

SUPERSEDED GUIDANCE - NEWER VERSION AVAILABLE

Guidance on the Biocidal Products Regulation

Volume V,

Guidance on active substances and suppliers (Article 95 list)

Version 2.0

December 2014



LEGAL NOTICE

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Guidance on the Biocidal Products Regulation: Vol V. Guidance on active substance and suppliers (Article 95 list)

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PREFACE

This Guidance describes the obligations under Article 95 of the Biocidal Products Regulation (EU) No 528/2012 (BPR) and how to fulfil them.

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NOTE to the reader:

Text written in *italics* originates from the BPR or its Annexes.

List of abbreviations

Standard term / Abbreviation	Explanation
BPD	Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products (Biocidal Products Directive)
BPR	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 (Biocidal Products Regulation)
CA	Competent Authority
IUCLID	International Uniform Chemical Information Database
LoA	Letter of access
OECD	Organisation for Economic Co-operation and Development
PT	Product type
R4BP	Register for Biocidal Products

List of terms and definitions

Standard term / Abbreviation	Explanation
Active substance	A substance or micro-organism that has an action on or against harmful organisms (Article 3(1)(c) of the BPR).
Alternative dossier	Dossier prepared and submitted by alternative suppliers.
Alternative supplier	Substance suppliers or product suppliers who are not actively supporting the Union approval of the active substance, yet benefit from the regulatory regime. In particular they include those who are not participants in the Review Programme yet make available existing active substances on the market (either on their own or in a biocidal product) before approval, and also those who are newcomers after the active substance is approved.
Applicant	Entities that submit an application to ECHA under Article 95 to be placed on the list of active substances and suppliers.

Standard term / Abbreviation	Explanation
Biocidal product	<p>Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.</p> <p>Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.</p> <p>A treated article that has a primary biocidal function must be considered a biocidal product (Article 3(1)(a) of the BPR).</p>
Complete substance dossier	A dossier complying with Annex II to Regulation (EU) No 528/2012 or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive (Article 95(1), first sub-paragraph of the BPR).
Compliance Check	A check on whether the submission is compliant with the requirements of Article 95. The compliance check depends on the type of submission (complete substance dossier, letter of access etc.) but as the first step ECHA checks the identity of the active substance.
Entity	Any natural or legal person.
EU representative	An entity established in the EU or the EEA appointed by a non EU manufacturer for the purpose of Article 95 to represent them.
evaluating Competent Authority (eCA)	The Competent Authority which assesses the active substance in the approval process (Article 7(1) of the BPR).
Existing active substance	A substance which was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific research or product and process-orientated research and development (Article 3(1)(d) of the BPR).
Formulator	For the purposes of this guidance, an entity that includes an active substance into formulations for making it available on the market.
Letter of Access (LoA)	An original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by the European Chemicals Agency, Member State competent authorities or the Commission, for the purposes of the BPR (Article 3(1)(t) of the BPR).
List of AS & suppliers (Article 95 list)	The list ECHA is to publish under Article 95(1) of the BPR.

Standard term / Abbreviation	Explanation
Making available on the market	Any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge (Article 3(1)(i) of the BPR).
New active substance	A substance which was not on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific research or product and process-orientated research and development (Article 3(1)(e) of the BPR).
Person	Natural (individual human being) or legal persons (legal entities).
Product supplier	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 (Article 95(1), second sub-paragraph of the BPR).
Product type	Means one of the product types specified in Annex V of the BPR.
Relevant substance	All active substances, and all substances generating an active substance, for which a dossier complying with Annex II to Regulation (EU) No 528/2012 or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive ("the complete substance dossier") has been submitted and accepted or validated by a Member State in a procedure provided for by this Regulation or that Directive (Article 95(1), first sub-paragraph of the BPR).
Review Programme	The work programme established by the Commission under Article 16 of Directive 98/8/EC for the assessment of existing active substances which is continued under Article 89(1) of the BPR, the detailed rules of which are set out in Commission Delegated Regulation (EU) No 1062/2014.
Review Programme participant	A person who has submitted an application for a substance/product type combination included in the Review Programme, or has submitted a notification found compliant pursuant to Article 17(5) of Commission Delegated Regulation (EU) No 1062/2014, or on whose behalf such application or notification has been submitted (Article 2(b) of Commission Delegated Regulation (EU) No 1062/2014)
Substance supplier	A person established in the EU who manufactures or imports a relevant substance, on its own or in biocidal products (Article 95(1), second sub-paragraph of the BPR).
Supporters of active substances	An entity which submitted an application for the approval of an active substance under Article 11 of the BPD, the Review Programme or Article 7 of the BPR.
Third party dossier	A dossier on an active substance submitted as part of a product authorisation application, which is not the same as the dossier used for the approval of the active substance, and that complies with the data requirements of Annex IIA or IVA and where relevant IIIA of the BPD or Annex II of the BPR.

1. Introduction

Article 95 of the of the Biocidal Products Regulation (EU) No 528/2012 (BPR) is titled “*Transitional¹ measures concerning access to the active substance dossier*”. The full text of Article 95, as amended by Regulation (EU) No 334/2014², is presented in Appendix 1 of this Guidance.

