

Practical Guide on Data Sharing

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.

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LIST OF ABBREVIATIONS

The following text conventions are used throughout the Practical Guide

Abbreviation	Explanation
AH	Authorisation holder
BPD	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)
BPR	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)
CAR	Competent Authority Report, also known as the assessment report.
EU	European Union
AS	Active substance
BPF	Biocidal product family
CAR	Competent Authority Report
LoA	Letter of access
MSCAs	Member State Competent Authorities responsible for the application of the BPR, designated under Article 81 of the BPR
R4BP	Register for Biocidal Products
SBP	Same biocidal product
SMEs	Small and Medium Sized Enterprises

PT Product Type

REACH 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
Access	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.
Agency	European Chemicals Agency, established under Article 75 of REACH
Article 95 List	The list of relevant substances and suppliers published by the Agency under Article 95(1) of the BPR
Biocidal product family	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)
Chemical similarity	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.

Data submitter	The company/person which submits the data to the Agency/MSCA in connection with an application under the BPD or BPR
Every effort	The level of diligence required when negotiating the sharing of data according to Article 63(1) of the BPR
Existing substance	active 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)
Fast track	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
Letter of access	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)
New substance	active 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)
Prospective applicant	Any person which intends to perform tests or studies for the purposes of the BPR (Article 62(1) BPR)
Review Programme	The work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Article 89 of the BPR
Related reference	In the context of an SBP authorisation, this is the biocidal product or

product	product family which has already been authorised, or for which the application has been made, which the SBP is identical to
Right to refer	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 this Guide and how will it help?

- (a) This Guide provides practical guidance on one of the core issues that underpins the whole EU biocides regulatory system: data sharing. Specifically, it explains the following:
- What prospective applicants and data owners should do in practice to prepare themselves for data sharing;
 - The way that negotiations should be conducted between parties; and
 - The possible outcomes of the negotiations.
- (b) The principal aim of this Guide is to provide assistance to all parties involved in data sharing under the BPR so that they may come to data sharing agreements. The BPR places parties under an obligation to use every effort – in good faith – to reach an agreement on the sharing of data. If no agreement is reached, in certain circumstances for certain types of data, the Agency can help prospective applicants by granting permission to refer to the requested data. This Guide provides tips and guidance on how parties can conduct their every effort negotiations successfully so that an agreement on a fair, transparent and non-discriminatory sharing of data and their costs is reached.

2. The data sharing rules: what practical steps the Prospective Applicant and Data Owner should take

In this section, the following are addressed:

- For the prospective applicant, (a) what to do to identify the relevant data and (b) once identified, what happens next.
- For the data owner, suggested preparations in advance of potential approaches from prospective applicants.

2.1 The Prospective Applicant

The BPR sets out the specific data that is required for the various processes. The following section sets out the steps an applicant can make to identify what data it needs, what data it is lacking and how to initiate negotiations.

If a prospective applicant has no data, they may consider contacting directly the data owner/submitter and request the list of the data submitted and to which it would be interested to have access. This would be particularly relevant for companies seeking Article 95 listing, and may be interested to have the right to refer to the entire data set submitted by the participant in the review programme.

.(a) Identification of the data lacking

Article 63(4) of the BPR states that the prospective applicant is only required to share the costs of information that it is required to submit for the purposes of the BPR. The starting point for any prospective applicant is therefore to ask oneself: “*what data am I lacking?*” both in terms of actual data missing and possibly improvements that could be made to the quality/robustness of the data that the prospective applicant has. As the right to refer to the data is granted on a per company/individual basis, in order to find the answer, prospective applicants will need to go through the following steps:

First Step: Identify the data requirements

- For dossier submissions under Articles 4 onwards of the BPR (approval of an active substance), the prospective applicant can identify all of the data that are expected in its dossier by reference to Annex II of the BPR and Annex III for at least one representative biocidal product.
- For dossier submissions under Articles 20 onwards of the BPR (authorisation of biocidal products), the prospective applicant can identify all of the data that are expected in its dossier by reference to Annex III of the BPR and Annex II of the BPR for each active substance in the biocidal product.¹
- For dossier submissions under Article 95 of the BPR (for inclusion on the Article 95 List), the prospective applicant can identify all of the data that are expected in its dossier by reference to Annex II to the BPR, or to Annexes IIA, IV or IIIA to the Biocidal Products Directive 98/8/EC (the “**BPD**”).² For active substances which have already been approved, the public version of the Competent Authority Report (the “**CAR**”) will also contain information on the data needed.

Second Step: Establish the extent to which the data needs can be met by reference to data the prospective applicant already has or to which it can obtain ready and free access³

In the following situations, the prospective applicant will not have to pay to share the required data:

- Where it already owns the data or has the right to use it for a BPR purpose.⁴

¹ Note that less data is required for an application for simplified authorisation, as set out in Article 20(1)(b) of the BPR.

² On this, see also the Agency’s Guidance on Article 95 of the BPR: <http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=bpr-data-sharing>.

³ See page 84 of the REACH Guidance at section 4.7.1 “*Step 1: Individual Gathering and Inventory of Available Information*” for guidance and information on the equivalent REACH rules. See also pages 56-58 which give guidance in particular on issues relating to copyright and the extent of the rights of parties to refer to published data and/or to data whose intellectual property is owned by a third party.

- Where the data endpoint concerned can be addressed with a data waiver or is not scientifically necessary.⁵
- Where the data that are lacking are no longer data protected under the applicable rules in the BPD/BPR. This is unlikely to be the case before 2017 as data protection periods under the BPD are, in the main, yet to expire. Furthermore, for existing active substances in the review programme (i.e. on the EU market on 14 May 2000 as an active substance of a biocidal product) where no decision on approval was taken before the entry into operation of the BPR, Article 95(5) of the BPR extends the protection period until 31 December 2025.

Third Step: List the data that are lacking

Compare and contrast the dossier data requirements with the data the prospective applicant already owns/has access to.

Fourth Step: Identify whether or not they are vertebrate animal data

Identifying whether or not a given test involves testing on vertebrate animals should not be difficult. If the test involves vertebrates, the prospective applicant is not allowed to repeat the study if the same study has been submitted already under the BPD/BPR. To find out if tests have been submitted, the prospective applicant can submit an inquiry to the Agency.

For any data sharing negotiations, both parties will need to make every effort to reach an agreement. If negotiations fail, the Agency can grant permission to refer to vertebrate data (on which, see further below at **section 4**).

Fifth Step: If the dossier submission is being made under Article 95 of the BPR ...

⁴ The prospective applicant might not own the data but nevertheless has reached an agreement with the data owner that it can use the data for BPR purposes. The concept of using the data will depend on the agreement with the data owner and could include a letter of access granting a right to refer to that data or the right to physically access to the actual studies and the right to submit those studies or a letter of access.

⁵ See Article 6(2) and Article 21 of the BPR for further details.

... the prospective applicant should be aware that in the event of unsuccessful negotiations, the Agency can also grant permission to refer to toxicological, ecotoxicological and environmental fate and behaviour studies relating to an existing active substance included in the review programme (on which, see further below at **section 4**).

Conclusion on Identification of the Relevant Data

At the end of these steps, the prospective applicant will have identified exactly what vertebrate animal data it is missing and, if inclusion on the Article 95 List is being sought, what existing active substance toxicological, ecotoxicological and environmental fate and behaviour studies it is missing. The prospective applicant will also have established if any non-vertebrate animal data are missing. In any case, the parties to the negotiations – the prospective applicant and the dataowner – must abide by the data sharing rules when an approach is made by the prospective applicant to the data owner – the principal one being that every effort must be used in those negotiations (see below for further details at **section 3.2**).

(b) Once the prospective applicant establishes that it is missing relevant data, what happens next?

This Guide places an emphasis on the prospective applicant's and data owner's right to contract freely between themselves. The starting point for data sharing therefore lies outside the BPR and in the hands of those two sets of parties.

If the prospective applicant and data owner come to a voluntary data sharing agreement, there is no reason to have recourse to the BPR's inquiry or dispute procedures. That may happen if, for example, the prospective applicant already knows what company/person owns the data it is looking to share – in that situation, it can simply choose to approach that company/person with a view to negotiating access without involving the Agency at all. And it may happen with regard to both complete dossiers of data, to "cherry-picked" studies and to any kind of study required. In short, anything can be negotiated between the relevant parties with regard to data sharing under the BPR in the knowledge that the dispute procedure only exists in certain circumstances (on which, see further below at **section 4**).

If the prospective applicant does not know who the data owner is, or whether the data it is looking for has already been submitted to the Agency/MSCAs, it can inquire with the Agency. Note that a dispute claim can be made at the earliest one month after an inquiry has been answered by the Agency. Those rules are found in Articles 62 and 63 of the BPR and, under them, there are three principal steps to take.

