

Guidance on the Biocidal Products Regulation

Volume V,

Guidance on active substances and suppliers (Article 95 list)

Draft Version 2.0

June 2014



1 LEGAL NOTICE

2 This document contains guidance on Regulation (EU) No 528/2012 of the European
3 Parliament and of the Council of 22 May 2012 concerning the making available on the
4 market and use of biocidal products (Biocidal Products Regulation, the BPR) and
5 Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March
6 2014 amending Regulation (EU) No 528/2012 concerning the making available on the
7 market and use of biocidal products, with regard to certain conditions for access to the
8 market.

9
10 Users are reminded that the text of the BPR is the only authentic legal reference and
11 that the information in this document does not constitute legal advice. Only the Court of
12 Justice of the European Union can give authoritative interpretations on the contents of
13 Union law.

14
15 The European Chemicals Agency does not accept any liability with regard to the contents
16 of this document.

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

Reference: ECHA-13-G-07-EN
ISBN: 978-92-9244-008-4-
Publ.date: xxx 2014
Language: EN

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1 DOCUMENT HISTORY

Version	Comment	Date
Version 1.0	First edition	
Version 2.0	Revision of the guidance addressing revision to Article 95 of the BPR and the following: Revision of section x.x in order to	

Comment [SJ1]: Text to be completed at the end of the consultation.

2

1 **PREFACE**

2 This Guidance describes the obligations under Article 95 of the Biocidal Products
3 Regulation (BPR) and explains the regulatory framework in place that allows to meet
4 them.

5 This document describes the BPR obligations and how to fulfil them.

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List of abbreviations

Comment [SJ2]: To be updated and completed during the process.

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
CA	Competent Authority
IUCLID	International Uniform Chemical Information Database
LoA	Letter of access
PT	Product Type
R4BP	Register for Biocidal Products

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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, as amended by Regulation (EU) No 334/2014, 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 "Relevant substances and suppliers" which includes the entities which submitted a complete substance dossier for active substance approval or product authorization under the Biocidal Products Directive No 98/8/EC (BPD), or who submit 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 authorization) may submit an application to ECHA to also be included on the list. The application 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 placed on the EU market if the substance supplier or product supplier is not included in the Article 95 list for the product type to which the product belongs.

This Guidance explains which entities may need to make a submission under Article 95 to keep their products on the market, and which do not need to make such 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 in the [Guidance on information requirements \(http://www.echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf\)](http://www.echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf).

A submission manual on how to submit an application for Article 95 via the Register for Biocidal Products (R4BP) has also been published separately by ECHA (http://www.echa.europa.eu/documents/10162/14938692/bsm_03a_active_subst_init_subm_en.pdf).

Comment [SJ3]: The name of this Guidance document and the link will be updated later in the process and when the Part A is updated by corrigendum to divide into the 4 Volumes of the new BPR Guidance structure (see ECHA Biocides Guidance website for further details).

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 of the BPR, is to *"ensure the equal treatment of persons placing active substances on the market" and to create a "level playing field [...] on the market for existing active substances"*.

The objective of ensuring equal treatment and creating a level playing field is aimed mainly at alternative suppliers. Alternative suppliers are manufacturers or importers of

1 an active substance (on its own or in a biocidal product), or formulators of biocidal
2 products, which do not support the Union approval of the active substance, yet benefit
3 from the regulatory regime. In particular they include those who are not participants in
4 the so-called Review Programme¹ established under Article 16(2) of the Biocidal
5 Products Directive 98/8/EC (BPD) yet place existing active substances² on the market
6 (either on their own or in a biocidal product) before approval, but they also include those
7 who are newcomers after the active substance is approved.³

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

11 The equal treatment objective of Article 95 is implemented through the publication by
12 ECHA of the list of relevant substances⁴ and suppliers, per product type (PT), which have
13 submitted a complete substance dossier and which has been accepted or validated by a
14 Member State in the context of a relevant procedure of the BPR or the formerly
15 applicable Union legislation (BPD). The persons who have submitted a complete
16 substance dossier under the BPR or BPD include the participants in the Review
17 Programme, entities supporting new active substances (applications under Article 11 of
18 the BPD or Article 7 of the BPR) and in case they have provided their own active
19 substance dossier (a so-called "third-party dossier") entities who have applied for a
20 biocidal product authorisation.

