ECHA
EUROPEAN CHEMICALS AGENCY

BPR Handbook

May 2023

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LEGAL NOTICE

This document aims to assist national helpdesks and users with their obligations under the BPR Regulation. However, users are reminded that the text of the BPR Regulation 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 regards to the use that may be made of the information contained in this document.

Version	Changes	Date
Version 0	First edition	May 2023

Introduction

The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. This regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment.

The text was adopted on 22 May 2012 and is applicable from 1 September 2013, with a transitional period for certain provisions. It repealed the Biocidal Products Directive (Directive 98/8/EC).

Biocidal products are classified into 22 biocidal **product-types (PT)**, grouped in four main areas – listed in Annex V to the BPR.

The basic principle in the BPR is that a biocidal product must be authorised before it can be made available on the market or used in the European Economic Area (EEA) and Switzerland. This takes place in two consecutive steps. First, the active substance (AS) is evaluated and, provided the criteria are fulfilled, is then approved in a specified product-type. The second step is the authorisation of each product consisting of, containing or generating the approved active substance(s).

Links:

Regulation (EU) No 528/2012 - the BPR

Understanding BPR – ECHA website

Biocides for non-EU companies

Product Types (PTs)

Introduction to the BPR and SME considerations

Guidance on biocides legislation

Technical agreements for Biocides

Biocides competent authorities (CA) meetings documents – all documents

Documents **finalised** at CA meetings

Related Q&As (Scope: General):

ID	Question
900	What is the Union list of approved active substances and where I can find it?
906	Should I register an active substance under the REACH Regulation?
908	Is a safety data sheet required for active substances and biocidal products according to the BPR?
986	Which active substances ('ASs') in a biocidal product containing more than one AS have to be approved before the product can be authorised under the BPR?
989	Do ecotoxicological and toxicological tests have to comply with the principles of good laboratory practice (GLP)?

990	Under the BPR, can I apply for approval of an active substance for which a non-inclusion decision has been taken under the BPD (Biocidal Product Directive)?
1021	Would a submission made under the REACH Regulation satisfy the requirements of the BPR?

1. Active substance approval

Active substances/PT combinations need to be approved before an authorisation for a biocidal product containing them can be granted. The approval of an active substance is granted for a defined number of years, not exceeding 10 years and is renewable.

The active substances/PT combinations are first assessed by an evaluating Member State Competent Authority and the results of these evaluations are forwarded to ECHA's Biocidal Products Committee, which prepares an opinion within 270 days. The opinion serves as the basis for the decision on approval which is adopted by the European Commission.

Links:

Approval of active substances – ECHA website

Practical guide on the approval of biocidal active substances

Biocidal Products Committee

BPC opinions on active substance approval

Combined CAR and CLH template – ECHA website

CA documents on active substances

1.1 List of approved substances

European Commission (EC) includes approved active substances for a given product type in the Union list of approved active substances. EC decisions on approval and non-approval for a given product type are published in the Official Journal of the European Union. The Union list of approved active substances mentioned in Article 9(2) of the BPR is publicly available on the ECHA dissemination site

1.2 Existing and new active substances

Existing active substances are those substances which were on the market on 14 May 2000 as an active substance of a biocidal product (for purposes other than scientific or product and process-orientated research and development), Art 3(1)(d) of the BPR. The existing active substances/PT combinations which were identified as such and for which a notification was accepted are included in Annex II, part 1 of the Review Programme Regulation (EU) No 1062/2014.

The transitional provisions laid down in Article 89 (2) of the BPR allow biocidal products containing an active substance/PT combination included in the Review Programme to be made available on the market and used, subject to national rules, pending approval of the substance and authorisation of the product, until three years after the date of their approval (shorter timeframes apply in case of non-approval).

New active substances are substances which were not on the market on 14 May 2000, as an active substance of a biocidal product for purposes other than scientific or product

and process-orientated research and development (Article 3(1)(e) of the BPR). Products containing such substances cannot be placed on the market during the transitional period. They can only be placed on the market after the substance is approved and the product is subsequently authorised under the BPR.