FIRST: Consider whether to submit an inquiry to the Agency⁶	
What the Law Says	What to do in practice
<p>Article 62(2) of the BPR states that prospective applicants (i.e. “persons intending to perform tests or studies”) “shall, in the case of vertebrate data, and may, in the case of other data, submit a written request to” the Agency “to determine whether such tests or studies have already been submitted to” the Agency “or to a” MSCA “in connection with a previous application under” the BPR or BPD.</p>	<ul style="list-style-type: none"> ➤ To submit a request, register and log onto R4BP. <ul style="list-style-type: none"> Ⓜ Go to: http://echa.europa.eu/support/dossier-submission-tools/r4bp/.⁷ Ⓜ Click on link to “R4BP” on the right hand side of that page. Ⓜ Fill in the registration form there if not already done. ➤ Click on the required application type (see http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals for more information) ➤ Complete the relevant section by using the drop down menu to identify the active substance you are interested in. ➤ The Agency checks to see if data have already been submitted for that substance.

⁶ See page 78 of the REACH Guidance at section 4.1 “The Purpose of the Inquiry Process” and section 4.2 “Is it obligatory to follow the inquiry process?” for guidance and information on the equivalent REACH scenarios.

⁷ See also Biocides Submission Manual Version 3.0 – section 7.1: http://echa.europa.eu/documents/10162/14938692/bsm_04_active_substances_en.pdf.

SECOND: The Agency's Reply	
What the Law Says	What to do in practice
<p>Article 62(2) of the BPR states that, on receipt of a request, the Agency will establish whether the studies identified have already been submitted to it or to an MSCA. If it does identify that the data have already been submitted to it or to an MSCA, it will <i>“without delay, communicate the name and contact details of the data submitter and data owner to the prospective applicant”</i>.</p>	<ul style="list-style-type: none"> ➤ If data have already been submitted to the Agency or to an MSCA for the purposes of the BPR or BPD, the Agency will notify the prospective applicant. ➤ The Agency will normally respond within 15 working days of the request being sent to it by the prospective applicant. ➤ The name and contact details (email address) of the company/person which submitted the data to the Agency/MSCA (the “data submitter”) will be communicated to the prospective applicant. ➤ The prospective applicant will also be given an asset number which must be retained as that will allow it to prove that it made the inquiry if matters proceed to a dispute. ➤ Note also that the Agency will not only notify the prospective applicant of these details but will also inform the data submitter that it has received a written request from a prospective applicant.

THIRD: Request of the Data Owner

What the Law says	What to do in practice
<p>Article 62(2) of the BPR says that the <i>“data submitter shall, where relevant, facilitate contacts between the prospective applicant and the data owner”</i>.</p> <p>Article 63(1) of the BPR says that, where a request to share data has been made, the prospective applicant <i>“and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested (...) Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.”</i></p>	<p>Once the prospective applicant receives the contact details of the data submitter from the Agency, it is up to it to send a request to the data submitter. A list of submitted individual tests or studies should be requested from the data submitter (see next step).⁸</p> <p>At this point, it is for the data submitter to assist with facilitating contact with the data owner where relevant. Both parties (prospective applicant and data submitter/owner) are under an obligation to use every effort to reach an agreement on sharing the data that have been identified. Accordingly, plan ahead.</p> <p>A template letter of request is provided at Annex 1.</p>

2.2 The Data Owner/Data Submitter: suggested preparations in advance of approaches from Prospective Applicants

⁸ If however, the prospective applicant cannot obtain this information from the data submitter, this may be an indication that the data owner is not making every effort. When negotiating data and cost sharing, note also that the prospective applicant is not necessarily required to have access to all submitted data, but only to the data required to submit for the purpose under the BPR.

- (a) Any company/person that owns data which have been submitted for any purpose either to an MSCA or to the Agency under the BPD/BPR is potentially going to receive a request for data sharing. It should also be anticipated by data owners that requests for access to individual studies (vertebrate and non-vertebrate) will be received as well as possible requests for access to complete dossiers.
- (b) Accordingly, although there is no legal requirement to do this under the BPR, what data owners may consider doing is completing the following two steps in order to avoid delays in the data sharing negotiation process.

First: Establish if an approach from a prospective applicant is likely

Review, as far as possible, the activities the data submitter/owner has undertaken to date under the BPD and/or the BPR. That review should look to identify the occasions on which its data, whether owned jointly or individually, have been submitted to any of the MSCAs in the EU or to the Agency. Include all of these. Either way, the fact that the relevant regulatory authorities will have recorded the data submitter's name in relation to the test/study means that there is the potential for it to be contacted by a prospective applicant.

An approach is therefore likely if:

- The data relate to an active substance in the review programme.
- The data relate to a new active substance which was approved or is being evaluated under the BPD or BPR.
- The data relate to a biocidal product which is being evaluated or has been authorised under the BPD or BPR.

In the context of Article 95 of the BPR, participants in the review programme are likely to be approached by a prospective applicant and should therefore consider preparing accordingly. Timing-wise, that potential is increased in particular by the 1 September 2015 deadline contained in Article 95.

However, note that any person/company which submitted data or owns data that has been submitted may be contacted by a prospective applicant to negotiate data sharing.

Second: Prepare accordingly

If data have been identified, consider doing the following:

- Make a detailed list of the data/studies/tests submitted and be prepared to share this list in case you are contacted by a prospective applicant interested in data sharing.
- Note the CAS and EC numbers of the substance concerned.
- Note the specifics of the study (date, author, type, etc)
- Collect information on study costs.
- Outline an internal set of procedures to deal with any approach that is received.
- Appoint members of staff to be responsible for dealing with such approaches.
- If the data are owned with others, coordinate as far as possible in advance with them on who will take the lead or share the lead in responding to an approach and how that will be undertaken.
- Consider the role of the data submitter if that is a company/person different from the data owner. In particular:
 - Check to see if the data submitter has a mandate to negotiate on the data owner's behalf;
 - Check to see if the data submitter has a mandate to negotiate access to a range of data (e.g. the complete dossier) so that negotiations do not necessarily have to take place on a study-by-study basis;
 - Check to see if the data submitter has a mandate to negotiate access with a group of prospective applicants; and

- In general, coordinate with the data submitter on the approach to data sharing that needs to be adopted.

Again, especially in the context of the upcoming deadline relating to Article 95 of the BPR, and in light of the obligation to make every effort to agree on sharing data, such information, in particular the list of studies, should be readily provided by the data submitters/owners upon request when prospective applicants make contact. In addition, as described below, data owners might also consider the option of a fast track route and to have developed possible scenarios to facilitate an agreement through a simplified negotiation.

2.3 Summary

- (a) The steps mentioned above are suggestions only with the aim of facilitating negotiations to share data between the prospective applicant and the data owner (or data submitter). The steps are neither prescriptive nor mandatory.
- (b) The key principle to bear in mind at all times is that any and all types of data can be shared under the BPR. The data can be vertebrate or non-vertebrate, they can be a single study or a complete dossier. It is up to the parties to agree what they wish to share, in the knowledge that under certain circumstances data sharing can be forced by the Agency for vertebrate animal data and for toxicological, ecotoxicological, environmental fate and behaviour data relating to the inclusion on the Article 95 List for an existing active substance in the review programme.
- (c) The negotiations may relate to obtaining the right to refer to the studies only in the form of an LoA, or also to obtain access to hard copies or actual copies of the data, and the right to use that data (either submitting copies or a letter of access). The parties are free to negotiate; however, the prospective applicant cannot be forced to buy “more” than the simple right to refer, while in turn the data owner cannot be forced to sell “more” than the simple right to refer.

Regardless of the type or extent of data access sought, the same principles of negotiation will apply: each party must approach those negotiations using every effort

to reach a data sharing agreement that is fair, transparent and non-discriminatory. The next section explains what that entails.

3. The data sharing rules: the type of negotiations that the parties must enter into and the way that compensation for data sharing can be calculated⁹

As this Guide aims in particular at facilitating the data sharing process, it is designed to assist parties successfully to reach an agreement and avoid disputes. Indeed, involving the Agency to establish whether the prospective applicant and the data owner have used every effort (perhaps after a long period of negotiation) should be a last resort where negotiations have failed. With that in mind then, the Guide below provides:

- an explanation of the type of negotiation that can take place; and
- a step-by-step approach to data sharing to show which factors are involved in an every effort negotiation and how the cost contribution can be determined in a fair, transparent and non-discriminatory manner.

