**LoA template for Article 95 of the BPR (also for product authorisation in accordance with Article 95(4))**

**NOTE to the reader: The template LoA has an appendix.**

*Please note that any final decision taken by ECHA on a submission for inclusion on the Article 95 list based on a letter of access will be conditional upon the letter of access being valid, with all access rights covered therein approved by the data owner(s). Should the data owner(s) challenge the inclusion of a company on the list on the grounds that the letter of access is not valid, ECHA reserves the right to remove that company from the list.*

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

European Chemicals Agency

Annankatu 18

P.O. Box 400

FI-00121 Helsinki

 [*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[[1]](#footnote-1) 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.

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: [*insert*] | Phone: [*insert*] |
| E-mail: [*insert*] | E-mail: [*insert*] |

**Appendix**

(*Please tick/complete as appropriate*)

□ Access is limited to the following studies:

[*include list of studies*]

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.

(*Specifically for the purpose of product authorisation, please tick/complete as appropriate*)

□ Use of the Letter of Access is limited to the beneficiary company[[2]](#footnote-2)

□ 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

1. 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 [↑](#footnote-ref-1)
2. 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 other applicants for product authorisations to make reference to the Letter of Access granted for the purpose of Article 95. [↑](#footnote-ref-2)