

**Practical Guide on**  
**Letters of Access**  
**under the Biocidal Products Regulation (EU)**  
**No 528/2012 (BPR)**

## Preface

This Guide provides an overview of the Biocidal Products Regulation (EU) No 528/2012, the **BPR**, and explains data sharing in that context. It is accompanied by three sister guides on Data Sharing, Letters of Access and Consortia. Each of the Guides has been discussed with a sample of SMEs, the European Chemicals Agency (the **“Agency”**), the Member State Competent Authorities (the **“MSCAs”**), representative associations, and law firms and technical consultancies.

This Guide should not be read in isolation. Other guidance documents are available from the Agency and reference to them is encouraged.

## Legal Notice

This document contains background guidance on the BPR in the context of data sharing. Users of the guidance 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. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency and the European Commission do not accept any liability with regard to the use that may be made of the information contained in this document.

## Table of Contents

- 1. What is a Letter of Access in the context of the BPR? .....8**
  - 1.1 Sharing data under the BPR ..... 8
  - 1.2 What is an LoA? .....10
- 2. When do you need an LoA under the BPR? ..... 12**
- 3. What you should be aware of as a prospective applicant or a data owner ..... 16**
  - 3.1 From the perspective of a prospective applicant.....16
  - 3.2 From the perspective of a data owner .....17
- 4. The process for obtaining an LoA ..... 18**
- 5. Access rights..... 19**
  - 5.1 The scope of access .....19
  - 5.2 Conditions relating to the use of the data .....21
- 6. How the Agency/MSCAs will use a Letter of Access ..... 23**
- 7. Data Sharing Agreements ..... 25**
- 8. Dos and Don'ts regarding LoAs ..... 27**
- 9. Template LoA for Fast and Standard Tracks..... 28**
  - 9.1 LoA template for Article 95 (also for product authorisation in accordance with Article 95(4)) .....30
  - 9.2 Template LoA for product authorisations only (in case template at section 9.1 cannot be applied).....32
  - 9.3 Template Cover Letter .....34
  - 9.4 Template short-form data sharing agreement in the form of Terms and Conditions .....35
  - 9.5 Template long-form data sharing agreement .....38

## LIST OF ABBREVIATIONS

The following text conventions are used throughout the Practical Guide

<b>Abbreviation</b>	<b>Explanation</b>
<b>AH</b>	Authorisation holder
<b>BPD</b>	Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (Biocidal Products Directive)
<b>BPR</b>	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)
<b>CAR</b>	Competent Authority Report, also known as the assessment report.
<b>EU</b>	European Union
<b>AS</b>	Active substance
<b>BPF</b>	Biocidal product family
<b>CAR</b>	Competent Authority Report
<b>LoA</b>	Letter of access
<b>MSCAs</b>	Member State Competent Authorities responsible for the application of the BPR, designated under Article 81 of the BPR
<b>R4BP</b>	Register for Biocidal Products
<b>SBP</b>	Same biocidal product
<b>SMEs</b>	Small and Medium Sized Enterprises
<b>PT</b>	Product Type
<b>REACH</b>	Regulation (EC) No 1907/2006 of the European Parliament and of the Council

of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

## LIST OF TERMS AND DEFINITIONS

For the purposes of the Practical Guides, the definitions in Article 3(1) of the Biocidal Products Regulation (EU) No 528/2012 (BPR) apply. The most relevant definitions are reproduced below, together with other standard terms used in the Practical Guides.

Standard Term	Explanation
<b>Access</b>	The term is used to mean the right to refer to data/studies when submitting applications under the BPR, further to an agreement reached with the data owner. Depending on the content of the data sharing agreement, it can also mean the right to inspect hard copies of studies and/or the right to obtain hard copies of studies.
<b>Agency</b>	European Chemicals Agency, established under Article 75 of REACH
<b>Article 95 List</b>	The list of relevant substances and suppliers published by the Agency under Article 95(1) of the BPR
<b>Biocidal product family</b>	A group of biocidal products having (i) similar uses; (ii) the same active substances; (iii) similar composition with specified variations and (iv) similar levels of risk and efficacy (Article 3(1)(s) BPR)
<b>Chemical similarity</b>	A check which can be made prior to the adoption of the approval decision for an active substance, which assesses the substance identity and chemical composition of an active substance originating from one source with the aim of establishing its similarity regarding the chemical composition of the same substance originating from a different source.
<b>Data submitter</b>	The company/person which submits the data to the Agency/MSCA in connection with an application under the BPD or BPR

<b>Every effort</b>	The level of diligence required when negotiating the sharing of data according to Article 63(1) of the BPR
<b>Existing active substance</b>	A substance which was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development (Article 3(1)(d) BPR)
<b>Fast track</b>	One method of obtaining an LoA for Article 95 purposes which envisages limited negotiations and a short written data sharing agreement. Also described as an " <i>over-the-counter</i> " transaction
<b>Letter of access</b>	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 competent authorities, the Agency, or the Commission for the purposes of the BPR (Article 3(1)(t) BPR)
<b>New active substance</b>	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 or product and process-orientated research and development (Article 3(1)(d) BPR)
<b>Prospective applicant</b>	Any person which intends to perform tests or studies for the purposes of the BPR (Article 62(1) BPR)
<b>Review Programme</b>	The work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Article 89 of the BPR
<b>Related reference product</b>	In the context of an SBP authorisation, this is the biocidal product or product family which has already been authorised, or for which the application has been made, which the SBP is identical to
<b>Right to refer</b>	Means the right to refer to data/studies when submitting applications under the BPR, further to an agreement reached with the data owner (the

right is usually granted through an LoA). This right to refer can also be granted by the Agency following a data sharing dispute under Article 63(3) BPR.