3.1 Type of negotiation that can take place: Fast Track vs Standard Track

The BPR does not prescribe what kind of negotiations should take place but this Guide suggests two approaches: the first is the “fast track”; the second is the “standard track”.

Before explaining the difference, regardless of the type of negotiations that are entered into between parties, the BPR requires (i) that every effort is used by the parties, and (ii) that the cost is determined in a fair, transparent and non-discriminatory manner. One clear message to take away is that these principles apply at all times whether or not it is a fast track or standard track negotiation that is followed.

The First Route: Fast-Track

It may be that prospective applicants and data owners will not wish to enter into negotiations beyond what is absolutely necessary to sell and buy a letter of access (an “LoA”). It may be that they are satisfied that they can agree to share data without complex contractual arrangements.

⁹ See also page 18 of the REACH guidance at section 1.3 “Key Principles for Data Sharing” and page 93 at section 4.9.2 “How to conduct negotiations in order to prevent data sharing disputes?” for more information and guidance in equivalent REACH scenarios.

There is, after all, nothing under the BPR itself that requires the parties to enter into lengthy and detailed negotiations to consider all the possible ins and outs of data sharing, and there is nothing that requires the parties to enter into non-disclosure or written data sharing agreements.

Such fast track negotiations may be appropriate in certain circumstances, for example where the negotiations are necessarily subject to a tight regulatory timeframe such as the 1 September 2015 deadline for listing on the Article 95 List. It may also be that the subject-matter of data sharing lends itself to an “over-the-counter” type negotiation because, in reality, the transaction is a simple one. That could be the case, for example, for certain commodity-type chemicals and simple data/dossiers, and especially when an LoA to the complete dossier is sought and offered.

The fast track route is designed to cater for the over-the-counter scenario. It may be that parties believe it is appropriate where (one or more of) the following factors are present:

- ✓ The prospective applicant is seeking a right to refer to the studies only, and not access to hard copies or actual copies of the data, for instance.
- ✓ The prospective applicant wants to be included on the Article 95 List.
- ✓ The prospective applicant is seeking a right to refer to a “complete substance dossier” which the data owner is willing to sell.
- ✓ The “complete substance dossier” is likely to be of interest to many prospective applicants¹⁰ and/or those applicants are each seeking a right to refer to the data for the same purpose.
- ✓ The costs of the dossier are easy to identify.
- ✓ The costs can be relatively easily calculated and applied equally (i.e. in the same amount) across all potential prospective applicants.

¹⁰ This may, for example, be the case with commodity substances, where a large number of prospective applicants each seeks to be included on the Article 95 List as suppliers for the commodity substances they use in their biocidal products.

- ✓ The data owner can show that the cost calculation has been made fairly and in a non-discriminatory fashion.
- ✓ The data owner is transparent about how that calculation was made and on which cost items it is based.

It may also be that the fast track is appropriate even where the parties agree to certain restrictions to the scope of the LoA. Such restrictions could include the following, for example:

- ✓ The prospective applicant is seeking a right to refer to support biocidal products in just one or more Member States and the parties agree that the data compensation is reduced *pro rata* on the application of objective criteria.
- ✓ The prospective applicant is seeking a right to refer to support biocidal products for a specific application or, for instance, it is not interested in consequential rights under Article 95(4) of the BPR and the parties agree that the data compensation necessitate decrements to the costs.

If the parties agree that a fast track procedure is appropriate to grant the right to refer to the data, the parties may consider using the template LoA in the Practical Guide on Letters of Access. It is designed to be downloaded, and signed by both parties. It can be accompanied by a simple set of terms of conditions, e.g. to reflect the understanding reached between the parties as to the scope of the LoA or as to payment terms (instalments, refund mechanism, etc.).

While a refund mechanism – or the upfront discount for the renouncement to a future refund – might require some discussions between the parties, also such agreements can be accommodated in the fast track procedure.

Similarly, the parties may also agree that the prospective applicant will contribute to the costs of potential additional studies that may be required to be undertaken by the data owner/submitter (for example in the review programme for existing active substances).

It is of course for each party to agree voluntarily that the fast track procedure – and simplified LoA/terms and conditions – is appropriate for it. In order to assist with that decision, it is

incumbent on the data owner to demonstrate that the cost calculation has been determined in a fair, transparent and non-discriminatory manner before the LoA is signed.

The Second Route: The Standard Track

The standard route LoA is proposed in any other situation other than described above under the fast-track route. In particular, the standard route would be more appropriate where the parties want to negotiate a tailor-made data sharing arrangement. That may be the case where, for example:

- ✓ The costs of the data to which access is being sought are complex (perhaps, for example, because of historical reasons or exceptionally high fees in the review programme for existing active substances).
- ✓ The prospective applicant wishes to review the studies or wants to negotiate additional special rights e.g. for uses other than under the BPR.

Where the parties raise an issue which requires a degree of negotiation before an agreement can be reached, the standard track route could be an option. Prior to entering into such standard track negotiations, the parties may choose to enter into a non-disclosure agreement.¹¹ A written data sharing agreement will also normally result from standard track negotiations. In that regard, the template non-disclosure agreement at **Annex 3** may be of assistance.

3.2 Overall: the type of negotiations expected

- (a) As noted, the core principle underpinning the data sharing rules is found in Article 63(1) of the BPR which requires both parties – the prospective applicant and the data owner – to “*make every effort to reach an agreement on the sharing of the results of the tests*”

¹¹ When confidential information is being exchanged between the parties, a non-disclosure agreement may become appropriate. Such information could include active substance profile, list of customers, names of Member States for which a product authorisation is sought, exact product type, etc. However, note that the actual elements for the costs calculation are not confidential information in the sense of being commercially sensitive; to the contrary, a cost breakdown needs to be provided by the data owner without requiring that a non-disclosure agreement be signed. Importantly, any non-disclosure agreement should not prevent the parties from disclosing information to the authorities, in particular the Agency in the dispute procedure under Article 63 of the BPR or infringe the principle of non-discrimination as regards eventual agreed costs.

or studies” that have been requested. Article 63(4) of the BPR reinforces the requirement for every effort to be used during the negotiation process by stating that “*compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner*”.

- (b) The obligation to use every effort during the negotiations falls to both the prospective applicant and the data owner – it is not a one-way obligation. In practice, in case of a dispute, the Agency will assess whether every effort has been made since the entry into force of the BPR on 1 September 2013.
- (c) But what does every effort mean? The BPR provides no legal definition. The Agency will provide more concrete guidance in the form of its decisions. A link to the Agency decisions taken to date can be found at <http://echa.europa.eu/regulations/biocidal-product-regulation/data-sharing/echa-decisions-on-data-sharing-disputes-under-bpr>.¹² Also, decisions of the Board of Appeal¹³ will be relevant. In the absence of a strict definition, the principal rule to follow is that each party is free to contract with the other party as it sees fit, subject to the requirements of the BPR. Whether every effort has been used by each party in the negotiations will be assessed by the Agency in the context of each individual case.

That said, the guidance below helps parties with ideas on what they can do to reach an agreement.

Act in time

Both parties must fulfil their data sharing obligations in a timely manner. They are encouraged to allow a reasonable time for the negotiations and to initiate efforts early. In case a dispute is lodged, the Agency will assess the every effort obligation on a case by case basis; there is no minimum or maximum time for negotiations. They should be aware of all the regulatory timing

¹² Decisions taken by the Agency in the context of the REACH Regulation are also useful points of reference: <http://echa.europa.eu/regulations/reach/registration/data-sharing/echa-decisions-on-data-sharing-disputes-under-reach>.

¹³ See <http://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions>.

that is applicable. They should also be aware of any (reasonable) timeframes that are set by the other party.

In that regard, and by way of example, if one party wishes to give the other a specific deadline by which it is to answer a question, it should come up with a timeframe that it itself would consider to be reasonable. “Reasonable” should take into account the situation of the other party, for example:

- If the other party is an SME, it may be under resource constraints and struggle to attribute time and human resources to the negotiations, or
- If the other party is a task force or consortium then bear in mind that decision-making may be slower, both because the decision has to be taken by more than one company/person and because it may be making or be in receipt of multiple requests for data sharing.

All in all, parties should treat each other as they would themselves. In setting deadlines, it would also assist to be as precise as possible – that will avoid confusion and ambiguity and should lead to smoother negotiations. By doing that, and should the negotiations be unsuccessful, the Agency will see whether clear and fair deadlines were given. And if the deadline is missed, follow up and ask why that was the case.

Keep records of all negotiations

Carefully record every substantive and relevant communication with the other party.