21 The list will also contain the names of the alternative suppliers who make a compliant
22 submission (complete substance dossier, letter of access or reference to a dossier for
23 which the data protection has expired) under Article 95(1).

24 Suppliers will remain on the list published by ECHA post approval of the relevant active
25 substance in order for a comprehensive list of suppliers to be maintained.

26 Inclusion on the list is key for biocidal products to remain on the market after 1
27 September 2015, as explained in the next section.

28

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

² Article 3(1)(d) of the BPR defines an existing active substance as: "*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*". This contrasts with new active substances, defined at Article 3(1)(e) as "*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*".

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 that this company is included on the list of relevant persons 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.

⁴ The relevant substances are 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 ("the relevant substances").

1 2.2 Process of Article 95 and regulatory consequences

2 2.2.1 Why should an application under Article 95 be made?

3 Article 95 creates an obligation on persons placing biocidal products on the market to
4 ensure that either the “substance supplier” or “product supplier” is included on the list
5 published by ECHA under Article 95(1) of the BPR.

- 6 • A **substance supplier** is defined as a person established in the EU who
7 manufacturers or imports relevant substance⁵, on its own or in biocidal products.
- 8 • A **product supplier** is defined as as a person established in the EU who
9 manufacturers or makes available on the market a biocidal product consisting of,
10 containing or generating a relevant substance.
11

12 As specified in Article 95(2), as of 1 September 2015, biocidal products consisting of,
13 containing or generating a relevant substance should not be made available on the
14 market if either “the substance supplier” or “the product supplier” is not included on
15 the list of active substances and suppliers for the relevant product-type(s).

16 In practice this means that for the biocidal products consisting of, containing or
17 generating relevant substance(s), only the following ones should be made available
18 on the market from 1 September 2015:

- 19 - those provided (directly or indirectly) by a product supplier included in the list;
- 20 - those containing active substance(s) provided (directly or indirectly) by substance
21 supplier(s) included in the list.

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

26

27 ECHA includes on the list persons who have submitted a complete substance dossier,
28 and indicate their role as either “substance supplier” or “product supplier”. The entities
29 to be listed can be distinguished into two groups:

- 30 • The persons who will be placed automatically on the list and will thus not have to
31 make an application under Article 95:
 - 32 ○ participants in the Review Programme;
 - 33 ○ supporters of new active substances (those who have submitted a dossier
34 under Article 11 of the BPD or under Article 7 of the BPR;
 - 35 ○ submitters of the so-called “third party dossiers” (alternative active
36 substance dossier submitted along with a product authorisation
37 application) recognised as complete by a competent authority.
- 38 • Other “substance suppliers” or “product suppliers” established in the European
39 Union may make an application at any time to be included in the list and submit

⁵ The relevant substances are 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 IIIA 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”).

1 the information requested under Article 95. Such entities would normally include:

- 2 o alternative suppliers of active substances (i.e. the “relevant substances”) in the Review Programme (under evaluation or already subject of an approval decision)⁶;
- 3
- 4
- 5 o alternative suppliers of new active substances after their approval;
- 6 o importers of a relevant substance if the substance supplier is not a natural or legal person established in the European Union;
- 7
- 8 o manufacturers of biocidal products consisting of, containing or generating a relevant substance, if the supplier of the active substance used in their products is not on the list;
- 9
- 10
- 11 o importers of biocidal products consisting of, containing or generating a relevant substance(s) if the product supplier is not a natural or legal person established in the European Union, and if the supplier of the active substance used in their products is not on the list.
- 12
- 13
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15
16 Non-EU manufacturers cannot be listed as substance suppliers or product suppliers, as per the legal definition of those roles. If the active substance or the biocidal product originates from a non-EU entity, the importer could apply to be listed as the “supplier”.

17
18
19 The following situations do not fall within the scope of Article 95 and therefore no submission is required:

- 20
- 21 · 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.
- 22
- 23

24 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(1).

25
26
27 In the case of Article 93 (concerning active substances in biocidal products covered by the BPR but not 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 Article 93, it is not obligatory for such substances/suppliers to be on the Article 95 list as from 1 September 2015.

