

Guidance on active substance suppliers

GUIDANCE ON REGULATION (EU) No 528/2012 CONCERNING THE
MAKING AVAILABLE ON THE MARKET AND USE OF BIOCIDAL PRODUCTS
(BPR)

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LEGAL NOTE

This document contains guidance on Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation, the BPR). This document describes the BPR obligations and how to fulfil them. However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

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List of abbreviations

Standard term / Abbreviation	Explanation
BPD	Biocidal Products Directive. Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products
BPR	Biocidal Products Regulation. 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
LoA	Letter of access
R4BP	Register for Biocidal Products

1. Introduction

Article 95 of the of the Biocidal Products Regulation (EU) No 528/2012 (BPR) is titled "Transitional measures concerning access to the active substance dossier". The full text of Article 95 is presented in Annex I of this Guidance. The objective of those provisions is set out in Recital 8 of the BPR which 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."*

This Guidance explains which entities have a direct obligation to make a submission under Article 95, those which will be considered to have made such a submission and provides guidance on the regulatory consequences.

A submission manual on how to submit via the Register for Biocidal Products (R4BP) will be published separately by ECHA.

It must be noted that the Commission has prepared a proposal on an amendment to the BPR which contains among others several amendments to Article 95. This proposal, dated 16 May 2013, can be found at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0288:FIN:EN:PDF>. ECHA will revise this Guidance document, where necessary, if this proposal is adopted.

2. Intention and basic provisions of Article 95

2.1 Intention of Article 95

The intention of Article 95 is laid down in recital (8) of the BPR: *“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. Biocidal products containing active substances for which the relevant person does not comply with that obligation should no longer be made available on the market. In such cases there should be appropriate phase-out periods for disposal and use of existing stocks of biocidal products.”*

The objective of ensuring equal treatment of persons placing active substances on the market is aimed mainly at alternative suppliers. Alternative suppliers are manufacturers or importers of an active substance, which do not support the Union approval of an active substance yet benefit from the regulatory regime. In particular they include those who are not participants in the Review Programme¹ under the Biocidal Products Directive 98/8/EC (BPD) yet place existing active substances² on the market (either on their own or in a biocidal product) before approval, but they also include those who are newcomers after the active substance is approved.³

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 place the active substance on the market.

The equal treatment objective of Article 95 is implemented through the publication by ECHA of the list of active substances suppliers which either made the submission under Article 95(1) or who are considered to have made such a submission. The latter entails the participants in the Review Programme but also entities supporting new active substances (applications under Article 11 of the BPD or Article 7 of the BPR).

Suppliers will remain on the list published by ECHA post approval of the relevant active substance in order for a comprehensive list of suppliers entitled to place active substances on the market to be established. Only biocidal products containing an active substance supplied from an entity on the list may be made available on the market after 1 September 2015.

2.2 Process of Article 95 and regulatory consequences

2.2.1 Process

In summary the process under Article 95 is as follows:

- Alternative suppliers have to submit information to ECHA as specified in Article 95(1): a dossier, a letter of access (LoA) or a reference to a dossier for which all

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

² Recital 7 of the BPR defines existing and new active substances: “A distinction should be drawn between existing active substances which were on the market in biocidal products on the transposition date set in Directive 98/8/EC and new active substances which were not yet on the market in biocidal products at that date.”

³ 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 a LoA thereto obtained from the entity which supported the approval of the active substance. After the biocidal product authorisation is obtained, the entity is free to change its source of supply to another company provided this company is included on the list of relevant persons published by ECHA under Article 95(2) and therefore participated in the costs of the assessment of the active substance.

data protection periods have expired. The submission is subject to a fee as specified in Annex III of 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 (Implementing Regulation (EU) No 564/2013).

- Supporters of new active substances and participants in the Review Programme will be considered as having made a submission under Article 95(1) and do not need to take any measures.
- ECHA carries out a compliance check on the information submitted by the alternative suppliers.
- As specified in Article 95(2) ECHA publishes a list containing the alternative suppliers who submitted the information under Article 95(1) and passed the compliance check. The list will also contain the participants in the Review Programme and supporters of new active substances post completeness check.