The objective of these provisions is set out in Recitals 8 and 58 to the BPR. Recital 8 states that “*To ensure the equal treatment of persons placing active substances on the market, they should be required to hold a dossier or have a letter of access to a dossier, or to relevant data in a dossier, for each of the active substances they manufacture or import for use in biocidal products.*”

Furthermore, Recital 58 of the BPR states that “*A level playing field should be established as quickly as possible on the market for existing active substances*”.

ECHA publishes a list of active substances and suppliers which includes the entities that submitted a complete substance dossier for active substance approval or product authorisation under the Biocidal Products Directive 98/8/EC (BPD), or who submitted such a dossier under the BPR.

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. The submission must comply with the data requirements for active substances of the BPR or the BPD.

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.

This Guidance explains which entities may need to make a submission under Article 95, and those which do not need to make a submission because they will be automatically included in the Article 95 list.

The Guidance also explains the information requirements of a compliant application, and how ECHA processes the applications. More detailed information on the information requirements can be found on the ECHA biocides guidance webpage (<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>) in the Part A documents of the four Volumes of the new BPR Guidance structure.

A submission manual on how to submit an Article 95 application via the Register for Biocidal Products (R4BP 3) has also been published separately by ECHA (see Biocides Submission Manual 3 at: http://www.echa.europa.eu/documents/10162/14938692/bsm_03a_active_subst_init_s ubm_en.pdf).

¹ ‘Transitional’ means that the provision of this paragraph bridges from the system under the BPD to the new BPR system and that the obligations under Article 95 will apply for new products and new market entrants as well

² Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market

2. Intention and basic provisions of Article 95

2.1 Intention of Article 95

The intention of Article 95, as described in Recitals 8 and 58 of the BPR, is to *"ensure the equal treatment of persons placing active substances on the market"* and to establish a *"level playing field [...] on the market for existing active substances"*.

The objective of ensuring equal treatment and establishing a level playing field is aimed mainly at alternative suppliers. Alternative suppliers are suppliers who are not actively supporting the Union approval of the active substance, yet benefit from the regulatory regime. In particular they include those who are not participants in the Review Programme³ but make available existing active substances on the market (either on their own or in a biocidal product) before approval, and they also include those who are newcomers after the active substance is approved.⁴

In other words, the aim is to ensure that all players contribute to the costs of the active substance approval process during the period when they make the active substance available on the market.

The equal treatment objective of Article 95 is implemented through the publication by ECHA of the list of active substances and suppliers, by PT, and the suppliers that have submitted a complete substance dossier that has been accepted or validated by a Member State under the BPR, or the BPD which the BPR replaced. Those who have submitted a complete substance dossier under the BPR or BPD include the participants in the Review Programme, entities supporting new active substances (applications under Article 11 of the BPD or Article 7 of the BPR) and entities who have applied for a biocidal product authorisation if they have provided their own alternative active substance dossier ("third party dossier").

The list will also contain the names of other suppliers called "alternative suppliers" who make a compliant submission (complete substance dossier, letter of access (LoA) or reference to a dossier for which data protection has expired) to ECHA under Article 95(1), second sub-paragraph.

Substance and product suppliers will remain on the list published by ECHA following approval of the relevant active substance (see also section 2.2.3).

Inclusion of the specific active substance source with the applicable PT in the list is key for biocidal products to remain on the market after 1 September 2015, as explained in the next section.

³ In the BPR the Review Programme is referred to as the work programme established under the first subparagraph of Article 89(1).

⁴ After an active substance is approved any entity wishing to place a biocidal product containing that active substance on the market requires an authorisation for the biocidal product. The application process involves submitting a dossier on the active substance, or an LoA to a complete substance dossier. This LoA can be obtained either from the participant who supported the approval of the active substance or from another supplier listed on the Article 95 list who submitted its own complete dossier. After the biocidal product authorisation is obtained, the entity can change its source of supply to another company provided that this company is included in the list published by ECHA under Article 95(1) and therefore participated in the costs of the assessment of the active substance and that the technical equivalence is established if the source of the active substance is different from the reference source. Such a change is considered to be an administrative change in accordance with 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.

2.2 Process of Article 95 and regulatory consequences

2.2.1 Why should a submission under Article 95 be made?

As specified in Article 95(2), as of 1 September 2015, biocidal products consisting of, containing or generating, a relevant substance should not be made available on the market if neither "the substance supplier" nor "the product supplier" is included in the list of active substances and suppliers for the relevant PTs.

Article 95 creates an obligation on persons making available biocidal products on the market to ensure that either the "substance supplier" or "product supplier" is included in the list published by ECHA under Article 95(1) of the BPR (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.

In practice only the following biocidal products should be made available on the market from 1 September 2015:

- biocidal products whose active substance(s) is supplied (directly or indirectly) by substance supplier(s) included in the list;
- biocidal products supplied (directly or indirectly) by a product supplier included in the list.

The persons established in the EU who are responsible for the making available on the market of a biocidal product should therefore be able to demonstrate, for each relevant substance it contains, the link of their product with either a substance supplier included in the list, or a product supplier included in the list.