- Every phone call or meeting that takes place should be followed by a note of what was discussed; that note should be shared with the other party (as in case of a potential dispute the Agency will only consider documents that have been exchanged between the parties), and with a request that it expressly agrees to its contents by email; makes changes to it; or be deemed to have accepted its contents as an accurate reflection of the meeting if it does nothing within a reasonable period of time (again, it would probably be better to pinpoint an exact time as opposed to stating a period of time to elapse).
- It would help if every substantive phone call or other verbal communication is converted into a contemporaneous written document (meaning, convert it within, for example, a day

of the communication happening); it should then follow the same exchange and approval process as above.

- It would assist if any substantive email sent to the data owner and vice-versa had a read receipt.
- Every substantive email should be saved and kept in a safe place, as both prospective applicant and data owner might need to provide the Agency with such documentation in case a dispute is lodged.

Be open, honest and realistic

- Do not hide essential negotiation points until the last moment; avoid ambushes.
- Indicate up front if certain treatment is being sought because, for example, of the prospective applicant's or data owner's SME status; do not be afraid to admit to lack of resources or experience or capabilities; and do so in the knowledge that the other side is encouraged to take this specifically into account.
- If face-to-face meetings are to be arranged, be sensitive to the fact that the other party may live in a part of the EU that is distant, and with which there are no direct transport links, etc; in other words, be reasonable and flexible in the expectation of how the negotiations will be conducted – consider email or other forms of communication instead.

Consider following these recommendations

- Be consistent and reliable.
- Make sure that every reasonable overture from the other party is replied to in a timely fashion.
- Make sure to give the other party a reasonable amount of time to react (weekends and holidays should not be counted in the timing).

- If you consider that the other party is delaying the negotiations, explain the reasons for urgency. Be sure to challenge the other party if they are slow in replying; ask them to speed up or provide reasons for their delay and comment appropriately (and politely). If there are no reasonable excuses being provided, document them and then issue the other party with a warning. Document that warning.
- Where a party receives an unsatisfactory reply, which it considers unclear, invalid or incomplete, it is the responsibility of the recipient to challenge that reply by addressing constructive, clear questions or arguments to the other party.
- Be sure to explain clearly what the specific data requests are; leave no room for ambiguity.

Conclusion on “Every Effort”

When trying to determine whether every effort has been made, consider using a third party (not necessarily a lawyer or consultant, just someone who is not one of the parties involved) and use common sense when going through the evidence that may demonstrate every effort on your part. Be very clear that the every effort obligation applies to all parties taking part in the negotiations. There is a reasonable expectation that where parties operate the rules with goodwill and in good faith, they will come to an agreement.

However, if negotiations fail, as a last resort the prospective applicant can request help from the Agency by lodging a dispute claim. Both parties should reflect on the fact that the system has been designed to be relatively straightforward. There are no fees to be paid to the Agency, for example, and no lawyers need to be involved.

Initially it will be for the prospective applicant under the dispute procedure to demonstrate to the Agency that it has adhered to this requirement. As mentioned before, the data owner will also be invited to submit its evidence proving that every effort was made, and the Agency’s assessment of efforts made will be based on the documentation provided by both parties. If the prospective applicant has made every effort while the data owner has failed to do so, the Agency will grant the prospective applicant permission to refer to the requested data.

The outcome of a dispute procedure will not satisfy either party in the same way that a mutually acceptable arrangement would. The dispute process should only be triggered if such a voluntary agreement cannot be reached. In that regard, parties should also bear in mind that the Agency will only look at the efforts made before the dispute was submitted. So take an appropriate amount of time to see through the negotiations before informing the Agency that an agreement could not be reached.

Also note that a voluntary agreement can still be found after a dispute claim has been lodged with the Agency, and even after the Agency has issued its decision. Therefore, be open for discussions also during an ongoing dispute procedure.

See Annex 2 for a take-away tips document

3.3 During the negotiations, the principles of compensation calculation¹⁴

- (a) The expectation is that all parties approach negotiations in good faith: the prospective applicant will gain access to the data it needs while the data owner will receive equitable compensation.
- (b) Data sharing negotiations, therefore, must not be viewed as a commercial opportunity but recognition of the fact that the efforts spent by the data owner in generating the data must be reasonably and fairly compensated by those who are now required to rely on them. It allows prospective applicants to afford access to required data which they would not be able to finance if they were to bear the entire costs on their own. This is of assistance in particular to SMEs. That is underlined by what the law says. Article 63(4) of the BPR states that *“compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner”*. So what does that mean?

¹⁴ See page 87 of the REACH Guidance at section 4.7.5 *“Step 5: Negotiation on Data and Cost Sharing, and Possible Outcomes”* for guidance and information on the equivalent REACH rules.

Transparency

While the concepts of fairness, transparency and non-discrimination have each to be met individually, if the negotiations are conducted transparently, it will become clear whether or not the parties are acting in a fair and non-discriminatory manner.

- Transparency includes the obligation for the data owner to provide details on the individual cost items, and the way that it has calculated its costs and applied its principles. Such information, including e.g. a cost breakdown or basic information on the calculation methods, should be disclosed by the data owner upon request. Any hesitation that such transparency may mean having to reveal confidential calculations, for example, might be balanced out by asking the prospective applicant to sign a non-disclosure agreement. Such an agreement is not a requirement under the BPR, or the law in general, but where negotiations touch on commercially sensitive issues (such as the territories in which the prospective applicant wishes to sell the relevant product), a non-disclosure agreement might be considered. In any event, for as long as it does not prevent the cost calculation from being determined in a fair and non-discriminatory manner, it should not compromise the transparency of the process. A template for such a non-disclosure/confidentiality agreement (an “NDA”) is found at **Annex 3**. However, note that neither party can insist on an NDA as a prerequisite before entering into data sharing negotiations.
- While transparency is key, prospective applicants are not under a legal requirement to identify themselves to data submitters/owners prior to the actual signing of a data sharing agreement. There is, of course, nothing preventing them from revealing their identity but the law does not require it. It could be, then, that the prospective applicant negotiates through a consultant or another third party. That said, the more detailed and complex the negotiations become – for instance, where use restrictions are being negotiated – the higher the data owner’s legitimate interest in certain information about

the prospective applicant's business might be, and hence the less the "anonymity" stands to be justified in terms of the every effort obligation.

Non-discrimination

The principle of non-discrimination has two dimensions:

- Firstly, one cannot treat persons in the same situation differently unless one can objectively justify that different treatment.
- Secondly, and conversely, one cannot treat persons in different situations in the same way unless one can objectively justify that same treatment.

The share of costs paid by every prospective applicant for the same rights should be the same. Examples of where different shares of costs may be justified include (but are not restricted to) the following:

- Access sought EEA-wide vs Access sought for a single Member State.
- Access sought for multiple product types vs Access sought for a single product type.
- Access sought including copies of the tests and studies, or other valuable information (such as robust study summaries) vs an LoA granting permission to refer without review of studies.

Fairness

Again, there is no clear black and white answer to what constitutes fair compensation following every effort negotiation. It will depend on the facts of each case. A fair approach is one which can be backed up by objective reasoning and evidence. And a fair approach is one where the parties entertain all reasonable arguments and politely decline or accept them.

3.4 General rules of thumb under Article 63 of the BPR: the typical costs basis balanced against typical increments/decrements¹⁵

Below, this Guide presents examples of the issues that might be discussed between prospective applicants and data owners when negotiating data sharing. They do not constitute an exhaustive list of issues and nor are they designed to encourage the parties to raise each and every one of them. Further, this Guide does not provide specific recommendations on what the actual outcome of the negotiations should be - it seeks only to explain to parties not experienced in this type of negotiation the issues that they are likely to face and for which they need to be prepared. The Guide is intended neither to be prescriptive nor mandatory nor exhaustive in that regard.

- (a) It is for the parties to the negotiations to agree to the various mechanisms and approaches to apply in the calculation of a fair, transparent and non-discriminatory cost. Under the BPR, no data owner can expect a prospective applicant to pay a proportionate share for the data if the data owner does not provide information allowing for an assessment of whether the overall compensation calculation can be objectively justified.
- (b) In calculating the compensation figure due to the data owner, it is important that prospective applicants understand that they might be asked to contribute a proportion not only of the cost (e.g. of the figure on the invoice paid by the data owner to the laboratory that conduct the test) but also of the total costs incurred by the data owner in the generation of the test/study. Those costs will be based as much on vouched expenditure indicated by invoices and receipts as on objectively justifiable calculations. However, the data owner will need to be prepared to answer the prospective applicant's questions regarding all cost items and to provide plausible justification and transparent information thereon.
- (c) The first challenge for the data owner, therefore, is to calculate the overall costs that it attributes to the generation of the test/study/complete dossier concerned; the data owner can expect the calculation to be questioned by the prospective applicant during

¹⁵ See page 96 (onwards) of the REACH guidance at section 5 "*Cost Sharing*" for information and guidance in similar REACH scenarios.

the negotiations. And the second challenge is to calculate the proportion of the overall costs that the prospective applicant will pay.