**Same biocidal product** A biocidal product/family which is identical to a related reference product/family, as per Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

**Standard Track** One method of obtaining an LoA which envisages detailed discussions on the rights covered by the LoA, together with a detailed written data sharing agreement

**Technical Equivalence** Mean similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54 of the BPR (Article 3(1)(w) BPR). Technical equivalence is a requirement for a product authorisation application but is not a requirement for an application under Article 95 of the BPR and is not a legal pre-requisite for data sharing under Article 62 and Article 63 of the BPR

## 1. What is a Letter of Access in the context of the BPR<sup>1</sup>?

### 1.1 Sharing data under the BPR

- (a) To understand what a Letter of Access (an “**LoA**”) is and its role under the BPR, it is important to understand the regulatory/legal context in which it is used. That context is data sharing, which can be voluntary (as part of a mutual arrangement between companies/persons) or, if negotiations are unsuccessful, the Agency can help the prospective applicant by granting a right to refer to the data (in certain circumstances specified by the BPR – see **section 4** of the Practical Guide on Data Sharing). The word “data” is commonly used to refer to scientific tests and studies, including, but not limited to, those involving vertebrate animals.
- (b) As explained in the Practical Guide on Data Sharing, the BPR requires companies/persons that own data to share those data on request with other companies/persons which require those data for a purpose under the BPR, for example, applying for authorisation of a biocidal product or applying for inclusion in the Article 95 List.
- (c) The rules under the BPR dictate which data are required to be contained in the dossier and how those data can be obtained. There are two dynamics at play here:
- First, what the authorities are allowed to do with any data submitted to them for a purpose under the BPR is limited by Article 59 of the BPR. That Article states that the authorities are not allowed to use the data submitted by one company/person (the “**data owner**” or “**previous applicant**”) for the benefit of any other company/person (the “**prospective applicant**”) unless the data owner has granted permission for that to be done. Accordingly, the relevant regulatory authorities have their hands tied to a certain extent with the use that they can make of the data that they have in their possession.

---

<sup>1</sup> For more on what the BPR is, see the Practical Introduction to the BPR and Small and Medium Sized Enterprises. Here is the link to the consolidated version of the BPR, including amendments: <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>.



- Second, as explained in the Practical Guide on Data Sharing, the BPR requires the data owners to make available requested data, or give a right to refer to that data, to prospective applicants if an agreement is reached on the sharing of the results of the tests or studies requested by the latter. Under certain conditions, where negotiations are unsuccessful, the Agency can grant the prospective applicant a right to refer to the requested data.
- (d) As a result of these two dynamics, companies/persons which are data owners will have to share data with companies/persons which are prospective applicants. It is in considering what the word “share” means that the concept of an LoA becomes relevant. Simply put, as an alternative to submitting an entire dossier of data which would include the studies themselves, a prospective applicant can, and must in certain circumstances, request from the data owner all<sup>2</sup> the scientific and technical data related to the tests and studies concerned as well as a right to refer to these data it has already submitted when making applications under the BPR. In cases where the parties agree that a right of reference is the access successfully negotiated between them, that right will normally be given by way of a grant of an LoA.
- (e) In practice, the process leading to the sharing of data and the granting of an LoA usually involves the negotiation of a written data sharing agreement between the prospective applicant and the data owner; that agreement will set out the terms and conditions under which the data owner agrees to give the prospective applicant access to its data in exchange for money/compensation (see a description of the main terms of a data sharing agreement at **section 7** below). The access rights agreed to are in turn implemented via an LoA, which is usually appended to the data sharing agreement. A template LoA is set out in **section 9** below. The “fast track” LoA negotiation described at **section 3.1** of the Practical Guide on Data Sharing suggests that an “over-the-counter” LoA can also be negotiated together with a simple-form data sharing

---

<sup>2</sup> According to Article 63(4) of the BPR the prospective applicant shall be required to share only in the costs of information that it is required to submit for the purposes of the BPR. Therefore, in practice, applicants only need to ask for data that they want/need, as further explained in the stepwise approach outlined in **section 2.1** of the Practical Guide on Data Sharing.

agreement, necessarily less full than the template data sharing agreement at **section 9.5** below.

- (f) Please note that parties are free to negotiate the mechanics of the LoA or the data sharing agreement as they wish. While the BPR requires the parties to make every effort to reach an agreement on sharing data, it does not require that a written data sharing agreement is entered into or that the template LoA in **section 8.1** is used.

## 1.2 What is an LoA?

- (a) Article 3(1)(t) of the BPR defines an LoA as:



*"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 Competent Authorities, the Agency, or the Commission for the purposes of this Regulation."*

- (b) Article 61 of the BPR further clarifies that an LoA must contain at least the following information:

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

- (c) These are prescriptive requirements which the relevant regulatory authorities – whether the Agency or an MSCA – will need to see before being able to rely on the LoA. Whatever negotiations take place, and whichever written or verbal or other type of agreement is reached between the data owner and prospective applicant, the LoA must conform to these requirements.

- (d) It is important to note what the LoA gives, and does not give, to the prospective applicant:

	
It entitles the relevant regulatory authorities to use the data that have already been submitted to them by another company/person to fill the data gaps in the prospective applicant's application dossier.	Not all LoAs give the prospective applicant the automatic right to pass on the LoA to any other party.
It may give the prospective applicant the right to pass on the LoA for the benefit of its customers, depending on the purpose for which the data submission is required (i.e. inclusion on the Article 95 BPR List).	It does not give the prospective applicant any automatic ownership rights in the data.
	It does not give the prospective applicant the automatic right to receive hard copies of the data.

- (e) As above, please note that parties are free to negotiate the mechanics of the LoA as they wish. Any of the rights that are not automatically given can be agreed to between the parties, perhaps (and as normally would be the case) in a separate written agreement between them.
- (f) Even without such an agreement, the LoA itself shows the relevant regulatory authorities that the data owner consents to the use of its data for the benefit of the named prospective applicant. The normal course of practice is that the prospective applicant attaches the LoA to its application to be submitted using R4BP<sup>3</sup>.

---

<sup>3</sup> R4BP is the “Register for Biocidal Products” which is the central hub run by the Agency through which all biocide applications must be made, in accordance with Article 71 of the BPR.

## 2. When do you need an LoA under the BPR?<sup>4</sup>

- (a) Broadly speaking, a prospective applicant may look to obtain an LoA in two circumstances:
- as part of an application for a biocidal product authorisation; and
  - as part of an application for inclusion in the Article 95 BPR List.
- (b) There is a third, less common case in which a prospective applicant may need an LoA:
- an application for the approval of an existing active substance (i.e. on the EU market on 14 May 2000 as an active substance of a biocidal product) for use in a new product type (“**PT**”)<sup>5</sup>

We will look at the three circumstances in turn.

- (c) Application for product authorisation: Article 20 of the BPR lists the documents that must be submitted to the authorities along with an application for authorisation for a biocidal product or a biocidal product family (a “**BPF**”)<sup>6</sup>:
- a dossier or LoA for the biocidal product meeting the information requirements set out in Annex III to the BPR;
  - a summary of the biocidal product characteristics; and
  - a dossier or LoA for the biocidal product meeting the information requirements set out in Annex II to the BPR (i.e. active substance data), for each active substance contained in the biocidal product.

---

<sup>4</sup> For more details, see **section 3** of the Practical Guide on Data Sharing.

<sup>5</sup> In some circumstances, an LoA may be of use for an application for a new active substance.