ECHA includes in the list those who have submitted a complete substance dossier that has been accepted or validated by an MSCA in a procedure provided for under the BPD or the BPR, and also the persons who has made a compliant submission to ECHA under Article 95(1) second sub-paragraph (complete substance dossier, LoA, or reference to a dossier for which data protection has expired), and indicates their role as "substance supplier" and / or "product supplier", the relevant PT, and the date of inclusion in the list. The entities to be listed can be distinguished into two groups:

- The persons who will be placed automatically on the list and will thus not have to make a submission to ECHA under Article 95, namely:
 - participants in the Review Programme;
 - supporters of new active substances (those who have submitted a dossier under Article 11 of the BPD or under Article 7 of the BPR);
 - submitters of third party dossiers.

⁵ The term "on its own or in biocidal products" also covers relevant substances supplied as technical concentrates, or any kind of formulated premixes which are destined to be further formulated into biocidal products and made available on the market.

- 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 (under evaluation or already the subject of an approval decision)⁶ who were not participants in the Review Programme;
 - importers of active substances (on their own or in biocidal products) in the Review Programme (under evaluation or already the subject of an approval decision)⁷ 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 biocidal products) who did not support the approval of the active substance;
 - manufacturers of biocidal products, if the supplier of the active substance(s) used in their products is not on the list;
 - entities which make available on the market biocidal products if the supplier of the active substance(s) used in their products is not on the list.

The definitions of substance supplier and product supplier, as set out in Article 95(1), second sub-paragraph, specify that those entities must be established in the EU. Non-EU companies may be represented by an EU representative, for the purpose of Article 95, and be indicated on the list next to its EU representative. In addition, the EU importer could apply to be listed as the "supplier".

The following situations do not fall within the scope of Article 95 and therefore no submission is required:

- entities manufacturing or importing substances listed in Annex I of the BPR in categories 1 to 5 and 7 or biocidal products containing only such substances on the market.
- Article 95 only applies to biocidal products made available on the market. Biocidal products, according to Art. 3(1) a) second indent, that are produced on-site and that are only used on-site (e.g. ozone generated from ambient air) do not fall within the scope of Article 95 as they are not made available on the market.

Note that in the case of re-imports of an active substance or biocidal product manufactured in the EU, the re-importer should ensure that its active substance(s) supplier (the EU manufacturer) is on the list published under Article 95(1). Alternatively, the re-importer could be listed in the list published under Article 95(1).

In case an entity manufactures an active substance for future export and for placing on the market outside of the European Union (on its own or in biocidal products) it does not need to be on the list.

In the case of the situation set out in Article 93 (concerning active substances in biocidal products covered by the BPR but not previously covered by the BPD and available on the EU market on 1 September 2013), the obligation to be listed on the Article 95 list only applies from when the application for active substance approval is submitted for Article 93 purposes and is accepted/validated by a competent authority, such that the active substance becomes a "relevant substance". Given the 1 September 2016 deadline under

⁶ It is noted that this includes alternative suppliers for the active substances listed in Category 6 of Annex I of the BPR: carbon dioxide, nitrogen and (Z,E)-Tetradec-9,12-dienyl acetate.

⁷ It is noted that this includes alternative suppliers for the active substances listed in Category 6 of Annex I of the BPR: carbon dioxide, nitrogen and (Z,E)-Tetradec-9,12-dienyl acetate.

Article 93, it is not obligatory for such substances/suppliers to be on the Article 95 list as from 1 September 2015, but as soon as a dossier for the purposes of Article 93 is submitted and validated, all product and substance suppliers need to be on the list.

2.2.1.1 Listing of daughter companies and affiliates

If a company is included in the Article 95 list, its daughter companies and affiliates are not automatically listed or explicitly covered by this listing. However, the link between the products and the company on the list can be demonstrated by documentary evidence proving the traceability. Therefore, to comply with the provisions of Article 95 it would be sufficient that one company is listed if the daughter companies or affiliates are part of the supply chain linking the product to the company on the list.

However, if for any reason (e.g. market subdivision by customers requiring that not all supply chain links are disclosed to the customers), some affiliates or daughter companies, although they are part of the supply chain linking the product to the company on the list and thus do not need to be on the Article 95 list, want to be also on the list they have to make an Article 95 submission.

2.2.2 Active substances generated in-situ

It has been agreed between MSCAs and the Commission (November 2014⁸), that for all substances generated in situ, the active substance must be defined by reference to the precursor(s) supported in the dossier submitted to the Review Programme and to the substance generated.

This may in certain cases lead to a re-definition of the substance, as originally notified (e.g. ammonium sulphate to be redefined as monochloramine generated from ammonium sulphate and a chlorine source), and/or to the creation of additional entries, when data on several precursors were provided in a dossier, or when multiple dossiers were submitted for a substance (e.g. chlorine dioxide to be redefined as chlorine dioxide generated from sodium chlorite by electrolysis and as sodium chlorate generating chlorine dioxide).

