EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL
Safety of the food chain
Pesticides and Biocides

CA-March15-Doc.4.9a

59th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Templates for letters of access

The practical guides on data sharing, letters of access and consortium have no w been released[1].

The guide on letters of access contains templates for letters of access, the use of which is encouraged to achieve harmonisation and facilitate the implementation of the BPR.

The Commission services will present these templates during the CA meeting and explains how it is intended that they should be used.

[1] Available on CIRCA BC at https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp

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9.1 LoA template for Article 95 (also for product authorisation in accordance with Article 95(4))

[*Letterhead of entity granting the Letter of Access*]

European Chemicals Agency
Annankatu 18
P.O. Box 400
00121 Helsinki
Finland

[*Date*]

Dear Sir or Madam,

LETTER OF ACCESS FOR THE PURPOSES OF ARTICLE 95(1) OF REGULATION (EU) No 528/2012

[*Name of the Article 95 applicant*] wishes to apply for inclusion as [*indicate role: substance supplier and/ or product supplier*] for the relevant substance [*add name of relevant substance*] in product-type [*add product-type number(s)*] in accordance with Article 95(1) of the Biocidal Products Regulation (EU) No 528/2012.

On behalf of [*name of entity which has the right to grant the LoA*], I hereby authorise ECHA to use [*all the data in the complete substance dossier/the studies listed in the Appendix which are contained in the complete substance dossier*] *(delete as appropriate)* for the above-mentioned relevant substance/product-type submitted by [*name of the entity supporting the approval of the active substance/PT, normally the same entity granting the LoA*] and accepted by the Competent Authority[26] in [*name of Member State whose CA evaluated the dossier*] in support of the application of [*name of the Article 95 applicant*].

I hereby declare that [*name of the entity granting the LoA*] has the right to grant the above-mentioned access.

[26] The complete substance dossier can also be one which the Agency has assessed for Article 95 purposes, in which case the LoA should refer to the name of the supplier who submitted that complete substance dossier, and the Agency as the body which accepted the dossier as compliant.

This letter of access shall be effective as of [*insert date*].

Yours faithfully,

[*name and signature of person authorised to sign on behalf of entity granting the LoA*]

Grantor:	[*insert*]	Beneficiary Company:	[*insert*]
Contact person:	[*insert*]	Contact Person:	[*insert*]
Address:	[*insert*]	Address:	[*insert*]
Phone/email:	[*insert*]	Phone/email:	[*insert*]

Appendix

Unless provided otherwise below, the Letter of Access granted for the purpose of Article 95 shall apply without limitations for the purpose of product authorisation and shall also cover studies submitted for the purpose of the approval of the active substance after the granting of this letter of Access.

(*tick/complete as appropriate*)

☐ **Use of the Letter of Access is limited to the beneficiary company**[27]

☐ **Use of the Letter of Access is limited to certain Member States**

[*specify clearly in which Member States the LoA can be used*]

☐ **Access is not granted to studies submitted for the purpose of the approval of the active substance after the granting of this Letter of Access**

☐ **Access is limited to the following studies:**

[include list of studies]

**

[27] Note: This box should only be ticked when both parties have agreed, at the request of the beneficiary company, to limit the application of the consequential rights provided for under Article 95(4) of the BPR. If the box is ticked, the beneficiary company will not be entitled to allow applicants for product authorisations to make reference to the Letter of Access granted for the purpose of Article 95.

9.2 Template LoA for product authorisations only (in case template at section 9.1 cannot be applied)

[*Letterhead of entity granting the Letter of Access*]

1. Date: [*Insert*]

2. To: Competent Authorities of [*Insert name of relevant MS*]

3. Subject: **Letter of Access for Product Authorisation**

4. Beneficiary:

[*Insert name of prospective applicant(s)*], located at [*insert details of its registered office*], wishes to apply for (*delete as appropriate*):

the authorisation of [*insert name of the prospective applicant's biocidal product or biocidal product family*] in accordance with Regulation (EU) No 528/2012 for the Product Type [*insert number(s)*].

the authorisation of [*insert name of the prospective applicant's biocidal product (family)*], a biocidal product (family) identical to [*insert name of the data owner's biocidal product (family)*] in accordance with Commission Implementing Regulation 414/2013 for [*insert Member State(s) or European Union*].

5. Entity granting the Letter of Access:

[*Insert name of entity granting the Letter of Access*] located at [*insert details of its registered office*] has the right to grant access to the data package specified in section 6 of this letter.

6. Details of data subject to this letter:

This Letter of Access covers:

[*specify data to which access is granted*].

7. Extent of Access:

This Letter of Access states that the above data may be used or referred to by the Competent Authorities addressed above to assess [*insert the beneficiary's name as entered in section 4*]'s application for the above-mentioned purpose.

8. Effective Date

This Letter of Access shall be effective as of [*insert date*].

Signed by: [*signature of representative of entity granting the Letter of Access*]

9.3 Template Cover Letter

CASCADE RIGHTS UNDER ARTICLE 95(4) of the BPR

[*Company letterhead*]

Date _____

[*Name and address of the relevant Member State Competent Authority*]

Dear Sir or Madam,

Reliance on Article 95 Letter of Access for product authorisation

[*Insert name of prospective applicant*], located at [*insert details of its registered office*], wishes to apply for the authorisation of a biocidal product [*or biocidal product family*] in accordance with the Biocidal Products Regulation (EU) No 528/2012 (BPR).

The undersigned hereby confirms that the above named company/person is allowed to make reference to the Letter of Access granted to [*Insert name of company/person which is the named beneficiary of the LoA granted for Article 95 purposes*] for the purposes of Article 20(1) of the BPR, in accordance with Article 95(4) of BPR. A copy of that Letter of Access is attached.

Signed: [*signature of representative of company/person which is named as the beneficiary on the LoA*]

Name and capacity: _____

Signed	[*Data Owner*]	[*Beneficiary Company*]
Date	_____	_____