- (d) In general, data may be owned by one company/person (perhaps the simplest scenario) or by a number of companies/persons further to an agreement between them or by a legally established task force/consortium made up of member companies. In each of these scenarios, there are common cost factors that a data owner can take into consideration. Those factors may become more complicated, the more data owners there are. In addition to the theoretical negotiations/cost calculations case scenario that can be found at **Annex 4**, below are some issues regarding the compensation calculation that may be raised by one or both of the parties during the negotiations.

(i) Laboratory costs

It is the responsibility of the parties to agree to the costs model that is the most appropriate for them. There are, typically, two bases for laboratory costs calculation: the actual costs incurred and a calculation of replacement costs. Both can be equally valid.

- Actual costs: these are the costs actually borne by the data owner at the time they were incurred. Arguments to the effect that replacement costs must be used instead (for example, that it would have been cheaper to have commissioned a laboratory elsewhere to conduct the test) may be relevant if, for example, the studies were generated in-house or the test specification goes beyond what would have been required as a minimum for the regulatory purpose. Any laboratory costs should be vouched according to invoices and proof of payment of the invoice.
- Replacement costs: where, for example, the costs cannot be vouched because the specific invoicing documentation is missing, an agreement may be reached on the estimated replacement value. This could, for example, be relevant for studies conducted in-house.

Among others, the following factors may be taken into account in that estimation:

- The same test would have to be considered.
- The same type and quality of study will have to be considered.¹⁶
- The average of three independent quotations could be used, for example, or a third party could be considered to conduct the assessment of replacement costs.

(ii) Fees paid to third parties

The data owner may want the fee costs it has incurred for an existing or new active substance to form part of the compensation calculation. The fees could include:

- Fees paid to technical consultants (for advice, for example, on the type of data that need to be generated).
- Fees paid to legal consultants (for advice, for example, on the BPD/BPR rights and obligations).
- Fees collected by the Agency/MSCAs on submission of dossier and Rapporteur Member State dossier evaluation fees.

Any fee claim in this regard would have to be specifically attributable and proportionately attributed to the data which are the subject of the negotiations, taking into account the fact that the prospective applicant may have to bear similar costs in its own approval/authorisation process.

(iii) Internal work/Administration costs

A data owner may look to attribute a figure to the value of the work spent by the data owner(s) (and its staff) on generating the test/study. This claim would amount to a

¹⁶ See page 97 of the REACH guidance at section 5.2.2 “Data Validation Approaches” for information and guidance on how to establish the quality of a given test/study.

figure for the “sweat equity” invested by the data owner(s). It implies, amongst other things, that:

- A figure may be calculated on the value given to one person’s day of work.
- A figure may be calculated on the number of days per person spent on generating or ensuring the generation of the test/study.
- A figure may be calculated on the expenses incurred such as travel expenses and other general office expenses.

Any claim made on this basis would have to be specifically attributable, and proportionately attributed, to the data which are the subject of the negotiations. Any claim would have to be fully documented and individually vouched.

(iv) Risk factor costs/risk premium

The data owner may wish to apply a risk factor (or “risk premium”) to an individual study / cost item or the overall costs, claiming that this is to cover the risk undertaken when originally investing in the tests / dossier. It remains the case that the data owner must justify any claim with fair, transparent and non-discriminatory reasoning; there is no scenario which per se would require the application of a risk premium. Arguments that could be made to challenge the risk premium include the following:

- A prospective applicant may find such a claim appropriate only after successful completion of the approval of the active substance, or, as a minimum, if the studies concerned show a negative (no effect) result which was accepted for risk assessment.
- The prospective applicant could argue that it only now falls under a legal requirement to access the data. The BPR does not require that it covers the financial implications of previous legislation which were not applicable to its situation.

- A prospective applicant could argue that it was the data owner's decision to incur the costs at the time it did; accordingly, the usual commercial risks of that decision need to be accepted by it. Further, if related costs incurred long time ago, they could have been amortised in the meanwhile.
- Charging a risk premium may result in the compensation being sought becoming prohibitive, in which case the data owner needs to justify why such a compensation is fair and non-discriminatory.
- The prospective applicant might challenge the level of the risk premium applied as well as its determination, and could request the data owner to bring forward objective criteria justifying the proposed factor.

(v) Inflation

Data owners may seek to add a cost for inflation to individual cost items or an average inflation to the overall cost figure reached. This could be considered in particular where there has been a significant passage of time since the costs have been incurred. The inflation rate could be calculated by reference to Eurostat (<http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home>). That said:

- A study that is, for example, 15 or 20 years old could attract a high inflation rate and adding that cost to the overall compensation costs could be unfair.
- In particular in relation to existing active substances for which data protection generally expires on 31 December 2025 (see Article 95(5) of the BPR), it can be argued that older data (which sometimes date back to the 1980s or 1990s) have already been compensated for in the past under different regulatory regimes, justifying reduced compensation.
- The prospective applicant might challenge both the application and the determination of the inflation rate.
- It remains the case that the data owner must justify any claim by reference to fair, transparent and non-discriminatory reasoning.

(vi) Interest

Prospective applicants may face claims from data owners regarding interest to be paid. While there is no scenario which per se would require the application of interests, the data owner might try to explain this, for example, with the costs related to its own earlier submissions, which required it to pay money that it could otherwise have invested. That said:

- The prospective applicant could argue that it only now falls under a legal requirement to access the data. The BPR does not require that it covers financial implications of previous legislations which were not applicable to its situation.
- A prospective applicant could argue that it was the data owner's decision to incur the costs at the time it did, and not to invest the money otherwise; accordingly, the usual commercial risks of that decision need to be accepted by it.
- Charging interest may result in the compensation being sought becoming prohibitive, in which case the data owner needs to justify why such a compensation is fair and non-discriminatory.
- The prospective applicant might challenge the interest rate applied as well as its determination, and could request the data owner to bring forward objective criteria justifying the proposed interest rate.
- The prospective applicant might argue that the interest on the costs incurred previously have been amortised in the intervening period.

It remains the case that the data owner must justify any claim by reference to fair, transparent and non-discriminatory reasoning.

(vii) Cascade rights of reference/letters of access

Article 95(4) of the BPR expressly allows the companies/persons named on the Article 95 List and to whom a right of reference/LoA to data has been granted to cascade that

right/letter to other third parties which are applying for product authorisations under Article 20 of the BPR. Those other applicants would, it is expected, be their customers. Naturally, the number of cascade applicants will not be known at the time of the granting of access to the data owner's data. If the prospective applicant wishes to limit the number of entities which could benefit from cascade rights, it might seek decrements in the cost compensation.

(viii) Overall costs relate to the whole dossier but only one study access is being sought

It is reasonable and fair only to expect the prospective applicant to contribute for the costs relating specifically to the generation of the data it is seeking access to, as opposed to, for example, the overall costs relating to the generation of the entire dossier of data for the active substance concerned. The prospective applicant can do so because the BPR expressly allows data sharing for individual studies out of dossiers with hundreds of studies in them.

If the prospective applicant is therefore seeking access only to one specific study, it can reasonably question the overall cost calculation on the basis that that study constituted only a percentage of the overall costs (of the sweat equity calculation, etc). As a result, it will be able to ask that only a relative percentage of the study costs, as adjusted by the increments and decrements negotiated between the parties, should be considered to calculate its fair contribution.

(ix) Only limited access is being sought

The prospective applicant may wish to contribute less to the costs if its request is for limited access. For example, it may seek access for only one Member State as opposed to EU-wide for its product authorisation.

In such cases, the prospective applicant is requesting that it be treated differently from other prospective applicants asking for more extensive rights. As compensation must be calculated in a non-discriminatory manner, it is important that the data owner is sufficiently flexible to accommodate this. Appropriate mark-ups and downs,

consistently applied to different prospective applicants, must be made. In terms of how to make them, some example calculation methods include:

- Where the prospective applicant is seeking to refer to the study in only a limited number of Member States, the reduction could be calculated by reference to an objective criterion.
- Where the prospective applicant is seeking only to have a right of referral and not a right to receive hard copies. This could be the basis for applying a decrement.

(x) Overall cost-sharing mechanism across multiple parties

In order to avoid the unfairness that would result if the data owner were compensated several times for the same cost item related to the generation of the test/study, and also to ensure that the prospective applicant only pays its proportionate share, the data owner and all prospective applicants may wish to find a refund mechanism which allows them to take into account:

- Those companies/persons which have already made a contribution;
- Those which are currently seeking to make a contribution; and
- Those which may make a contribution in the future.