<sup>6</sup> This concept refers to a family of biocidal products with similar purposes, which can be grouped under a single authorisation providing their difference in composition remains within a specified range. Individual products do not need to be authorised separately. New products to be included in the authorised family must simply be notified to the relevant authority 30 days before placing the new product on the market. More information on these variants can be found at **section 5** of the Practical Guide on Consortia.

- (d) In addition to the “standard” application for a biocidal product authorisation, the BPR and related legislation introduce new variants of biocidal product authorisation, for which LoAs may also be needed. Among those variants is the procedure for the authorisation of a same biocidal product/same BPF. The procedure for applications for the authorisation of a same biocidal product/same BPF is set out in Commission Implementing Regulation (EU) No 414/2013<sup>7</sup>. This procedure can be used for the authorisation of a biocidal product that is identical to another biocidal product or product family, which has already been authorised or for which an application for such authorisation has been submitted (known as the “related reference product”). Article 2 of Commission Implementing Regulation (EU) 414/2013 requires the submission of LoAs to all other data supporting the authorisation of the related reference product. Where an application concerns a same biocidal product authorisation of an individual product within a BPF, a prospective applicant will only need to purchase an LoA covering all the data relevant for that individual product, as opposed to the data package supporting the entire BPF authorisation.
- (e) Application for inclusion in the Article 95 List: under Article 95(1) of the BPR,<sup>8</sup> the Agency will publish a list of persons established within the EU from whom it has received:
- a complete active substance dossier; or
  - an LoA to a complete active substance dossier; or
  - a reference to a complete active substance dossier containing only data for which data protection periods have expired,<sup>9</sup> for the PTs to which their products belong. Participants in the review programme for existing active substances

---

<sup>7</sup> Here is the link to Regulation 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ 2013 L125/4: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013R0414>.

<sup>8</sup> Article 95 of the BPR was amended by 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, OJ 2014 L103/22.

<sup>9</sup> The third scenario is hypothetical as of the date of this guidance because data protection periods are yet to expire.

that was started under the predecessor to the BPR, the Biocidal Products Directive 98/8/EC (the “BPD”), are also included in the Article 95 List.<sup>10</sup>

- (f) Article 95 of the BPR sets out a procedure whereby substance and product suppliers can ask the Agency to be included on the Article 95 List. If the supplier does not own the data itself or have access to it another way, it can fill the gap by using an LoA as negotiated with the relevant data owner.
- (g) There are two important procedural aspects of Article 95 of the BPR to be noted.
- First, from 1 September 2015, only biocidal products consisting of, containing, or generating an active substance, sourced from a “substance supplier” or “product supplier” included on the Article 95 List for the PT to which the product belongs, can be made available on the EU market.<sup>11</sup> Moreover, Article 95(4) of the BPR provides that if the prospective applicant negotiates an LoA to the complete substance dossier or to part of it with the data owner for the purpose of Article 95, it is entitled to allow all applicants for product authorisation (e.g. its customers) to make reference to that letter of access when submitting an application for a product authorisation in accordance with Article 20(1) of the BPR.<sup>12</sup>
  - Second, where negotiations between the parties are not successful, in order to help applicants meet the 1 September 2015 deadline, Article 95(3) of the BPR provides that companies/persons seeking LoAs for inclusion on the Article 95 List can ask the Agency to grant a right to refer to toxicological, ecotoxicological and environmental fate and behaviour studies relating to existing active substances in the review programme (see **point (h)** below), even if the studies do not involve tests on vertebrates.

---

<sup>10</sup> For further information on the requirements of Article 95, refer to Article 95 guidance on the Agency’s website: <http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=vol5partB#vol5partB>.

<sup>11</sup> Please see the Agency's Guidance on Active Substances and Suppliers (Article 95 List) for further information: <http://echa.europa.eu/biocides-2015>.

<sup>12</sup> This also applies where the supplier has obtained a right to refer from the Agency under Article 63 of the BPR.

- (h) Application for the approval of an existing active substance in a new PT: many existing biocidal active substances are being assessed in the context of a review programme that was started under the predecessor to the BPR, the BPD.<sup>13</sup> In most cases, an active substance was only notified in specific PTs such as, for example, “disinfectants” (PT1) and “insecticides” (PT 18).<sup>14</sup> Products containing active substances in PTs that had not been notified had to be withdrawn from the EU market. Under the BPR, a prospective applicant can apply for the approval of an existing active substance in a PT for which the substance was not notified under the BPD. If the prospective applicant does so, it will need to compile a dossier of scientific data (see Article 6 of the BPR for details) and, to the extent that the prospective applicant is missing data or requires data, it will need to consider negotiating an LoA from the relevant data owner.

---

<sup>13</sup> Further information on the Review Programme is available on the Agency’s website at: <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance>.

<sup>14</sup> For a complete list of the PTs, see Annex V to the BPR.

### 3. What you should be aware of as a prospective applicant or a data owner<sup>15</sup>

#### 3.1 From the perspective of a prospective applicant

- (a) As discussed above, a prospective applicant may either compile its own dossier (without repeating tests on vertebrates) on an active substance or biocidal product, or negotiate access to the necessary data that were developed and submitted by the data owner under the BPR/BPD.<sup>16</sup>
- (b) Where the prospective applicant is buying access to the necessary data submitted by another company/person, the LoA assumes a pivotal role. In general, the option of submitting an LoA should be more time and cost-effective provided the data sharing negotiations proceed smoothly.<sup>17</sup>
- (c) Obtaining a LoA means that the prospective applicant will not need to duplicate the data owner's efforts and investment in developing the data.<sup>18</sup> However, opting for an LoA has certain disadvantages:
  - The prospective applicant does not have control over the quality of the data. The prospective applicant nevertheless remains responsible for the safety and efficacy of its products and what it communicates to the market through its Safety Data Sheets, for example. The prospective applicant may want to take steps to protect itself legally should the quality of the data be in question.
  - The prospective applicant will normally not receive physical hard copies of the data, which however may be necessary for compiling its dossier (for example when extrapolating data from an active substance to a biocidal

---

<sup>15</sup> For more details on this topic, see **section 2** of the Practical Guide on Data Sharing.

<sup>16</sup> A combination of own data and letter(s) of access is also possible.

<sup>17</sup> Should the negotiations fail, the Agency may intervene under Article 63(3) of the BPR. For more information please see **section 4** of the Practical Guide on Data Sharing.

<sup>18</sup> This advantage applies equally to other forms of data sharing than LoAs, e.g. negotiating receipt of copies of studies and the right to use/refer to them.



product) or may even be requested by an MSCA in the context of a product authorisation application. Adequate provisions may be needed in a data sharing agreement to cater for these situations.