2.2.2 Regulatory consequences

As specified in Article 95(3) as of 1 September 2015, biocidal products should not be made available on the market if the manufacturer or importer of the active substance(s) in the product, or the importer of the biocidal product is not included on this list. As a consequence a formulator who is neither a manufacturer nor importer of the active substance(s) used in its formulations must ensure that its supplier(s) of the active substance(s) are on the list.

It is important to note that the requirement to be on the list applies also after an active substance product-type combination is approved. This means that newcomers (first time manufacturers or importers wanting to enter the EU market) also need to be listed.

The obligations for alternative suppliers apply from 1 September 2013. Since the regulatory consequences apply from 1 September 2015 onwards it is recommended that alternative suppliers submit well in time and preferably as soon as possible after 1 September 2013.

It has to be noted that Article 95 also states that:

- The relevant person to whom a LoA to the dossier on the active substance has been issued shall be entitled to allow applicants for the authorisation of a biocidal product containing that active substance to make reference to that LoA in applications for product authorisation as described in Article 20(1);
- By way of derogation from Article 60 of the BPR, all data protection periods for active substance product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but not yet approved under the BPR shall end on 31 December 2025.

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

3. Submissions under Article 95

3.1 Who should submit the information requested under Article 95?

The procedure under Article 95 concerns manufacturers or importers (or associations thereof) of an active substance on its own or in a biocidal product wishing to place these on the EU market after 1 September 2013. Those affected can be distinguished into two groups:

- Those who have to make an application and submit the information requested under Article 95:
 - o alternative suppliers of active substances in the Review Programme⁴ and of new actives post approval;
 - o the importer of the biocidal product containing the active substance(s) if the relevant person is not a natural or legal person established in the European Union.
- Those who will be placed automatically on the list and will thus not have to make an application and submit the information requested under Article 95:
 - o participants in the Review Programme;
 - o supporters of new active substances (those who submitted a dossier under Article 11 of the BPD or under Article 7 of the BPR): their application will be considered as equivalent to the submission required under Article 95 and they will be added to the list after passing the completeness check.

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

- entities manufacturing or importing active substances listed in Annex I of the BPR in categories 1 to 5 and 7 or biocidal products containing only such active substances on the market;
- entities who submitted an application under Article 93. This relates to active substances in biocidal products covered by the BPR but not by the BPD and available on the EU market on 1 September 2013 and which are not included in the Review Programme. In particular, this relates to in-situ generated active substances.

Note that in the case of re-imports of an active substance manufactured in the EU, the re-importer should ensure that his active substance(s) supplier (the EU manufacturer) is on the list published under Article 95(2).

3.2 Which information should be submitted?

In accordance with Article 95(1), the information to be provided consists of:

- (a) a dossier complying with the requirements of Annex II, or where appropriate, with

⁴ 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.

Annex IIA of Directive 98/8/EC; or

(b) a letter of access to a dossier as referred to under point (a); or

(c) a reference to a dossier as referred to under point (a) and for which all data protection periods have expired."

Submissions can consist of both a LoA and data for the endpoints not covered by the LoA⁵. Some remarks on these submissions:

