not to grant permission to refer to the relevant studies. We urge to continue negotiations even when a dispute has been submitted.

A data-sharing dispute must be settled before the application concerning that data can be submitted.

¹⁵¹ 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 Biocidal Products Regulation. See Commission Regulation (EU) No 613/2013. Note that the new Review Programme regulation is likely to be adopted in Autumn 2014.

¹⁵² Ref: Article 95(3) of the BPR.

¹⁵³ Ref: Article 63(3) of the BPR.

¹⁵⁴ <https://comments.echa.europa.eu/comments/cms/Article633.aspx>

ECHA decisions on data-sharing disputes are published on ECHA's website.¹⁵⁵

Where the negotiations started before 1 September 2013

As under the previous legislation (Directive 98/8/EC) there was no mandatory data-sharing obligation per se, the new obligation under the BPR cannot have retroactive effect, and ECHA cannot take into consideration what was achieved or negotiated prior to 1 September 2013 in a data-sharing dispute.

Where negotiations started before the entry into application of the BPR, parties should identify the remaining points of disagreement and the points on which they have reached an agreement as of 1 September 2013. This can serve as a basis for the negotiations that must take place after 1 September 2013.

It remains mandatory for "any person intending to perform tests or studies on vertebrate animals" to submit an inquiry to ECHA and to negotiate for at least one month after receiving the relevant contact details, before being entitled to submit a data-sharing dispute claim. This applies equally to a claim for toxicological and ecotoxicological studies not involving tests on vertebrates under Article 95.

COST



RELATED FEES

No fees are applicable for these processes.

HELP



TO CONTACT FOR FURTHER INFORMATION

ECHA Helpdesk

» <http://echa.europa.eu/contact/helpdesk-contact-form>

¹⁵⁵ <http://echa.europa.eu/regulations/biocidal-product-regulation/data-sharing/echa-decisions-on-data-sharing-disputes-under-bpr>

MORE



INFORMATION

Legislation relevant to biocides

- » <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

Regulatory aspects

Data sharing

- » <http://echa.europa.eu/regulations/biocidal-products-regulation/data-sharing>

Practical Guide: Special Series on Data Sharing

- » <http://www.echa.europa.eu/web/guest/practical-guides/bpr-practical-guides>
 - Introduction to the BPR and SME considerations
 - Data Sharing
 - Letters of Access
 - Consortia

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>
 - Inquire to share data for active substances

National authorisations

- » <http://echa.europa.eu/support/dossier-submission-tools/r4bp/submit-applications-for-national-authorisation>
 - Inquire to share data for biocidal products

• Biocides Submission Manuals

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

BSM Technical guide: using R4BP 3

- » http://www.echa.europa.eu/documents/10162/14938692/bsm_02_using_r4bp3_en.pdf

BSM Application instructions: active substances

- » http://www.echa.europa.eu/documents/10162/14938692/bsm_04_active_substances_en.pdf

BSM Application instructions: national authorisations

- » http://echa.europa.eu/documents/10162/14938692/bsm_06_national_authorisation_en.pdf

Q&As

» <http://echa.europa.eu/support/qas-support>

Questions and Answers on Data sharing under BPR

» <http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/biocidalproductsregulation/datasharing>

Research and development

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

According to Article 56 of the Biocidal Products Regulation ((EU) No 528/2012) (BPR) tests and experiments for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal products (BP) or a non-approved active substance (AS) intended exclusively for use in a BP may take place only under certain conditions¹⁵⁶.

In particular, the BPR requires that the person responsible for the experiment or test draws up and maintains written records which have to be made available to the competent authority (CA) upon request.

Furthermore, where the experiments or tests may involve or result in release to the environment of the BP, the person responsible for the experiments or tests needs to notify the CA of the Member State (MS) where the experiment or test will occur.

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Any person intending to carry out an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised BP or a non-approved AS intended exclusively for use in a BP. These provisions are only applicable to ASs and products that would normally need to be approved or authorised according to the BPR to be made available on the market and used.

More precisely, as stated in CA document CA-Nov14-Doc.7.5¹⁵⁷ the provisions should only apply to companies intending to start:

(a) The activity of research and development on new active substances (i.e. substances not on the EU market for biocidal purpose before 14 May 2000)¹⁵⁸.

156 Ref: Art 56 BPR

157 <https://circabc.europa.eu/sd/a/f50810e3-e752-4c55-b608-85799b13603b/CA-Nov14-Doc.7.5%20-%20Final%20-%20Application%20of%20R&D%20provisions.doc>

158 Article 3(1)(e) of the BPR).

(b) The activity of research and development on existing ASs which do not benefit from the transitional provisions¹⁵⁹. It can concern, for instance, existing ASs which were not supported under the Review Programme and for which companies submitted applications for approval under Article 11 of Directive 98/8/EC (BPD) or will submit, applications for approval, or applications for Annex I inclusion under the BPR.