- The data sharing agreement may contain use restrictions, which could limit the way the prospective applicant can use the data.

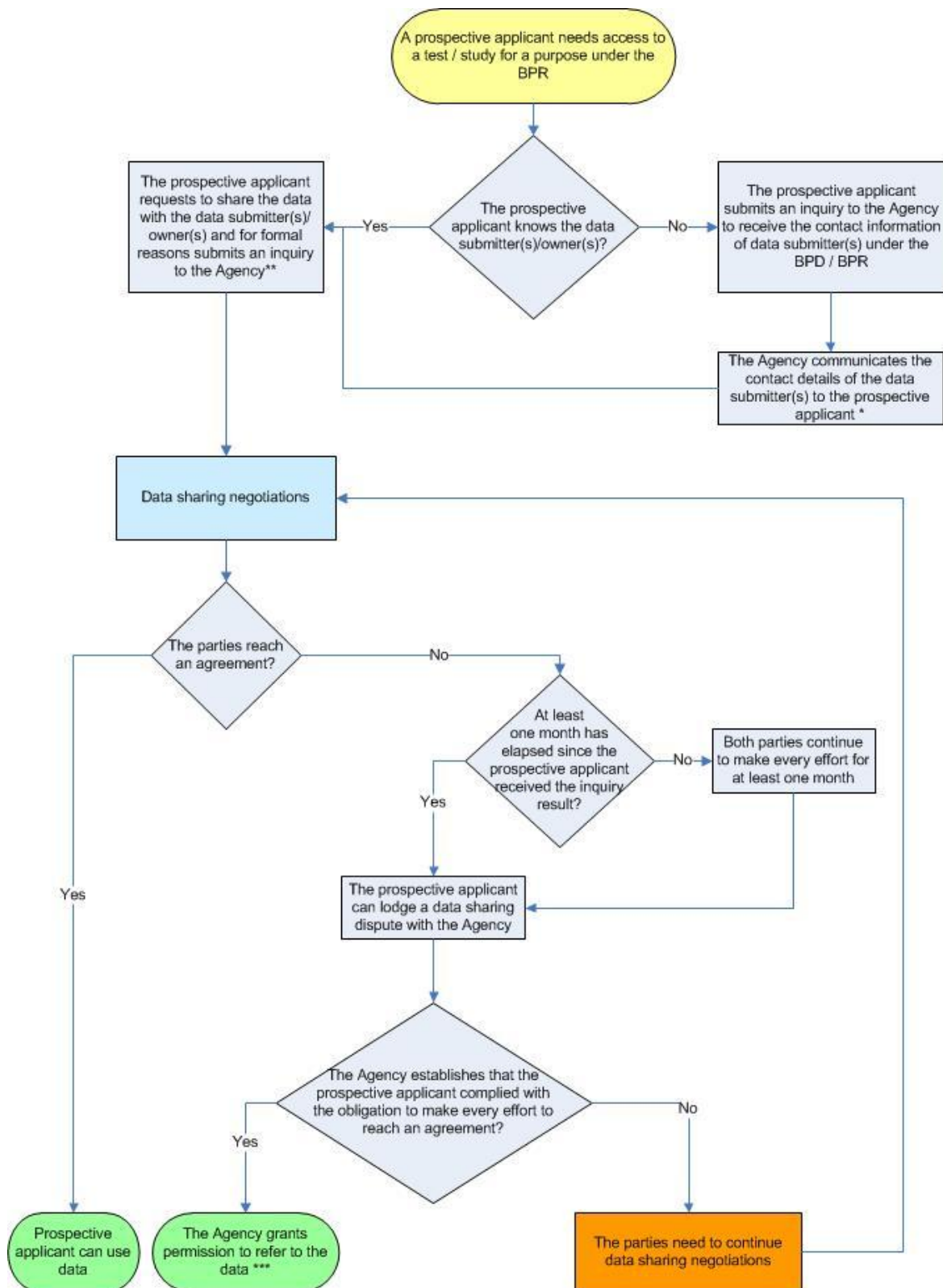
- (d) On the other hand, the main benefit when buying an LoA is that the costs of the data are shared (in a fair, transparent and non-discriminatory manner) which allows prospective applicants to invest less than what would normally be required for conducting the tests or studies individually. Another potential benefit is that further mutually agreed upon restrictions in data access (such as use, territory restrictions or limitations in the consequential rights under Article 95 of the BPR), may bring the compensation costs paid by the prospective applicant to the data owner even further down (through decrements or additional reductions).

### 3.2 From the perspective of a data owner

- (a) From the perspective of the data owner, the sharing of data with other companies/persons might be requested for any of their data, notwithstanding that the Agency can only enforce data sharing in the circumstances described in **section 4** of the Practical Guide on Data Sharing. The data owner will need to prepare adequate records and costs of the tests and studies in its dossier(s) for which prospective applicants may seek access. The data owner should also consider if and how it will handle any accompanying use restrictions of data such as restrictions limiting the use of the data to a certain territory (e.g. the EU) and purpose (e.g. data submissions under the BPR, to the exclusion of applications under other legislation).
- (b) Also, by seeking compensation for the costs incurred in generating the data in exchange for issuing an LoA, the data owner will be able to recover some of its investment – in that regard, see **section 3.4** of the Practical Guide on Data Sharing for an indication of the type of costs it can look to recoup.

#### 4. The process for obtaining an LoA

The main steps in the negotiation process are set out in **section 2.1** of the Practical Guide on Data Sharing. The following diagram captures the principal steps in summary:



Notes:

\* At the same time, the Agency informs the data submitter(s) that an inquiry has been received.

\*\* The prospective applicant can request to share data, i.e., start data sharing negotiations, without submitting an inquiry. However, as the prospective applicant can lodge a data sharing dispute at the earliest one month after the receipt of the data submitter's contact details through the inquiry procedure, it is recommended to still submit an inquiry for formal reasons. This can be done at any stage of the negotiations.

\*\*\* The data sharing dispute decision only becomes valid once the prospective applicant provides a proof of payment. Further, if ECHA grants permission to refer following the dispute procedure, this only covers vertebrate data. If inclusion on the Article 95 list is sought, it may also cover toxicological, ecotoxicological, or environmental fate and behaviour studies.

Note further that parties are encouraged to seek a voluntary agreement at all stages, i.e. also during data sharing dispute procedure as well as in case the Agency has granted a permission to refer to certain data. Reaching a voluntary agreement can serve *inter alia* to include those studies not covered by the permission to refer and to avoid that a national court might be asked to assess the payment.