- Article 95 does not require the prior establishment of technical equivalence via an application to ECHA under Article 54. However regardless of the submission type (full dossier, LoA or a combination of both) information regarding the identity of the active substance as defined in Annex II of the BPR or Annex IIA of the BPD needs to be provided.
- for a dossier submitted complying with the information requirements in Annex II of the BPR or Annex IIA of the BPD it is required to submit the following (in line with Annex III of Regulation (EC) 1451/2007 which specifies the requirements for the complete dossier and summary dossier for submissions under the Review Programme):
 - o Document II A summarising the intrinsic properties of the active substance, Document III A ((robust) study summaries), Document IV (original test reports) level and an IUCLID file (see Part I of the "Technical Note for Guidance (TNsG) on Dossier Preparation and Study Evaluation" published under the BPD⁶ for an explanation of the dossier structure including Document II, III and IV). An applicant may propose to adapt the data as explained in Article 6(2) of the BPR. If data are waived a justification will have to be provided. It is not allowed to submit a test proposal as otherwise the dossier does not satisfy the data requirements and is therefore incomplete;
 - o a reference list of the studies submitted;
 - o Listing of Endpoints (LOEP) (see Part I of the "TNsG on Dossier Preparation and Study Evaluation" published under the BPD⁶ for an explanation of the LOEP).
- where relevant the decision from ECHA on the permission to refer to requested data in line with Article 63 must be submitted (see also below section 3.3);
- a LoA should contain at least (Article 61) :
 - o *"the name and contact details of the data owner and the beneficiary;*
 - o *the name of the active substance or biocidal product for which access to the data is authorised;*
 - o *the date on which the letter of access takes effect;*
 - o *a list of the submitted data to which the letter of access grants citation*

⁵ It must be noted that future developments in the Review Programme may be considered, as the evaluation by the Rapporteur Member State is on-going for the concerned active substance product-type combination: additional data may be requested during this process.

⁶ This TNsG is available from the ECHA web-site at: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>.

rights."

- for the endpoints not covered by the LoA, the information stated above (Document II, III and IV (original test reports), an IUCLID file, reference list and LOEP) needs to be submitted.

As stated above, the 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: i) *Fee per submission of a letter of access to a dossier already found complete by the Agency or an evaluating Competent Authority:* EUR 2,000 ii) *Fee per 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 20,000; iii) *Fee per submission of a new dossier:* EUR 40,000.

Alternative suppliers will have to submit the required information through the Register for Biocidal Products. This Guidance does not contain detailed guidance on how to submit applications through the Register. This will be made available separately by ECHA via the publication of a submission manual. This will contain a template for a LoA which may be used by alternative suppliers.

3.3 Data sharing

The data sharing provisions of Chapter XIV on data protection and data-sharing of the BPR apply in the context of submissions under Article 95(1). 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 tests not involving vertebrate animals (as described in Sections 8 and 9 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.

If the alternative supplier and the data owner of the study cannot reach an agreement on sharing data, the alternative supplier should inform ECHA. ECHA has no role in the negotiations and cannot be a party or take over this responsibility. The task of ECHA in the context of the data sharing dispute claim 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.

ECHA will perform an assessment based on the documentary evidence submitted by both parties involved in the negotiations. Any decision taken by ECHA to grant permission to the alternative supplier will only be taken after the latter has demonstrated that every effort has been made to reach an agreement with the data owner. Furthermore, the alternative supplier must show that it has paid a share of the costs incurred by the data owner. In case of a decision in favour of the data owner, ECHA recommends the parties to continue negotiating even though a dispute claim was submitted.

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 web-site (ECHA, 2012).

4. Compliance check of submissions

After the submission, ECHA will check if the information submitted is complete and complies with the requirements of Article 95(1):

- is the information provided (directly and/or indirectly through a LoA) for all the

endpoints required, including justifications for the adaptation of information requirements, complete with respect to the requirements of Annex II of the BPR or, where appropriate with Annex IIA of the BPD?

- if a dossier is submitted, ECHA will check that the identity of the active substance supports the submission;
- if a LoA is submitted, ECHA will check that the identity of the active substance makes the LoA relevant to support the submission;
- for the studies submitted ECHA will check whether the information provided for the endpoints required, including waiving statements, is adequate and of sufficient quality;
- if a LoA is submitted, ECHA will check if the LoA complies with Article 61 of the BPR;
- if the submission consists of a reference to a dossier for which it is claimed that all data protection periods have expired ECHA will check this claim.

A positive outcome of the compliance check is a condition for being placed on the list. ECHA will inform the applicant if the submission is non-compliant stating also the reason(s) for the non-compliance.

It is recommended that alternative suppliers submit as soon as possible after 1 September 2013 to maximise the time for the compliance check. In case of a late submission ECHA cannot guarantee that the compliance check is finished before 1 September 2015, enabling ECHA to decide before that deadline if the alternative supplier will be placed on the list.