(c) The activity of research and development on BPs containing the ASs listed under (a) and/or (b).

(d) After the date of approval or inclusion into Annex I to the BPR, the activity of research and development on the concerned existing or new AS (e.g. developing a new use of the AS within the scope of the approved product-type (PT)), and new BPs containing them.

WHEN



TIMELINES, AND DEADLINES RELATED TO THE OBLIGATION/PROCESS

When planning the experiments or tests that may involve or result in release to the environment of the BP, the applicant needs to take into account that the notified tests or experiments cannot be started before 45 days have passed from the notification.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Article 56 of the BPR lists the requirements for maintaining written records of experiments or tests, and for their notification when the experiments or tests may involve or result in release to the environment. *BSM Application instructions: national authorisations* available on ECHA's website explains what types of information files should be prepared and included in a notification of experiment or test.

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* available on ECHA's website.

The person responsible for the experiment or test shall draw up and maintain written records, to be made available to the CA upon request, containing the following information:

- identity of the product or the active substance,
- information on labelling,
- quantities supplied,
- contact information of those persons who received the product or the active substance,
- a dossier containing all available data on possible effects on human or animal health or impact on the environment.

¹⁵⁹ Ref: Articles 89 (i.e. not part of the review programme) and 93 of the BPR

HOW



PROCEDURE TO FOLLOW

Creation of a IUCLID 5 dossier:

The person submitting a notification of an experiment or test 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.

Submitting and processing an application:

The notification of experiment or test should be submitted through R4BP 3 to the MSCA where the experiment or test will occur. Following confirmation that the submission has passed the initial checks by ECHA, the application will be forwarded to the relevant CA. The CA draws up an opinion if it decides to prohibit or impose conditions on the experiment or test.

Notifiers 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 requesting any additional information, the application may be rejected or the processing may be completed disregarding the information that has been provided after the deadline.

RESULT



OUTCOME OF THE OBLIGATION/PROCESS

The respective CA may issue an opinion prohibiting or imposing conditions on the experiment or test, if the proposed experiments or tests are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on the environment. Examples of such conditions include measures to reduce the exposure e.g. quantities of the product or active substance that can be used in the experiment/test or on the extension of the areas to be treated.

In the absence of an opinion from the CA after 45 days from the notification, notified tests or experiments may take place.

The CA must inform the other CAs and the Commission of its decision.

TO NOTE**EXCEPTIONS AND PARTICULAR CASES**

For BPs regulated in accordance with national rules during the transitional period established under Article 89 of the BPR, the provisions of Article 56 of the BPR do not apply. Nevertheless, each MS can decide to establish specific provisions on research and development under their national rules for these situations.

COST**RELATED FEES**

Fees are not foreseen for this process.

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>

MORE**INFORMATION****Legislation relevant to biocides**

» <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

Regulatory aspects

Research and development

» <http://echa.europa.eu/regulations/biocidal-products-regulation/bpr-research-and-development>

Relevant Biocides competent authorities meetings documents

» <https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942>

CA-Nov14-Doc.7.5 – Final: Guidance on the application of provisions on Research and Development under Article 56 of the BPR

Guidance on Biocides legislation

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

Submission

- **Submission instructions**

- » <http://echa.europa.eu/support/dossier-submission-tools/r4bp/submit-applications-for-national-authorisation>
 - Notification of experiment or test

- **Biocides Submission Manuals**

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

BSM Technical guide: using IUCLID

- » http://echa.europa.eu/documents/10162/14938692/bsm_01_using_iuclid_en.pdf

BSM Technical guide: using R4BP 3

- » http://echa.europa.eu/documents/10162/14938692/bsm_02_using_r4bp3_en.pdf

BSM Application instructions: national authorisations

- » http://echa.europa.eu/documents/10162/14938692/bsm_06_national_authorisation_en.pdf

- **IUCLID Manuals**

- » <http://iuclid6.echa.europa.eu/support>

Q&As

- » <http://echa.europa.eu/support/qas-support>

Appeals

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The Biocidal Products Regulation ((EU) No 528/2012 (BPR)) foresees the possibility to appeal certain decisions taken by the European Chemicals Agency before the ECHA Board of Appeal (BoA).¹⁶⁰ Appeals are possible against the following types of decisions:

Decisions to reject the application due to non-payment of the ECHA fee:

- approval of active substance;
- amending Annex I to the BPR;
- renewal of approval of active substance;
- Union authorisation of biocidal product;
- renewal of Union authorisation of biocidal products;
- technical equivalence.