For those substances to be redefined, Articles 13, 14 and 17 of Regulation (EU) No 1062/2014 (the Review Programme Regulation) must apply and persons affected by the substance re-definition must be given the possibility to take over the role of participant.

For those substances not covered by a substance re-definition, it was agreed that Article 93 of the BPR would apply, and that persons affected by the new definition of a biocidal product (which is extended under Article 3(1)(a) of the BPR, from the previous definition in the BPD, to include all substances generating active substances) would also be given the possibility to submit an application for approval, and to benefit from the transitional period under Article 93 BPR.

With regard to Article 95, the list published by ECHA will reflect this agreement and in situ generated active substances supported under the Review Programme will be described by reference to the precursor(s) supported in the dossier submitted to the Review Programme and to the substance generated.

Current participants in the Review Programme have been listed as substance/product suppliers.

Other companies will be added to the list provided they submit their own dossier, or an LoA to such a dossier.

⁸ See CA-Nov14-Doc.4.1 "Management of in-situ generated active substances in the context of the BPR", available at CIRCABC.

In the case of in situ generated active substances, the dossier or the LoA will need to cover data on both the in situ generated active substance and the precursor(s), which form the representative product, supported in the dossier under evaluation.

Suppliers of substances to be used as precursors for the in situ generation of active substances included in the Review Programme have to submit to ECHA their own dossier on the precursor(s) and the in situ generated active substance, or a letter of access to such a dossier, in so far as the precursor(s) placed on the market and the active substance generated from this(ese) precursor(s) are the same as the ones supported under the Review Programme. These suppliers will have to be listed by 1 September 2015.

In addition, the additional precursor(s)/active substance combinations not currently supported under the Review Programme would not need to be included in the Article 95 list (as no "complete substance dossier" according to Article 95(1) would have been submitted). However, as soon as a "complete substance dossier" has been submitted under Article 13 of the Review Programme Regulation or Article 93 of the BPR and accepted, the substance would be included in the Article 95 list and consequently Article 95(2) would apply.

2.2.3 Renewal of an Article 95 inclusion following renewal of an active substance approval

An active substance will be approved for a maximum of ten years. To achieve renewal of the approval, an interested entity must make an application under Article 13 of the BPR, including relevant new data. To ensure equal treatment, following the renewal of an approval of an active substance, ECHA will remove from the list any entity which was not an applicant in the renewal procedure or has not submitted all the relevant new data, or an LoA to that data, to ECHA within 12 months of the renewal (Article 95(7) of the BPR).

2.2.4 Overview of the process

The main steps of the process under Article 95 for the establishment of the list are described below and presented in Figure 1:

- a) as specified in Article 95(1), first sub-paragraph, ECHA publishes a list of the relevant substance PT combinations for which a complete substance dossier has been submitted and accepted or validated by a Member State in a procedure provided under the BPD or BPR. The list will also contain the names of the entities who have made those submissions (participants in the Review Programme, supporters of new active substances and those who have submitted a third party dossier after the validation step is passed), and indicate if they are substance suppliers or product suppliers;
- b) alternative substance suppliers or product suppliers may make a submission to ECHA to be included on the list. Such applicants have to submit certain information to ECHA as specified in Article 95(1), second sub-paragraph: a complete substance dossier, an LoA or a reference to a dossier for which all data protection periods have expired (or combination);
- c) the submission is subject to a fee as specified in Annex III of Implementing Regulation (EU) No 564/2013⁹;

⁹ Commission Implementing Regulation (EU) No 564/2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012

- d) ECHA carries out a compliance check on the information submitted by the alternative suppliers and decides whether or not the application is compliant with the requirements of Article 95;
- e) if the alternative supplier's application passes the compliance check and the application is approved, ECHA will include the alternative supplier in the list and indicate if they are substance suppliers or product suppliers.

Since the regulatory consequences apply from 1 September 2015 onwards and since the time needed by ECHA to perform the assessment might vary considerably (in relation to foreseeable peaks of workload related to the submission of a high number of applications in a short period of time), it is recommended that alternative suppliers submit their applications in sufficient time and preferably as soon as possible. The applicants should also consider allowing sufficient time to cover the possible need to provide additional data if the draft decision is negative or to make a new submission if the final decision on their submission is negative. More details regarding the compliance check of submissions and decision-making are provided in chapter 4.