5. List published according to Article 95(2)

5.1 Who will be placed on the list

ECHA will publish via its web-site a list of persons containing the names of:

- the alternative suppliers who submitted the information required under Article 95(1) and who passed the compliance check;
- the alternative suppliers for whom a decision has been taken by ECHA to give the permission to refer to the requested tests or studies in accordance with Article 63(3). It should be noted (as stated above in Section 4) that the alternative supplier will only be added to the list by ECHA if the remaining data on the active substance are provided, either through a LoA or the generation of data, to fulfil the requirements of submitting a complete dossier;
- the participants in the Review Programme;
- applicants who submitted a complete dossier for a new active substances under Article 11 of the BPD (new active substances) or a complete dossier under Article 7 of the BPR;
- alternative suppliers⁷ who submitted their own dossier for an active substance included on Annex I under the BPD to a Member State for product authorisation under the condition that the dossier is complete.

Note that the situation of formulators is addressed in the Commission's proposals to amend the BPR (see section 1), therefore this area may be subject to change.

5.2 Maintenance of the list

As of 1 September 2013 ECHA will publish the list containing the names of the participants on the web-site. Supporters of new actives applicants under Article 11 of the BPD and applicants under Article 7 of the BPR will be included on the list post completeness check. The alternative suppliers who submitted an application under Article 95(1) and passed the compliance check will then gradually be added to the list.

The active substance suppliers will remain on the list post approval of the relevant active substance. Newcomers after 1 September 2013 which are either alternative suppliers supplying existing active substances pre approval or post approval or supplying approved new active substances, will also need to make an Article 95(1) submission and be included on the list. The post approval continuation and expansion of the list is to ensure that all entities placing the active substance on the market have access to the relevant data in order to ensure equal treatment (for example in case of post approval change of supplier).

⁷ These are also called "third party dossiers".

6. References

ECHA 2012, Guidance on data sharing.

Annex I Text of Article 95 of the BPR

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

1. As of 1 September 2013, any person wishing to place active substance(s) on the Union market on its own or in biocidal products (the "relevant person") shall, for every active substance that they manufacture or import for use in biocidal products, submit to the Agency:

- (a) a dossier complying with the requirements of Annex II, or where appropriate, with Annex IIA of Directive 98/8/EC; or
- (b) a letter of access to a dossier as referred to under point (a); or
- (c) a reference to a dossier as referred to under point (a) and for which all data protection periods have expired.

If the relevant person is not a natural or legal person established within the Union, the importer of the biocidal product containing such active substance(s) shall submit the information required under the first subparagraph.

For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No 1451/2007, Article 63(3) of this Regulation shall apply to all toxicological and ecotoxicological studies including any toxicological and ecotoxicological studies not involving tests on vertebrate animals.

The relevant person to whom a letter of access to the dossier on the active substance has been issued shall be entitled to allow applicants for the authorisation of a biocidal product containing that active substance to make reference to that letter of access for the purposes of Article 20(1).

By way of derogation from Article 60 of this Regulation, all data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but not yet approved under this Regulation shall end on 31 December 2025.

2. The Agency shall make publicly available the list of persons that have made a submission in accordance with paragraph 1 or for whom it has taken a decision in accordance with Article 63(3). The list shall also contain the names of persons who are participants in the work programme established under the first subparagraph of Article 89(1) or have taken over the role of the participant.

3. Without prejudice to Article 93, as of 1 September 2015, a biocidal product shall not be made available on the market if the manufacturer or importer of the active substance(s) contained in the product, or where relevant, the importer of the biocidal product, is not included in the list referred to in paragraph 2.

Without prejudice to Article 52 and 89 disposal and use of existing stocks of biocidal products containing an active substance, for which no relevant person is included in the list referred to in paragraph 2, may continue until 1 September 2016.

4. This Article shall not apply to active substances listed in Annex I in categories 1 to 5 and 7 or to biocidal products containing only such active substances.

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