34 2.2.2 Overview of the process

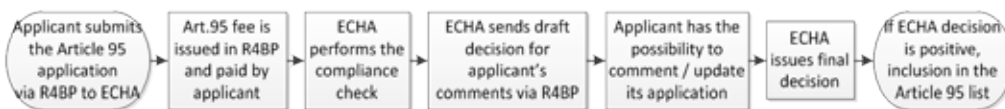
35 In summary the process under Article 95 is as follows:

- 36 · As specified in Article 95(1), paragraph 1, ECHA publishes a list of the relevant substances 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 made those submissions (participants in the Review Programme and supporters of new active substances post completeness check, and the ones who submitted the so-called “third party dossiers”), and indicate if they are substance suppliers or product suppliers.
- 37
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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.

- 1 · Alternative substance suppliers or product suppliers may make a submission to be
2 included on the list. Such applicants have to submit certain information to ECHA
3 as specified in Article 95(1), paragraph 2: a dossier, a letter of access (LoA) or a
4 reference to a dossier for which all data protection periods have expired.
- 5 · The submission is subject to a fee as specified in Annex III of Commission
6 Implementing Regulation (EU) No 564/2013 on the fees and charges payable to
7 the European Chemicals Agency pursuant to Regulation (EU) No 528/2012
8 (Implementing Regulation (EU) No 564/2013).
- 9 · ECHA carries out a compliance check on the information submitted by the
10 alternative suppliers and decides whether or not the application is compliant with
11 the requirements of Article 95.
- 12 · If the alternative supplier's application passes the compliance check and the
13 application is approved, ECHA will include the alternative supplier on the list.
- 14 · Since the regulatory consequences apply from 1 September 2015 onwards and
15 since the time needed by ECHA to perform the assessment might vary
16 considerably (in relation to foreseeable peaks of workload related to the
17 submission of a high number of applications in a short period of time), it is
18 recommended that alternative suppliers submit sufficiently in time and preferably
19 as soon as possible after 1 September 2013. The applicants should also consider
20 the possible need to provide additional data if the draft decision is not positive or
21 to submit a new application if the final decision on their first one is negative.

22



23

24 3. Submissions under Article 95

25 3.1 General provisions

26 3.1.1 Types of applications

27 In accordance with Article 95(1), an application under Article 95 could consist of the
28 following:

- 29 a) a dossier complying with the requirements of Annex II to the BPR or with Annex IIA
30 or IVA of the BPD and, where relevant, Annex IIIA to the BPD (“a complete
31 substance dossier”); or
- 32 b) a letter of access to a dossier as referred to under point (a) which has been accepted
33 or validated by a Member State in a procedure provided for by the BPR or the BPD;
34 or
- 35 c) a reference to a dossier as referred to under point (a) which has been accepted or
36 validated by a Member State in a procedure provided for by the BPR or the BPD and
37 for which all data protection periods have expired.

38 Submissions may also consist of both a LoA and data for the endpoints not covered by
39 the LoA.

40

1 3.1.2 Fees

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

5 a) Fee per submission of a letter of access to a dossier already found complete by the
6 Agency or an evaluating Competent Authority (CA): EUR 2,000;

7 b) Fee per submission of a letter of access to part of a dossier already found to be
8 complete by ECHA or an evaluating CA, together with complementary data: EUR
9 20,000;

10 c) Fee per submission of a new dossier: EUR 40,000.

11 3.1.3 Identity of the active substance

12 Regardless of the submission type (full dossier, LoA or a combination of both),
13 information regarding the identity of the active substance as defined in Annex II of the
14 BPR (or Annex IIA of the BPD) needs to be provided. In other words the sections 2.1,
15 2.8 and 2.9 of the IUCLID dossier need to be properly filled in and confirmed by spectral
16 data and a 5-batch analysis on the source which should be supported by this application.

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

19 3.1.4 Submission

20 Alternative suppliers will have to submit the required information through the Register
21 for Biocidal Products (R4BP). Please see the submission manual. In addition, for all
22 Article 95 submissions, a supporting document should be completed. This document is
23 found in the following link:

24 All data should be submitted in IUCLID.

25 Where relevant a decision from ECHA on the permission to refer to requested data in line
26 with Article 63 must be submitted (see also below section 3.3).

27 3.1.5 When to apply?