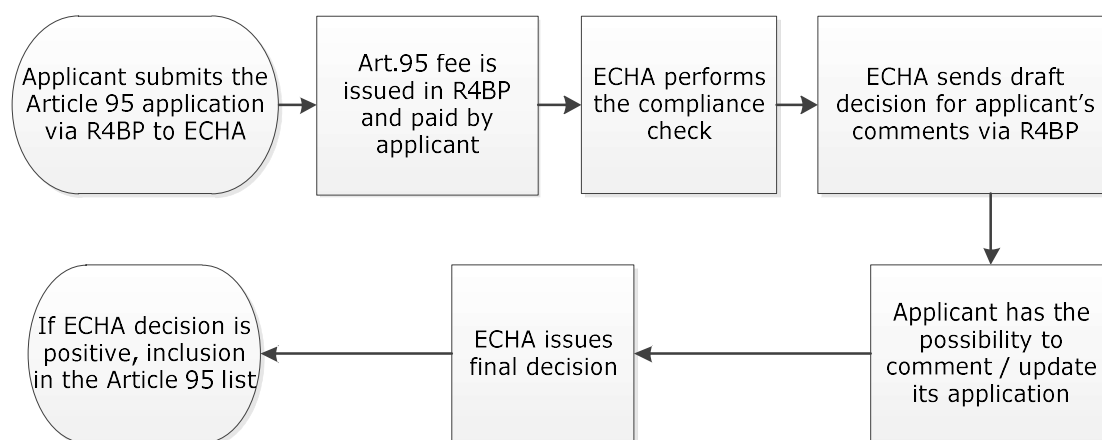


Figure 1: Main steps of the process under Article 95

3. Submissions under Article 95

3.1 General provisions

3.1.1 Types of submissions

In accordance with Article 95(1), second sub-paragraph, a submission under Article 95 could consist of the following:

- a) a complete substance dossier. Such a dossier is defined in Article 95(1), sub-paragraph 1, as one complying with the requirements of Annex II to the BPR or of Annex IIA or Annex IVA to the BPD and, where relevant, Annex IIIA to the BPD ("a complete substance dossier"); or
- b) a letter of access to a complete substance dossier, as referred to under point (a), which has been accepted or validated by a Member State in a procedure provided for by the BPR or the BPD or by ECHA in accordance with Article 95(1) of the BPR; or
- c) a reference to a complete substance dossier as referred to under point (a) which

has been accepted or validated by a Member State in a procedure provided for by the BPR or the BPD or by ECHA in accordance with Article 95(1) of the BPR and for which all data protection periods have expired.

Submissions may also consist of an LoA, data for the endpoints not covered by the LoA, and reference to data for which the data protection period has expired, where relevant.

Where relevant, a decision from ECHA granting permission to refer to requested data in accordance with Article 63(3) of the BPR must be submitted (see also below section 3.3).

N.B.: Information requirements of an Article 95 submission are identical for substance suppliers and product suppliers. Regardless of the supplier's role the information given should comply with the requirements for active substance approval.

3.1.2 Fees

A submission under Article 95(1) is subject to a fee to be paid to ECHA as set out in Annex III of Implementing Regulation (EU) No 564/2013. The fee depends on the content of the submission:

- Fee for submission of a letter of access to a dossier already found complete by the Agency or an evaluating Competent Authority (CA): EUR 2000;
- Fee for submission of a letter of access to part of a dossier already found to be complete by ECHA or an evaluating CA, together with complementary data: EUR 20000;
- Fee for submission of a new dossier: EUR 40000.

3.1.3 Identity of the active substance

For submissions based on complete substance dossiers or on a combination of information and LoA(s), information regarding the identity of the active substance as defined in Annex II of the BPR (or Annex IIA of the BPD) must be provided. In other words the sections 2.1, 2.8 and 2.9 of the IUCLID 5 dossier must be completed and confirmed by spectral data (IUCLID 5 section 3.6) and a 5-batch analysis (IUCLID 5 sections 2.9 and 5) on the source which should be supported by this application¹⁰. This information will only be used to assess the compliance of the submission with the information requirements specified in Article 95(1).

N.B.: Article 95 does not require prior establishment of technical equivalence via an application to ECHA under Article 54 of the BPR¹¹.

3.1.4 Information requirements for substances generating or releasing active substances in situ

In case of substances generated or released in situ the LoA or complete substance dossier will need to cover both the substance generated or released in situ and the precursor(s) supported in the reference dossier.

¹⁰ Corresponding sections in Annex II of the BPR to the IUCLID sections are as follows: IUCLID section 2.1=2.2, 2.4-7 and 2.12 in Annex II; IUCLID section 2.8=2.8 in Annex II; IUCLID section 2.9=2.9-10 in Annex II; IUCLID section 3.6=3.6 in Annex II; IUCLID section 5=2.11 and 5.1 in Annex II.

¹¹ If the active substance has been approved, and technical equivalence established, such information can be included in an Article 95 submission for information. For non-approved active substances a check of chemical similarity performed by ECHA could be done and the results included in the Article 95 submission for information.

3.1.5 Submission

Alternative suppliers will have to submit the required information through the Register for Biocidal Products (R4BP 3). Please see the submission manual "Biocides Submission Manual 3: Active substances. Part A: Initial submissions" at the following link:

<http://www.echa.europa.eu/web/guest/support/dossier-submission-%20tools/r4bp/-biocides-submission-manuals>

In addition, for all Article 95 submissions, a supporting document should be completed. This document is found at the following link:

<http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/r4bp/supporting-documents>

All data should be submitted in IUCLID 5. However, if the submission is an LoA to a complete substance dossier the LoA should be attached in R4BP. No IUCLID file is needed in such case.