Decisions on substance:

- Technical equivalence:
 - Rejection of application because additional information has not been provided;
 - Decision on technical equivalence.
- permission to refer to tests or studies;
- permission to refer to data for which the data protection period is deemed to have expired.

It is also possible to appeal against some of ECHA's decisions taken under certain related Commission regulations. These Agency decisions concern:

- Applications for recognition of SME status (see Commission Implementing Regulation (EU) No 354/2013);
- Notifications or applications for changes of authorised products (see Commission Implementing Regulation (EU) No 564/2013):
 - rejection of notification of administrative, or application for minor or major change because of non-payment of ECHA fee;
 - rejection of application for minor change because of failure to provide additional information.

¹⁶⁰ Ref: Article 77 of the BPR.

- Notifications of additional active substance/product-type combination to be examined in the Review Programme (see Commission Regulation (EU) No 613/2013¹⁶¹):
 - rejection of notification because of non-payment of ECHA fee;
 - rejection of notification because of failure to provide additional information.

The BoA set up within ECHA is responsible for processing appeals against the relevant decisions adopted by the Agency under the BPR and related Commission regulations.

The main rules for bringing an appeal against an Agency decision are the same as for appeals under the REACH Regulation¹⁶². They are further detailed in the Rules of organisation and procedure of the BoA¹⁶³.

WHO



WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

Any natural or legal person may appeal against any of the above decisions addressed to that person. Any natural or legal person may also appeal against a decision that is of direct and individual concern to them, even though the decision is addressed to another person.

WHEN



TIMELINES AND DEADLINES RELATED TO THE OBLIGATION/PROCESS

If the appeal is brought by the addressee of the decision, an appeal has to be lodged within three months of the notification of the decision to the person concerned. If the appellant (i.e. the person making the appeal) is not the addressee of the decision, the appeal must be lodged within three months of the day on which the decision became known to the appellant.

For the types of ECHA decisions set out above which are appealable to ECHA's BoA, an appeal must be brought to the BoA before an action can be brought to the Court of Justice of the European Union.

WHAT



INFORMATION REQUIREMENTS AND SOURCES

Information requirements:

Forms, a supporting check list as well as *Practice Directions* are available on the BoA's section of ECHA's website. *Practice Directions* give further advice on the information to be submitted by the appellants.

¹⁶¹ Note that new Review Programme regulation is likely to be adopted in Autumn 2014.

¹⁶² Ref: Article 77 of the BPR as well as Article 92(1) and Articles 93 and 94 of the REACH Regulation.

¹⁶³ Ref: Commission Regulation (EC) No 771/2008.

HOW



PROCEDURE TO FOLLOW

All procedural documents, as well as any other correspondence must be sent by post, telefax or email to and lodged at the Registry of the Board. Documents may also be lodged directly at ECHA's reception.

An appeal will be considered to be received only once the applicable fee has been received.

If, after consultation with the Chairman of the BoA, the Executive Director of ECHA considers the appeal to be admissible and well founded, he may rectify the decision within 30 days of the appeal being filed.

ECHA has the opportunity to lodge the defence within two months after being notified of the notice of appeal.

Each appeal lodged before the BoA is announced on [ECHA's website](#)¹⁶⁴. Within two weeks of the publication of the announcement, any persons who consider that they have sufficient interest may apply to intervene in the proceedings by submitting an application for leave to intervene.

Parties to appeal proceedings may request an oral hearing no later than two weeks from the date of notification of the closure of the written part of the proceedings. Alternatively, a hearing may also be organised at the request of the BoA. [Hearings](#)¹⁶⁵ are normally held in public. Following the oral procedure, the BoA takes a decision on appeals.¹⁶⁶

Appellants will find the relevant rules and further information on appeal proceedings in *Rules of Procedure*¹⁶⁷ and in the *Practice directions*, available on ECHA's website.

RESULT



OUTCOME OF THE OBLIGATION/PROCESS

The BoA may exercise any power which lies within the competence of ECHA or remit the case to the competent body of the Agency for further action.

An appeal has suspensive effect on the contested decision until the decision of the BoA is taken

An action, contesting a decision taken by the BoA, may be brought before the Court of Justice of the European Union.¹⁶⁸

164 <http://echa.europa.eu/about-us/who-we-are/board-of-appeal/announcements>

165 <http://echa.europa.eu/about-us/who-we-are/board-of-appeal/hearings>

166 Ref: Article 77 of the BPR, Article 92(1) and (2) and Articles 93 and 94 of the Regulation (EC) No 1907/2006.

167 Ref: Commission Regulation (EC) No 771/2008.

168 Ref: Article 263 of the Treaty on the Functioning of the European Union and Article 94 of the Regulation..

TO NOTE



EXCEPTIONS AND PARTICULAR CASES

An action concerning an ECHA decision where no right of appeal lies before its BoA may be brought before the Court of Justice of the European Union, in accordance with Article 263 of the Treaty on the Functioning of the European Union.