Necessarily, because it is not possible to foresee how many prospective applicants there will be, and indeed what level/type of access they will be seeking, there may have to be a mechanism agreed between data owner and prospective applicant to recalculate the prospective applicant's contribution each time that there is a new third party acquiring rights of access. The result may ultimately be that the prospective applicant is reimbursed a significant amount of the original contribution made.

Such a refund mechanism could be considered by the parties to be a necessary requirement to ensure fairness and non-discrimination. Problems may arise because, e.g.:

- Each data sharing is an individual negotiation and while the principles of non-discrimination and fairness must be adhered to, it is likely that prospective applicants will have different needs and desires.
- As different data sharing requests will cover different datasets (tests and studies), an objective refund mechanism will need to take into account potentially many different situations.
- As data may be protected for a period, the refund mechanism may need to be updated in light of changing circumstances.

It may be, though, that the parties do not agree to a refund mechanism but instead agree that the compensation to be paid to the data owner is significantly discounted upfront in return for no refund mechanism being established. Again, it is up to the parties to negotiate with every effort whatever they wish. And any agreement reached may not prejudice any agreement with an additional third party wishing to share the data at a later stage.

3.5 Beyond compensation, other typical terms and conditions of data sharing

(a) It will not be unusual, or unreasonable, for data owners to attempt to negotiate into a data sharing agreement certain terms and conditions. For example:

(i) Extra-territorial/extra-purpose use

Parties are free to agree that the prospective applicant can use the LoA for non-BPR purposes within, and outwith, the EU.

(ii) Extended/limited rights of access

Whether only an LoA is being negotiated (a relatively short document – see the template in the Practical Guide on Letters of Access) or whether the data owner will send actual hard copies of the test/study potentially stretching to hundreds of pages, will depend on whatever is agreed between the parties – it may well be that more

extensive rights of access to the data, indeed joint ownership of the data, are agreed between the parties.

Similarly, where there is agreement to allow the prospective applicant's affiliates and/or customers to benefit from the same access rights, the LoA should explicitly state so. Such is expressly permitted where data sharing negotiations are being conducted under Article 95 of the BPR. In such circumstances the affiliates and customers will not be required to engage in separate data sharing negotiations with the data owner; the LoA will simply flow down the supply chain. The way this occurs is that the prospective applicant which has secured the LoA will provide its customers (the applicants) with a cover letter. That cover letter will state that the prospective applicant allows the applicant to refer to the LoA. A template cover letter is provided in **Annex [x]** to the Practical Guide on Letters of Access.

(iii) Deposit

A data owner may ask a prospective applicant for a deposit before the start of negotiations. It may be asked because the data owner is looking for evidence from the prospective applicant that it has a real interest in sharing data. It may also assure the data owner that it is not wasting its time in preparing for and participating in negotiations. Clearly, though, the request for such a gesture cannot be an obstacle to the negotiations, not least because nothing under the law requires a deposit to be lodged. Accordingly, the decision by a prospective applicant not to pay a deposit if requested by the data owner can normally not be used as a reason to refuse to enter into negotiations; nor can it be used as an indication that every effort was not made.

(iv) Future data requirements

A further point that could be raised is whether an LoA should address future data requirements, for example those relating to the assessment of a substance which is ongoing in the review programme. In such circumstances the data sharing agreement underpinning the LoA may specify that it will cover any additional, subsequent studies to be submitted by the data owner and which may be necessary to support the applications contemplated by the prospective applicant as specified in the letter. Alternatively, the parties may agree that the data owner will provide a separate LoA for additional studies, which are outside the scope of the existing data sharing agreement. Both arrangements – and versions of them – are permissible under the law.

(v) A revocation clause

Where a data sharing agreement contains a clause to the effect that the LoA which it gives rise to is to be revoked such that it can no longer be relied upon by the prospective applicant and it must withdraw its product from the marketplace, this will be of no effect *vis-à-vis* the relevant regulatory authorities. Article 61(2) of the BPR makes it clear that once granted, the LoA remains valid for whatever period of time is mentioned in it and, accordingly, both the prospective applicant and the MSCAs/the Agency can rely on it.

To enforce a restriction that has been agreed to between the parties in a data sharing agreement, the data owner can have recourse to a national court.¹⁷ It could also consider contacting an MSCA or the Commission (in the case of a Union Authorisation) under Article 48(1) of the BPR which allows cancelling or amending an authorisation if it was “*granted on the basis of false or misleading information*”.

(vi) Technical Equivalence

It may be that a data owner will ask for proof of the fact that the prospective applicant’s source of active substance is technically equivalent to the reference source that was reviewed by the EU authorities and to which the data owner’s data relates; the prospective applicant may also wish to ensure that the studies it shares can be used by the relevant regulatory authorities for its source of active substance.

Technical equivalence or chemical similarity¹⁸ are not legal requirements for data sharing under Articles 62 and 63 of the BPR and are not required as part of an Article 95 List inclusion application.¹⁹ While an assessment of technical similarity might be in the interest of the prospective applicant as it provides it with reassurance that it will benefit from having paid the data owner for access to the data, the parties remain free to agree to this if they wish in the knowledge that the data owner cannot make such an assessment a precondition for data sharing.

See Annex 5 for a take-away document on cost factors

¹⁷ For instance, in case of failure by the prospective applicant to contribute towards the costs of additional studies required by the relevant regulatory authorities; or where the prospective applicant is placing its biocidal products on other territories than the ones it had agreed to in return for a reduction in the compensation costs.

¹⁸ Formal Technical Equivalence can only be carried out once the active substance is approved and the reference specification is agreed. Before approval, companies/persons can voluntarily agree to check the chemical similarity of the substance either by asking the Agency or a consultant to conduct this.

¹⁹ Note that technical equivalence will be required as part of the application for authorisation of a biocidal product where the active substance comes from a different source than the reference substance.

4. The Possible Outcomes of the Negotiations

4.1 Possible Outcome: The Negotiations are Successful

(a) What the BPR says

According to Article 63(1) of the BPR, an agreement can be reached between the parties in one of two forms: as a result either of party-to-party negotiations ending in an agreement between them or of the decision of an arbitration body. In both scenarios, the data owner shall either “*make all the scientific and technical data related to the tests and studies concerned available to the prospective applicant*” when submitting applications under the BPR, or “*shall give the prospective applicant permission to refer to the data owner’s tests or studies*” when submitting applications under the BPR.

(b) What to do in practice

- The starting point of any negotiations is the request of the prospective applicant sent to the data owner/submitter.
- The prospective applicant is not obliged to obtain access to or receive hard copies of the tests/studies – but, of course, this can result from the negotiations with the data submitter/owner. If it is negotiated, the prospective applicant can expect to have to pay more.²⁰
- If agreement is reached on data sharing, it should be in writing and signed by both parties; its wording should be unambiguous to avoid the potential for dispute. A template agreement is found in the Practical Guide on Letters of Access.
- If an agreement on sending the negotiations to an arbitration body is reached, it should also be in writing and signed by both parties; its wording should be unambiguous to avoid the

²⁰ The REACH guidance on the level of access that can be negotiated is set up in a hierarchy of: full co-ownership rights based on an equal share of the costs incurred to generate the data; or a full right to refer to the full study/test report through, for example, a global LoA; or a limited right to refer to the full study/test report through an LoA for specific BPR purposes in limited jurisdictions. See page 54 in the REACH guidance at section 3.3.3.8 “*Step 8: Sharing of the cost of the data*” for more information and guidance.

potential for dispute; and accordingly, it must be clearly accepted between the parties that they are committed to accepting the decision of the arbitration body.²¹

- Once a successful agreement is concluded, the prospective applicant can now refer to the data/complete dossier that was the subject of the negotiations for a purpose under the BPR. If an LoA is agreed as a result of the data sharing agreement, parties should consider using the template in the Practical Guide on Letters of Access.

4.2 Possible Outcome: The Negotiations are Unsuccessful²²

(a) What the BPR says

Article 63(3) of the BPR caters for the situation where no data sharing agreement can be reached.

Where that is the case, the prospective applicant can inform both the Agency and the data owner of the fact that agreement to share data has not been reached between the parties. The prospective applicant can do so at the earliest one month from the day of receipt of the contact details of the data submitter from the Agency further to an inquiry (see above). The prospective applicant will need to demonstrate to the Agency that *“every effort has been made to reach an agreement”*. *“Within 60 days”* of being informed, the Agency then *“shall give the prospective applicant permission to refer to the requested tests or studies on vertebrates”* and to the requested *“toxicological, ecotoxicological and environmental fate and behaviour studies”* if the purpose for which the approach has been made to the data owner is for inclusion on the Article 95 List for an existing active substance.