## 5. Access rights<sup>19</sup>

### 5.1 The scope of access

- (a) As explained above, a typical LoA granted for the purpose of a biocidal product authorisation, for example, is essentially a citation/quotation right: the competent authorities (i.e. MSCAs in the case of an authorisation to place biocidal products in specific EU Member States, the European Commission in the case of a Union authorisation, or the Agency in case of an application for inclusion in the Article 95 List) will accept the referencing of the data listed in the LoA to complete the data submission by the prospective applicant. But remember:

---

<sup>19</sup> For more details on this, see [section 3.5](#) of the Practical Guide on Data Sharing.

- An LoA does not automatically give data ownership rights;
  - An LoA does not automatically give the prospective applicant the right to receive hard copies of the data; and
  - An LoA is simply a piece of paper which permits the relevant regulatory authorities to refer to the previous applicant's data to fill in gaps in the prospective applicant's dossier.
- (b) Another key point to remember is that to be valid, the LoA must be specific and state the data in respect of which it grants citation rights.
- (c) Furthermore, the extent of rights granted by an LoA to add the prospective applicant's name on the Article 95 List may be different:
- First, Article 95 of the BPR extends the possibility for the Agency to grant a right to refer to requested data in certain circumstances (for those circumstances, see **section 2(g)** above).
  - Second, where a prospective applicant for inclusion on the Article 95 List chooses to submit an LoA rather than its own complete substance dossier, Article 95(4) of the BPR entitles it and its customers to refer to the data listed in the LoA when making applications for product authorisations under Article 20(1) of the BPR. Such customers need only submit an original cover letter signed by the prospective applicant to whom the LoA was initially granted, which declares that it is entitled to allow applicants for biocidal product authorisation (who should be named in the cover letter) to make reference to its LoA for the purposes of Article 20(1) of the BPR, attaching a copy of the LoA.<sup>20</sup>
- (d) The BPR is thus designed to greatly facilitate the product authorisation process: prospective applicants can gain access to a large amount of core active substance data, and focus on developing product data. In addition, the practical effect of Article 95(4) of the BPR is that the LoA flows down to the prospective applicant's customer as

---

<sup>20</sup> The use of the template LoA and template cover letter in **section 9** of this Guide is encouraged. .

described above, without the customer having to spend time and effort in the data sharing negotiations with the data owner. The parties may decide at the express request of the prospective applicant only that Article 95(4) of the BPR does not apply, and negotiate a reduced compensation to reflect that fact.

## 5.2 Conditions relating to the use of the data

- (a) The data sharing agreement underpinning the LoA<sup>21</sup> will typically specify various restrictions to the use that can be made of the data, although many of them will not be binding on the authorities. Therefore, if either party to the negotiations were to seek to enforce the conditions negotiated, they will need to bring a case before the national courts; the relevant regulatory authorities (the Agency, the European Commission, and the MSCAs) will not intervene because – legally – they cannot.
- (b) While **section 3** of the Practical Guide on Data Sharing goes into greater detail regarding the examples of restrictions which may be negotiated between the parties, in short, they are as follows.

### Restricted purpose

The LoA may, for example, specify the purpose for which access is being granted, and may state that the data owner only consents to the use of its data:

- In support of the prospective applicant's application for authorisation of a biocidal product containing the active substance "x"; and/or
- To allow the prospective applicant to be included/to remain (following the renewal of the approval of an active substance) on the Article 95 List.

### Future data requirements

---

<sup>21</sup> The authorities discourage the mention of contractual restrictions to the use of the data in the LoA itself.

A further point to consider, in particular where data protection covers a long period of time, is whether an LoA should cover future data requirements, for example additional data requested by the relevant regulatory authorities in the context of an ongoing active substance review programme. This position can be negotiated between the parties. This issue is also relevant for prospective applicants that are relying on consequential rights under an LoA issued for inclusion in the Article 95 List: where additional studies were necessary for the approval of the active substance concerned, which had not been submitted and assessed at the time the LoA was issued, then that LoA may not be sufficient to secure the authorisation of a biocidal product containing the newly approved active substance. In that case, prospective applicants applying for product authorisation may need to approach the owner of the additional studies to purchase a separate LoA covering those studies.

#### **Extra-BPR use**

If the parties have agreed that the prospective applicant may use the data outside the framework of the BPR, the agreement between them should state so clearly.

#### **Use by affiliates/third parties**

Similarly, where there is agreement to allow the prospective applicant's affiliates and/or customers, or consortium members, to benefit from the same access rights, the LoA should explicitly state so.

#### **Territorial restrictions**

The LoA also often contains territorial restrictions: for example, the LoA may state that access rights are granted only within the EU territory, or certain EU Member States, as opposed to worldwide.

## 6. How the Agency/MSCAs will use a Letter of Access

- (a) On receipt of an LoA, the MSCA and the Agency or Commission will check that the letter contains at least the following information:
- the name and contact details of the data owner and the beneficiary<sup>22</sup>;
  - the name of the active substance or biocidal product for which access to the data is authorised;
  - the date on which the LoA takes effect; and
  - a list of the submitted data to which the LoA grants citation rights.
- (b) Some Member States ask the prospective applicant to provide proof that the LoA was signed by a person with the power to represent the data owner.

**Prospective applicants are encouraged to use the template LoA set out in [section 9](#) of this Guide.**

- (c) As stated above, the relevant regulatory authorities cannot be expected to assist the two parties in enforcing obligations stipulated in an LoA or a data sharing agreement. For example, the expiry of an LoA which is limited in time, or revocation of an LoA due to a breach of a term in the data sharing agreement, will not invalidate a biocidal product authorisation that was granted on the basis of that letter. The fact that the revocation of an LoA will not affect a related authorisation is specifically stated in Article 61(2) of the BPR. Similarly, even if the LoA contains conditions, these can only be enforced by the national courts. Authorities will, however, protect the data and ensure their confidentiality in accordance with Article 66 of the BPR.<sup>23</sup>

---

<sup>22</sup> Where an LoA for inclusion in the Article 95 List has been passed on under Article 95(4) of the BPR, the cover letter will specify the beneficiary. See [section 5.1\(c\)](#) of this Guide for more details.

<sup>23</sup> That is, subject to applicable EU and national legislation providing for public access to the documents held by the authorities, such as Regulation (EC) 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145/43.

- (d) Authorities may, however, also be called upon to revoke an authorisation under Article 48(1)(b) of the BPR if the authorisation was “*granted on the basis of false or misleading information*”, which could be the case when an LoA is used for purposes excluded by the underlying data sharing agreement at the request of the prospective applicant (e.g. territorial limitation in return for a discount). This would in any event be limited to products authorised in accordance with the BPR.