3.1.6 When to apply?

For active substances in the Review Programme (under evaluation or already subject of a positive approval decision) or approved new active substances, it is recommended that applicants submit as soon as possible to maximize the time for the assessment of the compliance. In case of late submissions, ECHA cannot guarantee to complete the assessment of the compliance before 1 September 2015 and consequently the possible inclusion of the applicant on the list may not be achieved before that deadline.

For new active substances under evaluation an Article 95 application can be made as soon as the evaluating CA has validated the dossier.

3.1.7 Submission by consortia

The BPR does not provide for joint submissions under Article 95. Thus, submissions must be made individually and fees are charged per submission. However, if entities wish to co-operate to make a complete substance dossier, for example in a consortium, members of a consortium might decide that one member submits the complete substance dossier in a first step; following approval of the submission by ECHA, the submitting consortium member can issue LoAs to the other members of the consortium, who can then use the LoA for their own Article 95 submission.

3.2 Information requirements

3.2.1 Letter of Access

A submission for inclusion in the Article 95 list can be made by submitting an LoA to ECHA. The LoA must refer to a 'complete substance dossier', i.e. a dossier that has been accepted or validated by a Member State in a procedure provided for by the BPR or the BPD or by ECHA in accordance with Article 95(1), second sub-paragraph, of the BPR. This could be a dossier submitted in the Review Programme, or a dossier for a new active substance submitted under the BPD or the BPR, or a third party dossier (submitted as part of a biocidal product authorisation), or a dossier submitted by an alternative supplier.

Therefore, the LoA required for the Article 95 submission should be granted by the submitter of the 'complete substance dossier'.

If the submitter of the complete substance dossier is not the owner of the data, depending on the contractual arrangement in place, it may need to seek the agreement of the data owner to grant the LoA for the purpose of Article 95 to the alternative supplier.

It should be noted that according to Article 95(4) the substance and product supplier included in the Article 95 list to whom an LoA has been issued, are entitled to allow applicants for the authorisation of a biocidal product to make reference to that LoA for the purpose of Article 20(1) of the BPR. This also applies if the supplier to whom an LoA has been issued is itself applying for biocidal product authorisation.¹²

According to the BPR (Article 61), an LoA should contain at least:

- a) the name and contact details of the data owner and the beneficiary;
- b) the name of the active substance or biocidal product for which access to the data is authorised;
- c) the date on which the letter of access takes effect;
- d) a list of the submitted data to which the letter of access grants citation rights.

For the purposes of an Article 95 application, a list of the submitted data is not necessary if the LoA refers to a 'complete substance dossier' in its entirety.

Information stating which PT(s) the submission concerns should be given in the LoA.

3.2.2 Complete substance dossier

3.2.2.1 Should the dossier be compliant with the BPR or the BPD?

Article 95 defines a "complete substance dossier" as one complying with "BPR Annex II or BPD Annex IIA or IVA and, where relevant, Annex IIIA".

This wording is designed to cover dossiers on the active substance (for approval or as part of a product authorisation) submitted and validated under the BPD (until 1 September 2013) or under the BPR (including Article 95 alternative dossiers).

Since the BPD no longer applies, a complete substance dossier supporting an application under Article 95 should comply with Annex II of the BPR. However, ECHA intends to accept also a BPD compliant dossier where the dossier for the approval of the active substance was submitted and validated under the BPD.

3.2.2.2 General information requirements

ECHA's Guidance on information requirements on Biocides gives detailed information on how to prepare a dossier for an active substance.

Information should be submitted under the relevant headings in IUCLID 5. It is important to note that for each study provided the original study report has to be included. If LoA(s) are submitted for certain endpoints, a reference to the LoA needs to be included in the relevant IUCLID sections.

According to point 5 of Annex II (and Annex III) of the BPR, as a general principle, tests must be conducted according to the methods described in Commission Regulation (EC) No 440/2008. These methods ("EC methods") are based on methods recognised and recommended by international bodies, in particular OECD. In the event of a method being inappropriate or not described, other methods must be used which are

¹²Furthermore, this applies where ECHA has granted a permission to refer under Article 63(3) of the BPR. That decision can be used to support a biocidal product authorisation application under Article 20(1) of the BPR.

scientifically appropriate. Their use needs to be justified. Recommended test methods are listed in the endpoint sections of the Guidance on information requirements.

It should also be noted that although not explicitly mentioned in Article 95, the new studies submitted by the alternative suppliers may be used by the authorities for risk assessment purposes in the context of product authorisation.

3.2.2.3 Core data versus additional data sets

In accordance with the principle of equal treatment, an alternative dossier should be subject to the same information requirements as a dossier submitted to the Review Programme or for approval of a new active substance. That means that:

- all core data sets need to be submitted, including a summary, evaluation and draft risk assessment (section 13, Annex II of the BPR);
- PT specific additional data sets will be required according to Chapter V of the Guidance on information requirements on Biocides. This can be found in the Biocides Guidance document, Volume IV Environment, Part A Information Requirements, available on the ECHA biocides guidance webpage (<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>).

Additional data sets other than PT specific additional data sets could be required, e.g. due to the hazardous profile of the substance. One example is the requirements of Section 8.6 of Annex II of the BPR addressing *in vivo* genotoxicity studies. Depending on the outcome of the core data testing, additional tests may be required to assess the genotoxicity potential. This should be considered by the applicant in its risk assessment.