28 For active substances in the Review Programme (under evaluation or already subject of
29 an approval decision) or approved new active substances, it is recommended that
30 applicants submit as soon as possible after 1 September 2013 to maximise the time for
31 the assessment of the compliance. In case of a late submission, ECHA cannot guarantee
32 that the assessment of the compliance is finished before 1 September 2015 and hence
33 the possible inclusion of the applicant on the list is made before that deadline.

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

36 3.2 Information requirements

37 3.2.1 Letter of Access

38 An application for inclusion in the Article 95 list can be made by submitting a Letter of
39 Access (LoA) to ECHA. The LoA has to refer to a 'complete substance dossier', i.e. a
40 dossier that has been accepted or validated by a Member State in a procedure provided

1 for by the BPR or the BPD. Such a dossier could be a dossier submitted in the Review
2 Programme, or a dossier for a new active substance submitted under the BPD or the
3 BPR, or a so-called "third party dossier" (submitted as part of a biocidal product
4 authorisation).

5 Therefore, the LoA to be provided for the application should be granted by the submitter
6 of the 'complete substance dossier'.

7 If the submitter of the dossier is not the owner of the data, depending on the contractual
8 arrangement in place, the submitter may need to seek the agreement of the data owner
9 to grant the LoA to the applicant.

10 It has to be noted that Article 95(4) states that the supplier to whom a LoA has been
11 issued shall be entitled to allow applicants for the authorisation of a biocidal product
12 containing that active substance to make reference to that LoA in applications for
13 product authorisation as described in Article 20(1);

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

- 15 · "the name and contact details of the data owner and the beneficiary;
- 16 · the name of the active substance or biocidal product for which access to the data
17 is authorised;
- 18 · the date on which the letter of access takes effect;
- 19 · a list of the submitted data to which the letter of access grants citation"

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

22 In addition to the relevant LoA(s) this type of application needs to contain:

- 23 · information about the applicant as defined in Annex II of the BPR (or Annex IIA of
24 the BPD). Information regarding the identity of the active substance as defined in
25 Annex II of the BPR (or Annex IIA of the BPD);
- 26 · information on which PTs the application concerns (IUCLID 5, section 6).

27 The information listed above needs to be organised in the relevant sections of the
28 IUCLID 5 file. The LoA(s) should be submitted in IUCLID 5, section 13. If the LoA refers
29 to certain endpoints, also a reference to the LoA needs to be included in the relevant
30 sections.

31 **3.2.2 Complete substance dossier**

32 **3.2.2.1 Should the dossier be compliant with the BPR or the BPD?**

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

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

38 Since the BPD no longer applies, a complete substance dossier supporting an application
39 under Article 95 should comply with Annex II of the BPR.

40 However, given the limited differences in data requirements between the BPD and the
41 BPR, ECHA intends to accept also a BPD compliant dossier in case the dossier for the
42 approval of the active substance was submitted under the BPD.

1 3.2.2.2 General information requirements

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

4 Information should be submitted under the relevant headings in IUCLID. It is important
5 to note that for each study provided the original study report has to be included.

6 According to point 5 of Annex II and Annex III of the BPR, as a general principle, tests
7 shall be conducted according to the methods described in Commission Regulation (EC)
8 No 440/2008. These methods ("EC methods") are based on methods recognised and
9 recommended by international bodies, in particular OECD. In the event of a method
10 being inappropriate or not described, other methods shall be used which are scientifically
11 appropriate. Their use needs to be justified. Recommended test methods are listed in the
12 endpoint sections of the Guidance on information requirements.

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

16 3.2.2.3 Core data versus additional data sets

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

- 20 · all core data sets need to be submitted, including a summary, evaluation and risk
21 assessment (section 13, Annex II of the BPR);
- 22 · PT-specific additional data sets will be required according to Part V of the
23 Guidance on information requirements;
- 24 · other additional data sets would normally not be required.

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

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

31 3.2.2.4 Waiving of data

32 An applicant may propose to adapt the data as explained in Article 6(2) of the BPR. If
33 data are waived a justification will have to be provided. It is not allowed to submit a test
34 proposal as otherwise the dossier does not satisfy the information requirements and is
35 therefore incomplete.