Links:

Existing active substance – ECHA website

New active substance – ECHA website

Regulation (EU) No 1062/2014 – the Review Programme Regulation

CA documents on the Review Programme

Related Q&As (Scopes: Review Programme, submissions via R4BP 3):

ID	Question
1122	What happens if the withdrawal (by all the participants supporting the active substance/product-type combination) takes place after the evaluating Competent Authority (eCA) has submitted the draft Competent Authority Report (CAR) to the applicant?
1123	When will the Article 95 list be updated following the joining, or replacing of one of the participants by mutual agreement?
1124	When will the Article 95 list be updated following the notification to take over the role of participant?
1125	Who can submit notifications?
1126	Do you need to make separate notifications per active substance/ product-type combination, or can one notification cover for several product- types? Do companies need to pay the notification fee for each PT?
1127	Will a notifier (under Article 17) be reimbursed the fee that it had paid, if the notification is rejected?
1128	Can a group of companies (e.g. a taskforce) submit a joint notification?
1129	From which evaluating Competent Authority (eCA) should I get the agreement to evaluate my application?
1130	When submitting a notification to take over the role of participant for a substance which is on part 2 of Annex II of the Review Programme Regulation, is it necessary to provide evidence that the substance is an existing active substance?
1216	How can I add, replace or join new participants to my active substance evaluation under the review programme?
1620	Is a change of participant in the review programme the same as the change of a case owner in active substance evaluation?
1130	When submitting a notification to take over the role of participant for a substance which is on part 2 of Annex II of the Review Programme Regulation, is it necessary to provide evidence that the substance is an existing active substance?
1214	Where can I find my application related to the review programme in R4BP 3?

1.3 Redefinition

Where the evaluation of an active substance demonstrates that it does not exactly match the identity of the substance as included in the Review Programme, such that the evaluation does not allow conclusions to be drawn relating to the substance identity included in the Review Programme, the substance identity will be **redefined** by the evaluating Competent Authority after consultation with the participant (the person who supports the inclusion of the substance in the Review Programme). The substance will

continue to be evaluated in the Review Programme (for the relevant product-types) under the newly defined substance identity.

For the former substance identity (as included in Part 1 of Annex II of the Review Programme Regulation), ECHA will publish an **open invitation** to make a notification to take over the role of the participant. The possibility to notify does not cover the new substance identity, but only the original substance identity. A prospective participant needs to notify through R4BP 3 with a dossier in IUCLID format **within 12 months** from the date of the ECHA publication of the open invitation.

Links:
Existing active substance – ECHA website
ECHA's open invitations for notifications
Notification procedure
List of notifications

1.4 Annex I substances

Annex I to the BPR lists initially active substances identified as presenting a low risk under REACH or the Biocidal Products Directive, substances identified as food additives, pheromones and other substances considered to have low toxicity, such as weak acids, alcohols and vegetable oils used in cosmetics and food. Other active substances may be added provided that there is evidence that they do not give rise to concern. This procedure can be initiated by the Commission at its own initiative, or at the request of an economic operator (based in the EU or not), or a Member State.

The BPR establishes the criteria to identify substances that do not give rise to concern (Art. 28) while Commission Implementing Regulation (EU) No 88/2014 establishes the procedure for the submission by companies of requests for the amendment of Annex I (first inclusion of an active substance or amendments to the relevant restrictions) and their subsequent evaluation.

Biocidal products containing one or more of active substance(s) under Annex I are eligible for a **simplified authorisation procedure**.

Links:
Annex I amendment – ECHA website
ECHA dissemination site
Commission Implementing Regulation (EU) No 88/2014
BPC opinions on inclusion in Annex I
Simplified authorisation
CA documents on Annex I substances

Related Q&As (Scope: Simplified Authorisation):

ID	Question
902	How can a company request an amendment of Annex I of the BPR?

1.5 In situ generated AS

Biocidal active substances are called in situ generated active substances if they are

generated from one or more precursors at the place of use. The approval of such substances requires evaluation of the generated active substance and of the precursor(s) it is generated from, in the context of each PT.