## 7. Data Sharing Agreements

It should be borne in mind that an LoA is not always a standalone document: it is usually appended to a written data sharing agreement,<sup>24</sup> which sets out the terms and conditions under which the data owner agrees to give access to the data. Such terms and conditions typically cover the following:

- recitals describing the regulatory framework, i.e. the BPR;
- definitions of key terms, such as: Access Rights, Affiliate, Commencement Date, Compensation, Data, EEA/EU, LoA, , Regulatory Authority, Substance, Territory and Third Party;
- scope and purpose of the agreement, for example granting non-transferable, non-exclusive access rights to the data for the purpose of allowing the prospective applicant and where relevant its affiliates, customers and distributors to submit applications for authorisation of a biocidal product containing the specified active substance in the specified territory, and/or in support of applications to be on the Article 95 List;
- access rights to be implemented by the data owner issuing an LoA, as opposed to any transfer of ownership in the data or the provision of hard copies of the data;
- compensation: a specified sum and/or method of calculation of the compensation, and how and when it will be paid, and where relevant repayment of part of the compensation if the data owner enters into another data sharing agreement with another prospective applicant;
- limitation of liability: liability resulting from the prospective applicant's reliance on the data is often excluded unless caused by gross negligence or wilful misconduct, and no warranty or guarantee is given regarding the quality of the data or the approval of the applications made under the BPR on the basis of references to the data;
- conditions relating to assignment;

---

<sup>24</sup> Please see the template Data Sharing Agreement in **Section 9.5**.

- term i.e. duration of the contract and any events leading to the termination of the contract. As already noted, the BPR explicitly states that the revocation of an LoA will not invalidate an authorisation granted on the basis of that LoA;
- other standard clauses may specify what amounts to *force majeure* excusing a party's failure to execute the contract, a clause specifying which Member State law applies to the contract, and which courts will have the power to decide in the event of a dispute between the parties;
- an appendix listing the data to which access will be granted by the data owner; and
- an appendix containing a template LoA.

## 8. Dos and Don'ts regarding LoAs

DO...	DO NOT...
<p>✓ Submit an inquiry to the Agency to find out if the required data has already been submitted under the BPD/BPR and to obtain the contact details of the data submitter</p>	<p>✗ Duplicate animal testing</p>
<p>✓ Identify precise data requirements, including what BPR applications (or applications under other legislation) the LoA is intended to cover</p>	<p>✗ Apply different conditions for data access or different criteria to determine compensation due by different prospective applicants, unless there are objective differences between them</p>
<p>✓ Contact the data owner in timely fashion to negotiate access to vertebrate and if necessary, non-vertebrate data</p>	<p>✗ Delay data sharing negotiations</p>
<p>✓ Exchange detailed costing information and be transparent in data sharing negotiations</p>	<p>✗ Exchange commercially sensitive information during data sharing negotiations or otherwise infringe competition law</p>
<p>✓ Meet the every effort obligation, and keep records of the negotiations</p>	<p>✗ Expect the MSCA or the Agency to enforce any conditions or use restrictions relating to an LoA, which will be decided by national courts, other than where an MSCA may exercise the possibility to revoke an authorisation under Article 48 of the BPR</p>
<p>✓ Check that the LoA contains the information listed in Article 61 of the BPR</p>	<p>✗ Pay for access to data for which the data protection period has expired, or data which you do not need</p>

## 9. Template LoA for Fast and Standard Tracks

### (a) LoA template for use in both tracks: for Article 95(1) and for product authorisation, as per Article 95(4)

The Practical Guide on Data Sharing ([section 3.1](#)) explains that the negotiations between a prospective applicant and data owner/submitter could be an over-the counter/fast track type of transaction, where the parties do not wish to enter into negotiations beyond what is absolutely necessary to sell and buy an LoA. The parties might however need to enter into in-depth negotiations and choose to use the "standard track" route. In both instances, the parties may consider using the template LoA below at [section 9.1](#).

### (b) Appendix to the template LoA for the purpose of Article 95 and of product authorisation

The template LoA is accompanied by an appendix highlighting the essential scope of the LoA. It is designed to inform the MSCAs of that scope. It is recommended to submit the appendix with the LoA in order to allow the MSCAs to check whether the LoA submitted by the applicant with its application is valid for the purpose of the product authorisation application and covers the required data.<sup>25</sup>

### (c) Data Sharing Agreements

For the fast track LoA negotiations, the parties may consider entering into a short-form data sharing agreement in the form of a "Terms and Conditions" type document. A template for such a document is provided at [section 9.3](#) below. Do note that the prospective applicant does not need to submit the Terms and Conditions with the LoA, since whatever restrictions are indicated are not expected to be enforced by the regulatory authorities (see [section 6](#) above). That said, the Terms and Conditions could be of use, for example, in the context of any national court proceedings that a data owner or prospective applicant decides to take if the agreed upon restrictions are not complied with.

---

\*\*\*\*\*HYPERLINK \l "Section51C" [section 5.1\(c\)](#) above, Article 95(4) of the BPR facilitates product authorisation by allowing an LoA submitted for inclusion in the Article 95 List by a substance or product supplier, as the case may be, to be passed on to their customers preparing a dossier for product authorisation. Such customers need an original cover letter signed by the substance or product supplier, as the case may be, to whom the LoA was initially granted, and confirming that the customer is entitled to make reference to the LoA for product authorisation. The LoA template could therefore be accompanied by this simple cover letter to cascade  
\*\*\*\*\*

For the standard track LoA negotiations, the parties may consider entering into a longer form data sharing agreement, which is more comprehensive and details the understanding between the parties. A proposed template for a detailed Data Sharing Agreement is found at **section 9.4** of this Guide.

**(d) Alternative LoA template for the purpose of product authorisation where the default template cannot be applied**

For the sake of completeness, it may be that the template LoA below at **section 9.1** will not be relevant in certain limited circumstances. That may be the case, for example, where a data owner (either a participant in the review programme for existing active substances, or a company which secured its inclusion on the Article 95 List through an alternative dossier) is issuing an LoA to its own customers in order to help them obtain a biocidal product authorisation. A template for such an LoA is given at **section 9.2**.

**The use of the LoA templates in this section is encouraged to achieve harmonisation.**

## 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<sup>26</sup> 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.