COST



RELATED FEES

ECHA fee is applicable for this process. It is given in Annex III to *Commission Implementing Regulation (EU) No 564/2013*.

HELP



TO CONTACT FOR FURTHER INFORMATION

Board of Appeal

- » <http://www.echa.europa.eu/about-us/who-we-are/board-of-appeal/contact/enquiry-form>

MORE



INFORMATION

Legislation relevant to biocides

- » <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

ECHA's Board of Appeal

- » <http://www.echa.europa.eu/regulations/appeals>

Same biocidal product

WHY



PRINCIPLES BEHIND THE OBLIGATION/PROCESS

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

- a subsequent authorisation of the 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)¹⁶⁹, or
- already authorised under the Biocidal Product Regulation No 528/2012 (BPR)¹⁷⁰, 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 change¹⁷¹.

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.

169 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

170 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

171 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



The SBP regulation covers national, simplified and union authorisation procedure.

WHO IS CONCERNED BY THIS OBLIGATION/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)¹⁷² who is responsible for the 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 OBLIGATION/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 it 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 BPs¹⁷³:

- 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 date¹⁷⁴. 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 at a later date 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 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

¹⁷² 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>

¹⁷³ "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).

¹⁷⁴ Ref: Article 89(3) of the BPR.

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 only 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 authorisation¹⁷⁵. 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 BP¹⁷⁶ 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 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

¹⁷⁵ Ref: Article 89(4) of the BPR.

¹⁷⁶ "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.

HOW



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.

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 BP 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 authorisation¹⁷⁷.

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. On the basis of the BPC opinion, COM will take a decision on the authorisation¹⁷⁸.

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 t 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: national authorisations
- BSM Application instructions: simplified authorisations
- BSM Application instructions: Union authorisations
- BSM Technical guide: using SPC

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

RESULT



OUTCOME OF THE OBLIGATION/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 considered¹¹.

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

¹⁷⁷ Ref: Article 26 and Articles 29-30 of the BPR respectively.

¹⁷⁸ Ref: Articles 43-44 of the BPR.

TO NOTE



of the reference BP.

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 submit an application 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 market¹².

COST



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 the fourth entry of Annex II to Commission Implementing Regulation (EU) No 564/2013.

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

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 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: national authorisations

- » http://echa.europa.eu/documents/10162/14938692/bsm_06_national_authorisation_en.pdf

BSM Application instructions: simplified authorisations

- » http://echa.europa.eu/documents/10162/14938692/bsm_07_simplified_authorisation_en.pdf

BSM Application instructions: Union authorisations

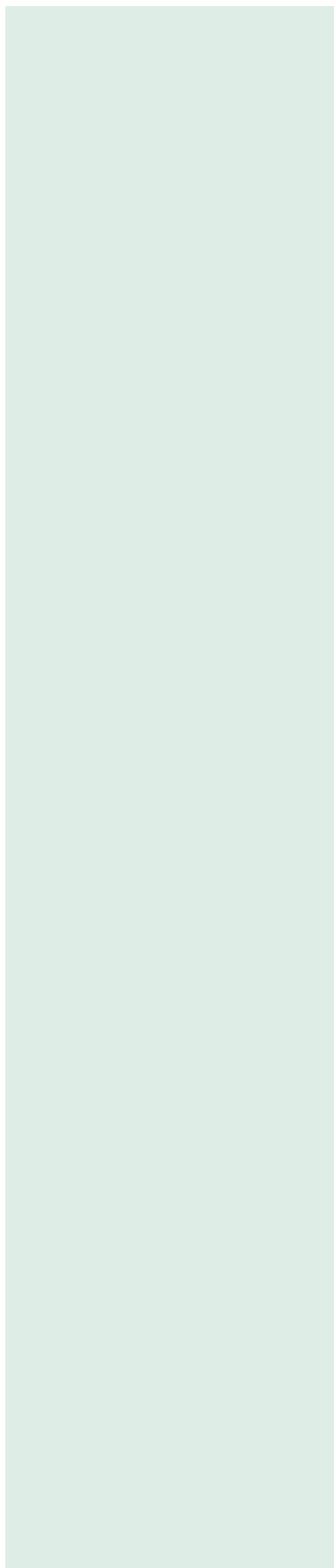
- » http://echa.europa.eu/documents/10162/14938692/bsm_08_union_authorisation_en.pdf

BSM Process of invoicing in R4BP 3

- » http://www.echa.europa.eu/documents/10162/14938692/bsm_09_invoicing_en.pdf

Q&AS

- » <http://echa.europa.eu/support/qas-support/qas>



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