Some AS/PT combinations were not eligible for inclusion in the Review Programme (because the active substance was not originally notified, or because the combination is only supported for other PTs), but companies had the possibility to submit an application for the approval of the in situ generated active substances. If this submission was done before 1 September 2016, the product benefits from the transitional provision of Article 93 of the BPR and can be maintained on the market, subject to national provisions. The information on whether an Art. 93 application was submitted for a given AS/PT can be found on the Art. 95 list with the corresponding inclusion reason 'Article 93'.

Links:

In situ generated active substances – ECHA website

Article 93 transitional measure

List of active substances and suppliers (Article 95 list)

CA documents on in-situ generated active substances

Related Q&As (Scope: In situ):

ID	Question
1205	What data on precursors are expected to support the assessment of active substances generated in situ?
1206	How can I prepare a dossier in IUCLID for the active substance and the precursor(s), including waiving of data?
1207	How can I report the conditions under which the in situ generated active substances are created?
1208	How can I derive reference specifications and reference sources (technical specifications)?
1209	Is a risk assessment for the precursors needed or is hazard assessment sufficient for the precursors?
1210	Do I have to assess the efficacy of precursors?
1211	Do I need to assess the substitution and exclusion criteria for the precursors?
1212	What needs to be classified?

1.6 Exclusion criteria and candidates for substitution

1.6.1 Exclusion criteria

In principle, active substances meeting the exclusion criteria set out in Art. 5(1) of the BPR will not be approved.

This includes:

- carcinogens, mutagens and reprotoxic substances categories 1A or 1B according to the CLP Regulation,
- endocrine disruptors,
- persistent, bioaccumulative and toxic (PBT) substances,
- very persistent and very bioaccumulative (vPvB) substances.

Derogations may be possible as laid down in Article 5(2) of the BPR, in particular when the active substance may be needed on the grounds of public health or of public interest

when no alternatives are available. In this case, approval of an active substance is granted for a maximum of five years.

To decide if the active substance may be approved or not, a consultation is organised to collect information on whether the conditions for derogation set out in Article 5(2) of the BPR are satisfied. The European Commission together with Member States will take into account the information collected when deciding whether to approve or not the concerned active substance.

Links:

Consultation on derogation to the exclusion criteria – ECHA website

Previous consultations on derogation to the exclusion criteria – non-confidential Comments submitted during consultations – CIRCABC

CA documents on Exclusion and substitution

Information on approved active substances with regard to certain exclusion substitution criteria – CIRCABC

1.6.2 Candidates for substitution

An active substance will be considered as a candidate for substitution if any of the following criteria are met:

- It meets at least one of the exclusion criteria,
- It is classified as a respiratory sensitiser,
- Its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use,
- It meets two of the criteria to be considered as PBT,
- It causes concerns for human or animal health and for the environment even with very restrictive risk management measures,
- It contains a significant proportion of non-active isomers or impurities.

If during the approval process of an active substance, the evaluating competent authority identifies an active substance as a potential candidate for substitution, this will be listed in the conclusions of its evaluation. In such cases, ECHA will initiate a public consultation. The information submitted during consultation will be taken into due account by the Biocidal Products Committee (BPC) before finalising its opinion.

Active substances which are candidates for substitution will not be approved for more than seven years, even in the case of renewal.

When an active substance is identified as a candidate for substitution, products containing that active substance will have to be subject to a comparative assessment at the time of authorisation and will only be authorised if there are no better alternatives.

Links:

Consultation on potential candidates for substitution

Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance

Analysis of alternatives template

Competent authority implementation note

Analysis of alternatives and tools to support substitution of biocides – webinar

CA documents on Comparative Assessment

Further relevant links are available under the abovementioned exclusion criteria section.

1.7 Renewal of AS approval

The approval of an active substance is granted for a defined number of years, not exceeding 10 years and is renewable. To support the renewal of an approval of an active substance, companies have to submit an application to ECHA at the latest 550 days (approximately 1.5 years) before the current expiry date of the approval.

If several companies are interested in supporting the same active substance, they should preferably cooperate and submit a single common application.

Since the approval of active substances relates to specific product-types, an approval application also relates to a specific active substance/product-type combination.