N.B.: For each study submitted, the full study report should be provided.

3.2.2.4 Waiving of data

An applicant may propose to adapt the data as explained in Article 6(2) of the BPR. If data are waived a justification must be given.

Detailed guidance for waiving of data can be found in ECHA's Guidance on Information Requirements for Biocides. on the ECHA biocides guidance webpage (<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>) in the Part A documents on Information Requirements of the four Volumes of the new BPR Guidance structure.

3.2.3 Reference to a dossier for which all data protection periods have expired

The data protection periods will end for the first dossiers in the Review Programme around 2017. ECHA intends to review this Guidance document and provide updated relevant information before that date.

By way of derogation from Article 60 of the BPR, all data protection periods for active substance PT combinations listed in Annex II to Regulation (EC) No 1451/2007 (the Review Programme) where a decision on their inclusion on Annex I to the BPD was not taken before 1 September 2013 will end on 31 December 2025.

3.2.4 Combination of letter of access and data for endpoints not covered by the LoA

For this type of submission, please follow the guidance given in sections 3.2.1 and 3.2.2 of this Guidance, as appropriate.

3.3 Data sharing and related disputes

As described in Recital (57) and Article 62(1) of the BPR there is a data sharing obligation on applicants: "*Applicants should share, and not duplicate, studies on vertebrate animals in exchange of equitable compensation.*" And, "... *testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort*". The data sharing provisions in Chapter XIV of the BPR apply in the context of submissions under Article 95(1).

To meet these requirements, any alternative supplier intending to perform tests must, in case of vertebrate animal tests, and may, in the case of non-vertebrate animal tests, make an inquiry to the Agency (Article 62(2)) to determine whether such studies have already been submitted to any CA or to the Agency under the BPD or the BPR. The Agency then communicates the name and contact details of the data submitters. If these studies are still protected according to Article 60, the prospective applicant has an obligation (according to Article 62(2)) to request from the data owner(s)/ data submitter(s), the studies involving vertebrate animals, and it has the option to request the sharing of data not involving testing on vertebrate animals and get a permission to refer to them.

Subsequently the data owner(s)/data submitter(s) and the alternative supplier are required, pursuant to Article 63(1) to make every effort to reach an agreement on the sharing of data under fair, transparent and non-discriminatory conditions. Should they not reach such an agreement, and as a last resort only, the alternative supplier must submit a data sharing dispute claim to ECHA according to Article 63(3). ECHA has no role in the data sharing negotiations between the parties; the task of ECHA is to assess whether the parties have made every effort to reach an agreement on the sharing of data under fair, transparent and non-discriminatory conditions. In order to support the claim, the alternative supplier will need to demonstrate that it made every effort, by (i) submitting documentary evidence and by (ii) showing that it has paid a share of the costs incurred by the data owner. Independently from the submission of the claim, ECHA recommends the parties to continue negotiating.

Furthermore, in the context of Article 95(1), the provisions of Article 63(3) apply not only to tests involving vertebrate animals but also to toxicological, ecotoxicological and environmental fate and behaviour tests not involving vertebrate animals (as described in Sections 8, 9 and 10 of Annex II of the BPR). The extended application of Article 63(3), by virtue of Article 95(1), is only in relation to active substances in the Review Programme and does not apply to new active substances.

As the data sharing provisions under the BPR are similar to those under the REACH Regulation, reference is made to the Guidance on data sharing under REACH available on the ECHA website (Guidance on data sharing <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>).

4. Compliance check of submissions and decision-making

When the invoice for a submission has been paid, ECHA checks whether the information submitted is compliant with the requirements of Article 95(1) as further detailed in Chapter 3 of this Guidance.

Evaluation of applications is done in a stepwise procedure as described below (see also Figure 1). All correspondence with the submitter is done via R4BP 3.

4.1 Compliance check

In this step ECHA checks that the identity of the active substance supports the submission.

- a) For the dossiers: ECHA goes through all information submitted by the applicant and checks that all relevant endpoints are covered by information of sufficient quality. The compliance check also includes evaluation of waivers.
- b) For the LoA: ECHA checks the correctness of the LoA. That includes checking that the LoA refers to a relevant active substance PT combination and that it is issued by an appropriate entity.
- c) For a submission based on expired data protection periods: ECHA checks that all data protection periods have expired for the information referred to.

Any information gaps or inconsistencies identified in the compliance check are described (endpoint by endpoint if the submission contains studies) and compiled in a draft decision.

4.2 Draft decision

The draft decision is sent to the submitter with a request to respond within a one-month commenting period. This commenting period can be extended by an additional two months upon request.

Submission of additional information is only possible during this commenting period. ECHA will base its decision on the information available at the end of the commenting period.

4.3 Final decision

After the deadline for comments on the draft decision ECHA reviews any comments received and takes these into account when taking its final decision on the submission. If additional information is received in response to the draft decision ECHA checks the submission again in light of the new information to decide whether or not the submission is compliant with Article 95(1).

The final decision is then sent to the applicant.