Before the Agency can grant a permission to refer, the prospective applicant also needs to show that it *“paid the data owner a share of the cost incurred”*; for further information regarding the *“proof of payment”* see below at (iv).

²¹ All companies/persons need to understand that any decision to go to arbitration usually means that (i) they should be able to influence who the arbitrator(s) is/are; (ii) there is, however, no appeal from the arbitrator’s decision; and (iii) the arbitrator’s decision is binding and enforceable in national courts. Careful consideration should therefore be taken before acceding to a request to enter the arbitration process and indeed, seeking legal advice in that regard is encouraged.

²² See page 91 of the REACH Guidance at section 4.9.1 *“Data Sharing Dispute According to Article 27(5)”* for guidance and information on the equivalent REACH rules.

Note that parties should continue negotiations during all stages of the dispute procedure. Also once a final decision is sent, parties are still free to come to a negotiated agreement rather than have a national court establish the “*proportionate share of cost*”.

Either party can appeal to the Agency’s Board of Appeal if they are not satisfied with the Agency’s decision (see below at (vii) for further detail on this).

(b) **What to do in practice**

(i) One month limit?

The one month timetable starts on the day that the prospective applicant receives the contact details of the data submitter from the Agency further to its inquiry. If negotiations have been underway without success and without an inquiry having been made (because, for example, the prospective applicant already knew who the data owner), the prospective applicant will need to go through the inquiry procedure described above and, if possible, continue negotiating for at least one month before lodging a dispute with the Agency.

The one month limit is designed to allow real and substantive attempts at negotiations to be made and it is not expected that substantive negotiations can realistically be concluded within that timeframe. Note that there is no upper time limit but, negotiations can go on for as long as necessary subject to the requirement, of course, that every effort is made and that there is no unreasonable delay on either party’s part. Any suspected delay should be acted upon by, for example, directly addressing the issue with the other party (in writing) and expressing the opinion that such a delay is not consistent with the every effort obligation.

(ii) Inform the Agency

To inform the Agency of a dispute, an on-line form is available at <https://comments.echa.europa.eu/comments cms/Article633.aspx>. Documentation requirements are indicated on that form.

(iii) Demonstrate “Every Effort” negotiations to the Agency:

- Every effort documentation may consist of the following:

- correspondence requesting access to the data;
 - correspondence from the data owner describing the conditions for the sharing of the data;
 - correspondence challenging on valid grounds the conditions imposed by the data owner/submitter;
 - any further justification, or modification, of the conditions provided by the data owner/submitter;
 - correspondence challenging those justifications that the prospective applicant would consider unfair, non-transparent or discriminatory; and
 - the notification informing the data owner/submitter that the Agency will be informed of the fact that an agreement has not been reached.
- Note that a new web form needs to be filled in and submitted for each data owner with whom negotiations have not been successful and for each substance which was subject to the negotiations (even if they were negotiated with the same party). The prospective applicant can, however, include several studies on one web form, if they have been negotiated with the same legal entity.
- Note also that, despite the notification having been made, the Agency will encourage the parties to continue with every effort negotiation until such time as the Agency issues its decision.
- A group dispute can be submitted if the negotiations have been conducted on behalf of a group of prospective applicants.

(iv) Proof of Payment

The Agency does not require proof of payment to be submitted at the time of lodging a dispute. That said, in the event that the Agency intends to grant permission to refer to the requested data, the prospective applicant will need to prove that it has paid the data owner a share of the costs that it incurred in the generation of the data before the Agency's decision can become

applicable; the Agency's draft decision becomes final only once the payment is proved to have been made. The proof of payment may take any appropriate form, including a bank statement or a receipt of a postal order. Inserting a request in its first letter of approach to the data owner to provide the prospective applicant with its bank account details or other mechanism of payment would assist with this process.

Whatever payment is made cannot be refused by the data owner. However, while the amount to be paid need only be "*proportionate*" and refer to "*the costs of information that [the prospective applicant] is required to submit for the purposes of*" the BPR, it is suggested that the calculation made by it is objectively justifiable, as the matter can be submitted to a national court (Article 63(3) of the BPR).²³ The Agency recommends in such situations that the prospective applicant pays the data owner for the items that were agreed or suggested during the negotiations. This means that the payment at least reflects what the prospective applicant had offered to pay.

(v) Right to refer when?

Following the receipt of a dispute claim via the web form (see above at (iii)), the Agency assesses whether every effort has been made by both parties. For that purpose, the other party to the dispute will also be requested to submit evidence regarding the negotiations within 10 working days. Once the 10 working days is up, the Agency will consider that it is in receipt of a full set of information whether or not the other party has submitted any evidence. The Agency issues its decision within 60 days upon receipt of this full set of documentation (however, the 60 days are not counted while the Agency is waiting for the proof of payment)

Two types of right need to be split out, which are dependent on the purpose for which an approach has been made.

- Permission by the Agency to refer to the data is in effect the equivalent of an LoA – it does not cover hard copies or summaries or any other type of information regarding the tests/studies owned by the data owner. This is a limitation that will

²³ If the data owner does not agree that he has been sufficiently compensated, "*national courts shall decide on the proportionate share of the costs that the prospective applicant is to pay to the data owner*".

need to be taken into account in case the Agency grants permission to refer. In such a situation, the prospective applicant might prefer proceeding with the negotiations based on the decision issued by the Agency and still aim to reach a negotiated agreement which might include additional access rights to the data.

- If the approach is made with regard to inclusion on the Article 95 List, Article 95(4) of the BPR provides that the same type of right (right to refer) extends beyond the prospective applicant to *“applicants for the authorisation of a biocidal product to make reference to that letter of access or that study for the purposes of Article 20(1)”*. This means that the prospective applicant will be able to use the right to refer to the requested data given by the Agency in support of obtaining authorisations of biocidal products for itself and its customers. The extent of that right is considered further in the Practical Guide on Letters of Access.

(vi) Consequence of an Agency decision not to grant permission to refer to the requested data

Should the Agency consider that the prospective applicant has not made every effort, both parties are required to resume negotiations given that they remain under the obligation to share data as well as to make every effort. If subsequent negotiations fail, the prospective applicant is free to re-submit a dispute claim with additional evidence of every effort.

(vii) Legal Remedies

Any decision of the Agency in a data sharing dispute can be challenged before the Agency’s Board of Appeal as provided by Article 63(5) of the BPR (*“An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article”*). The submission of an appeal would suspend the application of the decision subject to appeal.

* * * *

5. ANNEXES

Note that Templates may be subject to updates. Therefore it is recommended to consult the Agency's websites on a regular basis.

- **Annex 1:** Template Letter of Request to Data Submitter/Owner
- **Annex 2:** Summary table for data sharing negotiations
- **Annex 3:** Template Non-disclosure / Confidentiality
- **Annex 4:** Data Sharing Case Scenario
- **Annex 5:** Compensation Calculation Factors

Annex 1

TEMPLATE LETTER OF REQUEST TO DATA SUBMITTER/OWNER

[Company letterhead]

Date _____

Dear [*Name of Individual if provided by Agency*] or [*Sir/Madam*],

Re: Request for Data Sharing under Biocidal Products Regulation 528/2012 (the "BPR")

We understand that you – [*insert name of company/person indicated by the Agency*] – are the submitter of data relating to [*insert name of active substance or biocidal product*].

We are interested in seeking to share (*tick as appropriate*):

- certain data [*insert further information if available*] relating to this active substance
- the complete dossier [*insert further information if available*]

Should the data be protected, with this letter, and in terms of Article 63 of the BPR, we request that we enter into data sharing negotiations with a view to obtaining a right to refer and/or other rights to the data mentioned above.

We would appreciate a reply to this letter by the [*insert date*] with the following:

- List of the data (i.e. scientific tests and studies) you have submitted on [*insert name of active substance or biocidal product*];
- Confirmation that the data noted above are still protected whether under the BPR;
- An indication, where possible, of the cost compensation that will be requested for
 - Access to hard copies of the data
 - Right to refer to the data

and details on how this cost has been calculated; and

- Details of a bank account into which we can make a payment

We request that all communications on the subject matter in this letter be made to:

[Insert name, address, email and contact telephone numbers].