To facilitate this process, ECHA makes a list of upcoming deadlines where an application for renewal of active substance (AS-RNL) is due in the next 4 years. Companies are requested to express their intention to renew the active substance approval to ECHA at least one year before the legal deadline for submitting the application for renewal.

Links:

Renewal of active substances – ECHA website

Guidance on the data requirements and assessment of applications for renewal of approval of active substances

Practical guide on the renewal of approval of biocidal active substances

2. Article 95

Article 95 of the 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.

From 1 September 2015, a biocidal product 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.

Companies that have not already submitted their own dossier on an active substance under the BPD or the BPR (for active substance approval or product authorisation) may submit an application to ECHA to be included in the list. Not all companies need to be listed. It is sufficient that one company within the same supply chain is listed.

Links:

Active substances and suppliers – ECHA website

List of active substances and suppliers (Article 95 list)

Practical guide on the list of active substances and suppliers (Article 95 list)

Guidance on the Biocidal Products Regulation Volume V, Guidance on active substances and suppliers (Article 95 list)

Related Q&As (Scope: Active substance suppliers):

ID	Question
899	If a company obtains a Letter of Access (LoA) to a complete dossier and submits the LoA to ECHA for inclusion in the list of relevant substances and suppliers under Article 95 of the BPR, does it have to pay a fee to ECHA?
1004	How is the reference to Article 63(3) of the BPR in Article 95(3) to be understood? Does mandatory data sharing apply to all toxicological and eco-toxicological studies, as well as environmental fate and behaviour studies, including non-vertebrate studies?
1005	Does the data owner have to share non-vertebrate data, if asked for it?
1008	In case of affiliates/multinational company, do all affiliates need to be listed or is it enough to have one legal entity on the list?
1012	How long does it take to be listed on the Article 95 list once an application for Article 95 inclusion was made or a positive decision has been taken?
1013	Is it enough if either the manufacturer of the active substance or the manufacturer of the biocidal product is on the list?
1014	Where a product supplier is listed, will the name and the address of the manufacturer of the active substance and the location of the manufacturing sites be made public?
1015	Will trade names or qualities be given in the Article 95 list or how can a formulator be sure that its active substance is on the list?
1017	Can non-EU companies be included in the Article 95 list?
1018	What are the obligations of the EU representative for Article 95 under the BPR?
1019	Is it possible for the same company to be listed on the Article 95 list as a 'substance supplier' and as a 'product supplier' for the same substance?
1020	How can a small company become listed as a "product supplier" if the active substance supplier is not applying to be included in the list of active substances and suppliers?
1022	What if my application for inclusion in the Article 95 list is not approved?
1024	Are the fees applied per application or per number of product types (PT)s for which the listing has been requested?
1026	How can a company get contact details of the substance/product supplier under Article 95 to ask for the LoA?
1110	Can an EU-based toll manufacturer sell an active substance or a biocidal product (consisting of, containing or generating that active substance) to customers in its own right?
1111	Can an EU-based toll manufacturer manufacture active substances for a supplier which is not on the Article 95 list?
1112	Is an EU-based toll manufacturer of active substances obliged to be on the Article 95 list?

3. Data sharing and inquiry

Prospective applicants intending to perform new tests on vertebrate animals, have an obligation to find out which tests and studies are already available, by submitting an inquiry through R4BP 3 to ECHA. Prospective applicants may also inquire about tests and studies not involving tests on vertebrate animals. ECHA will provide the contact details of

the corresponding data submitters.

Links:

Data sharing – ECHA website

Inquiry page

ECHA decisions on data sharing disputes under BPR

Practical guide on data sharing under the biocidal products regulation

Practical Guide on BPR: **Special Series on Data Sharing** – Letters of Access , data sharing and consortia

Related Q&As (Scope: Data sharing)

ID	Question
819	What is the purpose of data-sharing?
820	Which actors have data sharing obligation under Biocidal Products Regulation?
821	What must any person do if they need to perform tests or studies?
822	What is meant by "compensation for Data Sharing"?
823	How shall the negotiations be conducted?
905	What are the data sharing requirements under the BPR?
910	What can a prospective applicant do if they do not reach an agreement to share data or costs with the data owner/submitter?
1003	What is a reasonable time for the negotiations for data sharing?
1006	Does the non-EU data owner have the obligation to share data?
1007	Is the data sharing obligation limited to situations where the applicant's substance is the same as the one on which the tests were carried out?