36 Detailed guidance for waiving of data can be found in ECHA's Guidance on Information
37 Requirements.

38 3.2.3 Reference to a dossier for which all data protection periods have 39 expired

40 The data-protection periods will end for the first dossiers in the Review Programme
41 around 2017. ECHA intends to update this Guidance with relevant information before
42 that date.

Comment [SJ4]: See earlier comment in section 1 Introduction regarding the name of this guidance document.

1 By way of derogation from Article 60 of the BPR, all data protection periods for active
2 substance product-type combinations listed in the Review Programme, but not approved
3 before 1 September 2013 shall end on 31 December 2025.

4 **3.2.4 Both letter of access and data for endpoints not covered by the** 5 **LoA**

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

8 **3.3 Data sharing and related disputes**

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

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

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

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

43 As the data sharing provisions under the BPR are similar to those under the REACH
44 Regulation, reference is made to the Guidance on data sharing under REACH available on
45 the ECHA web-site (ECHA, 2012).

4. Compliance check of submissions and decision-making

When the invoice for an application has been paid, ECHA checks if 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):

1) Compliance check

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

- For 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.

- For 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 a relevant entity.

- For an application 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 application contains studies - and compiled in a draft decision.

2) Draft decision

The draft decision is sent to the applicant with a request to respond within a one-month commenting period. This commenting period can be prolonged with 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.

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 application. If additional information is received in response to the draft decision ECHA checks the application again in light of the new information to decide whether or not the application is compliant with Article 95(1).

The final decision is then sent to the applicant.

4) Inclusion in the Article 95 list

If the application 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.

All correspondence with the applicant is done via R4BP.

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 web-site 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 made that submission and entities which successfully make the submission of an alternative dossier. The list will also indicate whether the person is a substance supplier or product supplier and the relevant product-type.

In short, the list will include:

- “existing” active substances and the respective participant companies, in the Review Programme established under Directive 98/8/EC (the Biocidal Products Directive, BPD);
- “new” active substances, for which applications were received according to Article 11 of the BPD or a complete dossier under Article 7 of the BPR; and the respective companies supporting their approval;
- entities who submitted an application for product authorisation which includes a dossier on the active substance that complies with the data requirements of Annex IIA of the BPD, (the so-called “third party dossiers”);
- the applicants for inclusion in the list (alternative suppliers) who made a submission which was found by ECHA compliant with the requirements of Article 95(1).

5.2 Maintenance of the list

Currently, there is a provisional list available on the ECHA website that comprises information received from the Commission. ECHA will publish the list containing the names of suppliers on its web-site in Q3/Q4 2014. Supporters of new active substances under Article 11 of the BPD and suppliers under Article 7 of the BPR are included on the list after the evaluating CA has accepted or 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.

Comment [SJ5]: This text will be removed prior to the publication of the guidance document.

6. References

ECHA 2012, Guidance on data sharing under REACH http://www.echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf

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

ECHA 2013, Guidance on information requirements under the BPR http://www.echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf

1 Appendix 1. Text of Article 95 of the BPR

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

4 **Article 95: Transitional measures concerning access to the active substance** 5 **dossier**

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

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

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

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

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

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

44 4. A substance supplier or a product supplier included in the list referred to in paragraph
45 1 to whom a letter of access has been issued for the purpose of this Article or a right to
46 refer to a study has been granted in accordance with paragraph 3 shall be entitled to
47 allow applicants for the authorisation of a biocidal product to make reference to that
48 letter of access or that study for the purposes of Article 20(1).

- 1 5. By way of derogation from Article 60, all data protection periods for active
2 substance/product-type combinations listed in Annex II to Regulation (EC) No
3 1451/2007, but for which a decision on inclusion in Annex I to Directive 98/8/EC was not
4 taken before 1 September 2013, shall end on 31 December 2025.
- 5 6. Paragraphs 1 to 5 shall not apply to substances listed in Annex I in categories 1 to 5
6 and category 7 or to biocidal products containing only such substances.
- 7 7. The Agency shall regularly update the list referred to in paragraph 1 of this Article.
8 Following the renewal of the approval of an active substance, the Agency shall remove
9 from the list any substance supplier or product supplier who has not, within 12 months
10 of the renewal, submitted all the relevant data or a letter of access to all the relevant
11 data, either in accordance with the second subparagraph of paragraph 1 of this Article or
12 in an application in accordance with Article 13.
- 13

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