4.4 Inclusion in the Article 95 list

If the submission is compliant with Article 95(1) the alternative supplier will be included in the list at its next update. Updating is foreseen to take place monthly.

4.5 Information on legal remedies

Decisions by ECHA under Article 95 can be subject to an application for annulment in accordance with Article 263 of the Treaty on the Functioning of the European Union. The procedure for lodging an application with the General Court is described at <http://curia.europa.eu>.

5. List of active substances and suppliers published according to Article 95(1)

5.1 Who is placed on the list?

ECHA has the obligation to publish via its website a list of relevant substances for which a complete substance dossier has been submitted and accepted or validated by a Member State in a procedure provided for in the BPD or the BPR. The list will include the persons who have made that submission, or a successful submission to ECHA in accordance with Article 95(1) sub-paragraph 2. The list will also indicate whether the person is a substance supplier or product supplier and the relevant PT.

In short, the list will include:

- “existing” active substances and the respective participant companies, in the Review Programme;
- “new” active substances, for which applications have been received according to Article 11 of the BPD or under Article 7 of the BPR; and the respective companies supporting their approval;
- entities who have submitted an application for product authorisation which includes a dossier on the active substance that complies with the data requirements of the BPD or the BPR, (third party dossiers);
- the applicants for inclusion in the list (alternative suppliers) who have made a submission which was found by ECHA to be compliant with the requirements of Article 95(1).

5.2 Maintenance of the list

ECHA updates the list containing the names of suppliers on its website on a regular basis (currently monthly) Supporters of new active substances are included in the list after the evaluating CA has validated the dossier. The suppliers who submitted an application under Article 95(1) and passed the compliance check will gradually be added to the list.

6. References

Guidance on data sharing [<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>]

Questions and Answers on Data sharing under the BPR [<http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/biocidalproductsregulation/datasharing>]

Key messages on Data Sharing Obligations under the BPR
[http://www.echa.europa.eu/documents/10162/17158508/key_messages_ds_bpr_en.pdf]

Guidance on information requirements for Biocides (see Part A documents of the four Volumes of the BPR Guidance): [<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>]

Appendix 1. Text of Article 95 of the BPR

(Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012)

Article 95: Transitional measures concerning access to the active substance dossier

1. As of 1 September 2013, the Agency shall make publicly available and shall regularly update a list of all active substances, and all substances generating an active substance, for which a dossier complying with Annex II to this Regulation or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive ("the complete substance dossier") has been submitted and accepted or validated by a Member State in a procedure provided for by this Regulation or that Directive ("the relevant substances"). For each relevant substance, the list shall also include all persons having made such a submission or a submission to the Agency in accordance with the second subparagraph of this paragraph, and indicate their role as specified in that subparagraph, and the product- type(s) for which they have made a submission, as well as the date of inclusion of the substance in the list.

A person established within the Union who manufactures or imports a relevant substance, on its own or in biocidal products ("the substance supplier") or who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance ("the product supplier"), may at any time submit to the Agency either a complete substance dossier for that relevant substance, a letter of access to a complete substance dossier, or a reference to a complete substance dossier for which all data protection periods have expired. Following the renewal of the approval of an active substance, any substance supplier or product supplier may submit to the Agency a letter of access to all the data which was considered by the evaluating competent authority as relevant for the purpose of the renewal, and for which the protection period has not yet expired ("the relevant data").

The Agency shall inform the submitting supplier of the fees payable under Article 80(1). It shall reject the application if the submitting supplier fails to pay those fees within 30 days and shall inform the submitting supplier accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall verify whether the submission complies with the second subparagraph of this paragraph and shall inform the submitting supplier accordingly.

2. As of 1 September 2015, a biocidal product consisting of, containing or generating a relevant substance, included in the list referred to in paragraph 1, shall not be made available on the market unless either the substance supplier or the product supplier is included in the list referred to in paragraph 1 for the product type(s) to which the product belongs.

3. For the purposes of making a submission in accordance with the second subparagraph of paragraph 1 of this article, Article 63(3) of this Regulation shall apply to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates.

4. A substance supplier or a product supplier included in the list referred to in paragraph 1 to whom a letter of access has been issued for the purpose of this Article or a right to refer to a study has been granted in accordance with paragraph 3 shall be entitled to

allow applicants for the authorisation of a biocidal product to make reference to that letter of access or that study for the purposes of Article 20(1).

5. By way of derogation from Article 60, all data protection periods for active substance/product type combinations listed in Annex II to Regulation (EC) No 1451/2007, but for which a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013, shall end on 31 December 2025.

6. Paragraphs 1 to 5 shall not apply to substances listed in Annex I in categories 1 to 5 and category 7 or to biocidal products containing only such substances.

7. The Agency shall regularly update the list referred to in paragraph 1 of this Article. Following the renewal of the approval of an active substance, the Agency shall remove from the list any substance supplier or product supplier who has not, within 12 months of the renewal, submitted all the relevant data or a letter of access to all the relevant data, either in accordance with the second subparagraph of paragraph 1 of this Article or in an application in accordance with Article 13.

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