4. Biocidal product authorisation

After active substance approval in the relevant product type, all biocidal products must get an authorisation before they can be made available on the market. Companies can choose between several alternative processes, depending on their product and the number of countries where they wish to sell it.

Links:

List of authorised biocidal products under the BPR

CA documents on Biocidal Products

Product assessment report templates – ECHA website

Related Q&As (Scope: General):

ID	Question
1899	Can the term "natural" (or similar) be a part of the trade name of biocidal product, even when the trade name is a registered trademark?

4.1 Union Authorisation (UA)

The BPR offers the possibility to have certain biocidal products authorised at Union level. This will allow companies to place their biocidal products on the market throughout the entire Union, without the need to obtain a specific national authorisation. UA gives the

same rights and obligations in all the Members States as those provided by national authorisations. UA can be granted to biocidal products with similar conditions of use across the Union, except those containing active substances meeting the exclusion criteria and those belonging to product-types 14, 15, 17, 20 and 21.

Links:

Union authorisation – ECHA website

Practical guide on Union authorisation of biocidal products

BPC Opinions on Union authorisation

Related Q&As: (Scope: BPR general)

ID	Question
1057	Is an annual fee payable to ECHA also for a Union Authorisation granted through the Same Biocidal Product regulation?
1548	What is the fee for Union authorisation of a same biocidal product application?

4.2 National authorisation (NA)

Companies planning to sell their products in one specific EU Member State must apply for product authorisation in that country. The national authorisation of a BP is granted by the competent authority of the Member State where the BP will be made available on the market (receiving MS) and is only valid for the approved terms and conditions stated therein.

Links:

National authorisation – ECHA website

Practical guide on national authorisation of biocidal products

4.3 Mutual recognition (MR)

If a company wishes to extend the national product authorisation to other markets in the EU, it can ask other Member States to recognise it. Companies can apply for mutual recognition either in sequence or in parallel.

To apply for mutual recognition **in sequence**, companies first need to get their product authorised in one Member State. After this, they can request other Member States to recognise this authorisation.

For mutual recognition **in parallel**, the company can submit an application for product authorisation in one Member State (called the reference Member State) and simultaneously ask other countries to recognise the authorisation as soon as it is granted.

If a concerned Member State does not agree on the conclusions of the assessment report and/or on the summary of the biocidal product characteristics in relation to the conditions of Article 19 of the BPR, the case will be referred to the Coordination Group (CG).

Links:

Mutual recognition – ECHA website

Practical guide on mutual recognition of biocidal products

Coordination group – ECHA website

Related Q&As (Scope: Submissions via R4BP 3)

ID	Question
1504	When can I submit a mutual recognition in parallel?

4.4 Simplified Authorisation (SA)

A simplified authorisation procedure aims to encourage the use of biocidal products that are less harmful for the environment, human and animal health. To be eligible for the simplified authorisation procedure a biocidal product must comply with all of the conditions set out in Art. 25 of the BPR:

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

Where a simplified authorisation is granted, the biocidal product may be made available on the market in other Member States **without the need** for mutual recognition. The authorisation holder, however, needs to notify each relevant Member State no later than 30 days before placing the product on its territory.

Links:

Simplified authorisation – ECHA website

Practical guide on simplified authorisation of biocidal products

Ca-March16-Doc.4.6 Final.Rev9 – QA On Simplified Procedure.Docx

Related Q&As (Scopes: BPR general, simplified authorisation)

ID	Question
1899	Can the term "natural" (or similar) be a part of the trade name of biocidal product, even when the trade name is a registered trademark?
903	How much are the fees for the simplified authorisation procedure according to the provisions of the BPR and how can a company apply for it?

4.5 Same Biocidal Products (SBP)

To meet the needs of companies and reduce their administrative burdens, applications for authorisations of same biocidal products can be requested where there is already an identical product authorised or where the identical product is under evaluation and not yet authorised.