---

<sup>26</sup> 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<sup>27</sup>**



**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*]

\*\*

<sup>27</sup> 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)

<i>[Letterhead of entity granting the Letter of Access]</i>	
<b>1. Date:</b>	<i>[Insert]</i>
<b>2. To:</b>	Competent Authorities of <i>[Insert name of relevant MS]</i>
<b>3. Subject:</b>	<b>Letter of Access for Product Authorisation</b>
<b>4. Beneficiary:</b>	
	<i>[Insert name of prospective applicant(s)]</i> , located at <i>[insert details of its registered office]</i> , wishes to apply for ( <i>delete as appropriate</i> ):
	 the authorisation of <i>[insert name of the prospective applicant's biocidal product or biocidal product family]</i> in accordance with Regulation (EU) No 528/2012 for the Product Type <i>[insert number(s)]</i> .
	 the authorisation of <i>[insert name of the prospective applicant's biocidal product (family)]</i> , a biocidal product (family) identical to <i>[insert name of the data owner's biocidal product (family)]</i> in accordance with Commission Implementing Regulation 414/2013 for <i>[insert Member State(s) or European Union]</i> .
<b>5. Entity granting the Letter of Access:</b>	
	<i>[Insert name of entity granting the Letter of Access]</i> located at <i>[insert details of its registered office]</i> has the right to grant access to the data package specified in section 6 of this letter.
<b>6. Details of data subject to this letter:</b>	
	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: \_\_\_\_\_



**Use by affiliates/consortium members/other third parties:**

*[Enter name(s) and details]*

**Access to hard copies of the following data is agreed:**

*[Specify clearly which data this covers and what type of access is being granted]*

**Territory(ies) in which the Letter of Access is granted:**

*[Specify clearly which Member States or other territories are covered by the LoA]*

**Access is also granted to studies submitted for the purpose of the review programme after the granting of this LoA: *[include date]***

**Technical equivalence:**

The responsibility to establish technical equivalence remains with the beneficiary company.

**Warranty:**

No warranty is given by the data owner that the Competent Authority of the Territory(ies) named above or the European Chemicals Agency will approve the beneficiary company's application for product authorisation or for inclusion on the Article 95 List as a result of relying on this Letter of Access.

**Applicable law:**

The following law is the applicable law governing this Letter of Access and these Terms and Conditions: *[specify applicable law]*

**Jurisdiction:**

Exclusive jurisdiction to hear any disputes arising from this Letter of Access or these Terms and Conditions resides in: *[specify details]*

<b>Signed</b>	<u>[Data Owner]</u>	<u>[Beneficiary Company]</u>
<b>Date</b>	_____	_____

## 9.5 Template long-form data sharing agreement

The present outline lists important elements of a data sharing agreement on the basis of BPR requirements, the available guidance and EU law.

Please note that this outline is by no means intended to be mandatory or prescriptive. It should rather serve primarily as a guideline or prompt for discussion in order to ensure that all parties address a range of aspects when entering into data sharing negotiations. Ultimately, it is for the companies concerned to assess the appropriateness of the provisions on a case-by case basis and decide which elements they wish to adopt (and at what level), but when making any decisions it is recommended that these issues should be taken into consideration. Use of this template should be made in consideration of the relevant national contract law (which will vary depending on the choice of law agreed by the parties).

Companies/persons are to apply this outline at their own risk and neither the European Commission nor the European Chemicals Agency will accept any liability or warranties resulting from the use of or reliance on this document and its application.

### **(Draft) Data Sharing Agreement for [active substance]**

#### **Between**

(1) [ ], whose registered office is at [ ]

Hereinafter referred to as the “Data Owner” or “Grantor”.

And

(2) [ ], whose registered office is at [ ]

Hereinafter referred to as the “Applicant” or “Grantee”.

Each referred to individually as a “Party” and collectively as the “Parties”.

#### **PREAMBLE**

*The Preamble serves the purpose of setting the scene and placing the agreement in context. It is usually a list of phrases. It may cover some or all of the following points: the approval status of the substance; a reference to Article 95 listing requirements; a reference to the principle that biocidal products may not be made available on the market or used unless authorized; a reference to the parties as being a data owner and prospective applicant and their interest in reaching agreement for BPR purposes.*

*The following are examples of phrases which may be relevant:*

Whereas the Substance [*Substance*] has been approved under the Biocidal Products Regulation (EU) 528/2012 (the “BPR”) by [*add reference to Commission Implementing Regulation or Directive amending Annex I to the BPD, as appropriate*];

Whereas a complete substance dossier on the Substance [*Substance*] has been accepted and validated by a Competent Authority as part of the active substance approval process under the BPR [or BPD];

Whereas Article 95 of the BPR foresees that substance and product suppliers may at any time submit to the European Chemicals Agency (the “Agency”) a complete substance dossier, or a Letter of Access (as defined below) to such a dossier, or a reference to a dossier for which all data protection periods have expired, if they wish to apply to be included on the Article 95 List published by the Agency (as defined below); Whereas Article 95 of the BPR provides that biocidal products consisting of, containing or generating a relevant substance may not be made available on the market as of 1 September 2015 unless either the substance supplier or product supplier is included on the Article 95 BPR List for the product type(s) to which the product belongs;

Whereas the BPR provides that biocidal products shall not be made available on the market or used unless authorised in accordance with the BPR;

Whereas Article 89(3) of the BPR provides that an application for authorisation must be submitted by [*date*] to the Agency or to a Member State Competent Authority (“MSCA”) in order to keep the product on the market;

Whereas the Grantor owns information that was submitted in the dossier used for the approval of [*Substance*] as listed in Appendix [ ] to this Agreement (the “Data”, as defined below);

Whereas the Parties recognize and support the dual aim set forth in Articles 62 and 63 of the BPR of avoiding duplication of Data and determining compensation for allowing access to such Data in a fair, non-discriminatory and transparent manner;

Whereas the Grantee is interested in obtaining Access Rights to the Data in [*product type*], in order to make an application to the Agency to be included on the Article 95 List, or make an application for a biocidal product authorisation with an MSCA or the Agency;

Whereas the Grantor is willing to provide a Letter of Access to the Data in the forms as set forth in Appendix [ ], against compensation determined in a fair, transparent and non-discriminatory manner, under the terms and conditions set forth hereinafter; and

Whereas for the purpose of this Agreement, the Parties shall not exchange competitive or market information including, by way of example and without limit to, prices, identity of customers, raw material costs, manufacturing costs, marketing or sales plans, business plans and profit margins.

NOW THEREFORE, the Parties do hereby agree as follows:

## AGREEMENT

### **Article I. Definitions**

*Consider including appropriate definitions for words that are used often throughout the agreement which could include the following*

1. The following terms and expressions shall have the meaning assigned to them below:

Access Right / Affiliate / Article 95 List / Authorisation / Commencement Date / Customer / Data / Data Compensation Price / Letter of Access / MSCA [Member State Competent Authority] / Substance / Sub-license / Territory / Third Party, etc.