The precondition for authorisation of same biocidal products is that these products are identical within the limited variations of an administrative change. The SBP regulation covers national, simplified and Union authorisation procedures. The same rules for a single biocidal product apply also for a biocidal product family. Same product authorisation can also be granted for an individual product of a biocidal product family.

Links:

Same Biocidal Products – ECHA website

Practical guide on same biocidal product authorisation

Regulation (EU) No 414/2013 – the Same Biocidal Products Regulation

CA-Sept21-Doc.4.6 – Mutual Recognition of same BP.docx

CA-March15-Doc.4.7-Final – BPF and SBP applications.doc

Webinar "Same Biocidal Product Regulation and new family SPC"

4.6 Biocidal Product Family

A biocidal products family is a group of biocidal products that are used for similar purposes and contain active substances with same specifications. A biocidal product family also has specified variations in the composition of the products to ensure that the level of risk is not increased or the efficacy of the product is not reduced. All products within a biocidal product family are covered by one authorisation and can be made available on the market.

Links:

Biocidal Product Family – ECHA website

CA-July19-Doc.4.2- Final – Guidance note on BPF concept_rev2.docx

CA documents on biocidal product families

Template overview of the biocidal product family

Webinar: How to manage your biocidal product family

Related Q&As (Scopes: SPC, submissions via R4BP 3):

ID	Question
1232	How can I ensure that minimum information is provided in a family SPC?
1230	How can I handle family applications submitted following the workaround solution with the new family SPC structure?
1233	How do I add an additional product type or type of formulation in a family SPC?

4.7 Changes of biocidal products

The biocidal product authorised under the BPR must comply with the terms and conditions stipulated in the product authorisation. Any changes to the product require that the authorisation holder invokes Article 50 of the BPR, with the aim of amending the product authorisation.

Three types of changes can be distinguished:

a) Administrative changes, that are further divided into two sub-types:
   - changes which must be notified before implementation; and
   - changes which can be notified within 12 months after implementation;
b) Minor changes, which should not affect the conclusion regarding the fulfilment of the conditions for authorisation; and
c) Major changes, when a need for reassessment of the risk and the efficacy can be expected to fulfil the conditions for authorisation.

The same rules as for a single product apply also for a biocidal product family.

If is not possible to determine the category to which the intended change belongs (e.g.

the change is not listed in one of the tables in the Annex to the Changes Regulation), the applicant may request ECHA to issue an opinion on the classification of the change.

Links:

Regulation (EU) No 354/2013 – the Changes Regulation
Practical guide on changes of biocidal products
Request to ECHA to provide an opinion on the classification of a change of a products – ECHA opinions on applications for classification of a change

Related Q&As (Scope: Submission via R4BP 3)

ID	Question
1351	How can I group SPCs and assets in a grouped submission of administrative changes?

4.8 Renewals of product authorisations

The BPR states that an authorisation of a biocidal product can be granted for a maximum period of 10 years. The renewal application must be submitted at least 550 days before the expiry date of the authorisation to the authority that granted the authorisation: the Member State Competent Authority (MSCA) who granted the first authorisation in case of national authorisations or to the Commission in case of Union Authorisation. If authorisations are subject to, or granted through, mutual recognition, the application should be sent to a reference MSCA – and at the same time to all MSCAs that have granted a related mutual recognition as set out by the MR Renewal Regulation.

Links:

National authorisation and mutual recognition renewal – ECHA website

Practical guide on renewal of national authorisation and authorisations subject to mutual recognition

Regulation (EU) No 492/2014 – the MR Renewal Regulation

CA-Sept21-Doc.4.12-SBP renewal.docx

Related Q&As (Scope: Submissions via R4BP 3):

ID	Question
1503	Can I submit renewals linked to mutually recognised applications when the (prospective) authorisation holders are different?

5. Technical equivalence

The purpose of technical equivalence is to enable 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 of the substances (the reference source) by having a different manufacturing process, a different manufacturing location or a different manufacturer.

Links:

Technical equivalence – ECHA website

Practical guide on technical equivalence

Guidance on the Biocidal Products Regulation Volume V, Guidance on applications for technical equivalence

Related Q&As (Scope: BPR General)

ID	Question
1992	What happened to the chemical similarity check service that ECHA used to offer?

6. Treated Articles

The BPR sets rules for the use of articles treated with, or intentionally incorporating, one or more biocidal products. The active substances contained in a biocidal product used in the treatment of the treated articles, have to be either:

- Already approved,
- Listed in Annex I,
- Covered by the provisions of Article 89 (the Review Programme), Article 93 and Article 94 of the BPR (Art. 94 list)

Manufacturers and importers of treated articles need to ensure that products are labelled according to both the regulation on Classification, Labelling and Packaging and the additional requirements defined by the BPR, namely Article 58.

The responsibility for identifying the nature of a product (i.e. whether it corresponds to a treated article, or not), lies with the national authorities.

Links:

Treated Articles- ECHA website

Treated articles: allowed active substances (Article 94 list)

CA documents on treated articles

Related Q&As (Scope: Treated Articles)

ID	Question
898	How to comply with the BPR for placing on the market treated articles?
904	Is my product a treated article, a biocidal product or neither?
988	Does the BPR foresee transitional measures for the labelling and information requirements for treated articles?
1025	Does Article 95 of the BPR apply to treated articles, i.e. can a mixture or article only be treated with or intentionally incorporate a biocidal product containing an active substance if the supplier has submitted a dossier or a letter of access to ECHA?

7. Fees

Fees payable to ECHA are found in the BPR fee regulation.

Fees payable to the evaluating Competent Authority (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. The contact information for national helpdesks is available in the ECHA website.

Links:
Regulation (EU) No 564/2013 – the BPR Fee Regulation

Related Q&As (Scope: Invoicing and payments):

ID	Question
759	Who sets ECHA fees and charges payable for the Biocidal Products Regulation?
760	Where can I find an overview of the fees?
761	When will I receive ECHA's invoice and where can I find it?
762	What is the deadline for paying ECHA's invoice?
763	How do I know I paid on time?
764	How do I pay ECHA's invoice?
765	What is ECHA's bank account number for the payment of invoices related to the BPR?
766	What reference should I indicate in my payment?
767	What are the consequences of not paying an invoice within the payment due date?
768	If my application is rejected/withdrawn before or during validation or during the assessment, do I receive a refund?
769	Why is ECHA's invoice without value added tax (VAT)?
770	Why are the activities of ECHA not taxable?
771	How long does it take until ECHA receives my payment?
772	How does ECHA handle my payment?
773	How can I ensure a successful submission of the application/notification allowing it to pass to the next step?
774	How can I see that ECHA has received and validated my payment?
775	When should I provide ECHA with a payment advice?
776	What is a proof of payment and when does it need to be sent to ECHA?
777	Does ECHA send credit notes?
778	If I have received two invoices and one credit note, which invoice reference number do I indicate in the payment?
779	If I have already paid the invoice for which ECHA later issues a credit note, how will the paid amount be credited back to my company?
780	What are the rules of a refund?
781	Do ECHA invoices have to be electronically signed?
782	How can I prepare my accounts payable department or my accounting company in view of ECHA's invoices?
783	What information about my company appears on ECHA's invoice and credit note?
784	Does ECHA need a purchase order for my application?
785	What is the contact address of ECHA's accounting department (accounts receivable)?
786	My company information has changed and the invoice is not correct; does ECHA issue updated invoices?
917	How do I indicate my company size?
1354	What documents are needed in R4BP 3 for SME status recognition under Biocidal Products Regulation?

8. Legislation

The legal text of the Biocidal Products Regulation (EU) No 528/2012, the related implementing and delegated acts, and the Article 3(3) Commission decisions are available in this link.

9. Other supporting material

The aim of the Biocides Submission Manual (BSM) series is to provide industry users with detailed and illustrative technical assistance. The BSM series describes how to build IUCLID dossiers for the various Biocidal Product Regulation applications and how to submit and manage those applications in R4BP 3 until a successful outcome is achieved. Submission manuals

Various forms and templates are required to be filled in by either applicants, or authorities when filing, or evaluating an application, respectively.

Forms and templates

Other supporting documents may be needed for each of the application types under the Biocidal Products Regulation.

Supporting documents