2. Otherwise any definitions specified in the BPR shall apply to this Agreement.

### **Article II. Scope and Purpose**

*The following description is proposed as an example; it is neither exhaustive nor required*

This Agreement establishes and defines the terms, conditions, respective rights and obligations of the Parties with respect to the granting of a non-exclusive Access Right to the Data by the Grantor to the Grantee in the Territory for the principal purpose (the “Purpose”) of allowing the Grantee to make an application to the Agency for inclusion in the Article 95 List as a supplier of the Substance and/ or [delete as appropriate] to obtain Authorisations in the Territory.

The Access Right shall be implemented via a Letter of Access as set out in Article IV of this Agreement.

### **Article III. Obligations of the Parties**

*Below are examples of the type of obligations and access rights that Parties to a data sharing agreement can agree to; they are neither required nor prescriptive*

- 3.1 The Grantor agrees to grant to the Grantee an Access Right, in accordance with Article [ ] of this Agreement, to make an application to the Agency to be included in the Article 95 List and/ or [delete as appropriate] to obtain Authorisations in the Territory.
- 3.2 The Grantee agrees, as consideration for the Access Right granted pursuant to Article [ ], to pay to the Grantor a Data Compensation Price as set forth in Article [ ] of this Agreement.
- 3.3 The Access Right granted to the Grantee in accordance with Article [ ] shall not entitle the Grantee to view, copy or receive copies of the Data or parts thereof.

### **Article IV. Access Right**

*Below are examples of the type of access rights that Parties to a data sharing agreement can agree to; they are neither required nor prescriptive*



- 4.1 Upon payment of the Data Compensation Price, the Grantor grants the Grantee a non-exclusive Access Right. The Grantor acknowledges the Grantee's rights under Article 95(4) of the BPR. *[also possible to state that the Grantee agrees to a limitation on the exercise of its rights under Article 95(4) of the BPR, with a description of those limits]*
- 4.2 The Access Right shall be implemented by the Grantor issuing [a Letter of Access to the Agency *or, in case the LoA is only for product authorisation and not Article 95: a Letter of Access to the MSCA, as set out in Appendix [...]* of this Agreement]
- 4.3 The Parties expressly recognise and agree that the Data remains the exclusive property of the Grantor and that its intellectual property rights and any other protection rights connected with the Data, including, but not limited to, patents and trademarks, are and shall continue to be the exclusive property of the Grantor.

#### **Article V. Data Compensation Price**

*Provide rules on the calculation and payment of the data compensation – refer to the principles laid down in the Practical Guide on Data Sharing. Special attention can be paid to rules that will facilitate data sharing and payment for an SME, for example*

- 5.1 The Data Compensation Price is [*amount*], excluding VAT where applicable, payable in the following manner:
- (i) An initial up-front payment of [*amount*]; and
  - (ii) Three (3) additional yearly payments of [*amount*] each year, respectively, for years 2016, 2017, and 2018, due and payable on the anniversary of the Commencement Date.
- 6.2 The Parties expressly agree that the Compensation Price shall be adjusted in case the Grantor grants Access Rights to the Data to one or more Third Parties.

*The following Articles VII onwards are standard type clauses that can be found in many different types of agreement and can be amended as required; they are optional, to be included only on the agreement of both parties*

#### **Article VI. Liability**

- 6.1 The Parties shall undertake their obligations specified hereunder in good faith and according to all applicable laws and regulations.
- 6.2 The Grantee acknowledges that in no event shall the Grantor be liable to the Grantee for any damage of any kind, whether direct or indirect (including, but not limited to, consequential damages, lost profits and trading losses), that may result from reliance on the Data by the Grantee, unless caused by gross negligence or wilful misconduct.

#### **Article VII. Confidentiality**

- 7.1 Without prejudice to Article 63 of the BPR, the Parties shall keep in strict confidence and shall not disclose to any Third Party information shared or acquired as a result of

the performance of this Agreement except as provided in a Sub-licence or to comply with the data sharing and other procedures of the BPR.

7.2 The provisions of this Article7 shall survive the termination or expiry of this Agreement.

#### **Article VIII. Term and Termination**

This Agreement shall take effect as of the Commencement Date and cannot be terminated before [*end of data protection period*] except upon mutual agreement of both Parties.

#### **Article IX. Severability**

To the extent that any provision of this Agreement is found by a court, tribunal or competent arbitration panel to be invalid or unenforceable, that provision notwithstanding, the remainder of this Agreement shall remain in full force and effect and such invalid or unenforceable provision shall be deleted.

#### **Article X. Assignment**

Neither Party shall have the right to assign this Agreement, nor any of its rights hereunder, nor delegate any of its obligations hereunder, without the prior written consent of the other Party, which shall not be unreasonably withheld.

#### **Article XI. Entire Agreement**

11.1 This Agreement, which incorporates Appendices [ ] and [ ] and [ ], represents the entire agreement between the Parties for the purposes of granting the Access Right and supersedes any prior agreement (whether oral or written) relating to the subject-matter of this Agreement between the Parties.

11.2 This Agreement may be amended at any time by mutual agreement between the Parties in writing.

#### **Article XII. Force Majeure**

The Parties shall not be liable or be deemed to be in breach of this Agreement by reason of any delay in performing or any failure to perform any of its obligations in connection with this Agreement if the delay or failure is due to any cause beyond its reasonable control, including (without limitation), any governmental or regulatory measures, natural disasters (earthquakes, hurricanes, floods) wars, riots or other major upheaval and performance failures of parties outside the control of the Parties (e.g. disruptions in telephone service attributable to the telephone company or labour actions by employees of a common carrier).

#### **Article XIII. Applicable Law and Competent Jurisdiction**

13.1 This Agreement is construed under and shall be governed by the laws of [*country*], including its conflict of laws rules.

13.2 The Parties shall first attempt to settle amicably any dispute arising out of this Agreement. Any dispute with regard to the interpretation and application of this

Agreement that cannot be settled amicably between the Parties shall be exclusively resolved by [national Courts/Arbitration – delete and detail as appropriate].

**Article XIV. Notices**

Notices under this Agreement shall be given in writing by registered mail to the addresses specified below in relation to each undersigning Party.

[company name]  
[address].

And

[company name]  
[address].

*Note that the rules applying to the signing and dating of the agreement will depend on the law (agreed by the parties) applying to the contract*

**Signed** \_\_\_\_\_  
\_\_\_\_\_

**Dated** \_\_\_\_\_  
\_\_\_\_\_

**Appendix**

**Letter of Access** - See section 9.1 and 9.2 for examples of template LoAs which can used