Yours sincerely/faithfully *[delete as appropriate]*,

Annex 2
SUMMARY TABLE FOR DATA SHARING NEGOTIATIONS

DOS of Every Effort	DON'TS of Every Effort
<ul style="list-style-type: none"> ✓ Be reliant, consistent and open in all negotiations ✓ Act with due regard to the regulatory timing ✓ Keep written records of all steps of the negotiations, every email, call and meeting ✓ Treat the company/person you are negotiating with as you would expect to be treated ✓ Be clear and unambiguous in what you are seeking ✓ Be sensitive to the capacity, size, situation of the party you are negotiating with ✓ Reply promptly to all reasonable requests/questions/communications ✓ Give the other party a fair and reasonable amount of time to reply to you 	<ul style="list-style-type: none"> ✗ Expect the other party to do your work for you ✗ Give an unreasonable timeframe in which to complete the negotiations ✗ Ambush the other party with surprises ✗ Disclose confidential or commercially sensitive information ✗ Ignore the costs (time, resources, etc) involved in the negotiations ✗ Delay ✗ Send confusing signals

Annex 3

TEMPLATE NON-DISCLOSURE/CONFIDENTIALITY AGREEMENT²⁴

**NON-DISCLOSURE/CONFIDENTIALITY
AGREEMENT**

BETWEEN: [*Name and address of Data Owner*], represented by [*name and position of person signing the agreement*], hereinafter referred to as the “**data owner**”;

AND: [*Name and address of prospective applicant*], represented by [*name and position of person signing the agreement*], hereinafter referred to as the “**prospective applicant**”;

Together the “**Parties**”

WHEREAS THE PARTIES CONFIRM THAT:

The prospective applicant is seeking to refer to data that the data owner owns;

The prospective applicant is seeking to do so for a purpose under the Biocidal Products Regulation 528/2012 (the “**BPR**”);

The data owner and prospective applicant are under an obligation to enter into every effort negotiations to share data;

The Parties are entering into data sharing negotiations; and

A non-disclosure agreement is necessary to reassure the Parties that the use to which any information exchanged or otherwise disclosed during the negotiations will be limited to the legitimate purpose as established in the BPR.

²⁴ This is a general template with typical clauses. 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).

THE PARTIES HAVE THEREFORE AGREED AS FOLLOWS:

1. Disclosure of Information

- a. A Party may disclose to the other Party information with a view to negotiating the sharing of data for a purpose under the BPR (the “**Purpose**”). The Parties agree that the terms and conditions set forth in this Agreement shall govern any such disclosure of information. Without prejudice to Article 63 of the BPR, all information disclosed by a Party or by Affiliates of a Party to the other Party or its respective Affiliates orally, electronically, writing or by any other means during the data sharing negotiations shall be considered as confidential unless expressly stated otherwise by the disclosing Party. All such confidential information shall be referred to hereinafter as “**Information**”. Information shall also include the identity of the Parties, the contents of this agreement and the fact that they have entered into this Agreement.
- b. The Information, including any material support containing Information, will remain the exclusive property of the disclosing Party and the receiving Party will not acquire any right, title, license or interest on or to the Information.
- c. For any disputes arising from the supply, receipt or use of Information by an Affiliate of a Party, this Party shall bear sole responsibility for the purposes of this Agreement. “**Affiliate**” shall mean any company controlling, controlled by, or under common control with a Party to this Agreement, control meaning in this context the direct or indirect ownership of more than fifty percent (50%) of the voting stock/shares of a company, or the power to nominate more than half of the directors, or the power otherwise to determine the policy of a company or organisation.

2. Use of Information

- a. The receiving Party undertakes not to use the Information disclosed to it for any

purpose except the Purpose. Without prejudice to Article 63 of the BPR, this Agreement does not constitute a license by implication or otherwise to use the Information commercially or otherwise.

- b. The Parties shall disclose the Information to their employees, Affiliates, external experts and/or consultants only on a need to know basis and only to the extent absolutely necessary for the Purpose. Each Party shall require that its Affiliates, external experts and/or consultants also have such policies and procedures in place to ensure their compliance with these confidentiality obligations.
- c. Nothing in this Agreement shall prevent Parties from disclosing to the European Chemicals Agency or any other relevant regulatory authority any Information demonstrating that every effort in terms of the BPR has been used in the negotiations for the Purpose.
- d. The obligations specified in this Article shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information:
 - i. was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this Agreement; or
 - ii. is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this Agreement on the part of the receiving Party; or
 - iii. becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information; or
 - iv. was independently developed by the receiving Party without access to the disclosing Party's Information.

3. Applicable law and dispute resolution

- a. 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*].

- b. This Agreement shall be governed by the laws of [], without regard to any principle of conflict or choice of laws that would cause the application of the laws of any other jurisdiction.
- c. If at any time any provision of this Agreement is or becomes invalid or illegal in any respect, this shall have no effect on the validity of the remaining contractual provisions. The invalid provisions are to be replaced, backdated to the time of their becoming ineffective, by provisions which come closest to achieving their objective as agreed by the Parties.

4. Assignment

This Agreement may not be assigned by a Party hereto without the express written consent to such assignment by the other Parties.

5. Other

- a. No amendment or modification of this Agreement shall be valid or binding on the Parties unless made in writing and signed on behalf of each of the Parties by their respective duly authorised officers or representatives.
- b. This Agreement shall be valid when signed by duly authorised representatives of the Parties and shall be binding on each Party for 10 (ten) years as from the date of signature of the last signatory, even if at the end of the negotiations a data sharing agreement is not signed between the Parties, or until such time as the Information enters into the public domain.

This Agreement shall be executed in multiple counterparts which together shall constitute but one original.

Signed

Dated

Annex 4

DATA SHARING CASE SCENARIO

Company A is a large multi-national chemicals company with offices in various Member States of the EU. It manufactures and has developed a dossier for active substance “Sandsoap” which is a biocide used in PT 1, human hygiene. This dossier is part of the review programme and **Company A** is a participant in the review programme. Biocidal products containing Sandsoap can be placed on the market under the transitional rules of Article 89 of the BPR and in accordance with the systems or practices currently in place in the Member States, this until a decision on the approval (or not) of Sandsoap will be taken and enter into force. Further, **Company A** is automatically included on the Article 95 List for Sandsoap in PT 1.

Company B is a manufacturer of biocidal products using Sandsoap which it has been placing on the market in several Member States. However, Company B is not a participant in the review programme for Sandsoap for PT 1. Therefore, from 1 September 2015, Company B needs to ensure that its substance supplier or Company B itself is included on the Art 95 list. **Company B** will need to assess whether (1) it will buy Sandsoap from **Company A** (an authorised "substance supplier" on the Article 95 List), or (2) it will itself make an application, as a "product supplier", with the Agency to become included on that list by 1 September 2015. This decision may be driven by a further need for data support when Sandsoap is approved and access to the data used to secure this approval becomes mandatory for authorising **Company B's** products. Irrespective of the above consideration, Company B will need to explore buying access to data in **Company A's** dossier (or build their own dossier subject to the limits with regard to repeating vertebrate animal tests).

1st Interaction

Company B looks up the Article 95 List and identifies **Company A** as a supplier of Sandsoap, PT 1. It contacts the Agency via R4BP and requests the contact details of the data submitter for studies on Sandsoap to confirm that **Company A** is the right company to be negotiating with. The Agency responds after having established that **Company A** is the data submitter.

2nd Interaction

Company B contacts the data submitter and begins negotiations. Here the data submitter is an EU affiliate of **Company A** (which owns the data) designated by it to conduct the data sharing negotiations on its behalf (below, they will be referred to both as “**Company A**”).

As with all negotiations under the BPR, both **Company A** and **Company B** have to make every effort to negotiate a data sharing agreement. **Company B** sends a letter using the template in the Practical Guide on Data Sharing informing **Company A** that it needs access to data in **Company A's** complete dossier. It asks, amongst other things, what the cost for that access would be. Because the exact data has not been specifically identified in that letter, **Company A** asks **Company B** to clarify its request and also the type of access it wants, e.g. Article 95 LoA, LoA for product authorisation, or hard copies of the data including the right to use the data.

3rd Interaction

Company B is unsure of its legal rights and obligations under the BPR and related legislation. It asks **Company A** to explain these rights and obligations. **Company A**, while not obliged to provide free legal advice, is under an obligation to make every effort, which could include directing **Company B** to the Commission’s Guides as well as to ensure its communication is clear and understandable.

4th Interaction

Company B reviews the European Commission's Guides but still has questions; it therefore receives advice from its consultants, from an MSCA helpdesk, from the Agency, etc. It specifies to **Company A** that it would like an LoA for specific studies related to Sandsoap so that it can be included on the Article 95 List.

5th Interaction

Company A responds with its offer for an Article 95 LoA, and also asks **Company B** to sign a non-disclosure agreement because the discussions are going to be potentially complex and also to lodge a deposit. **Company A** explains that the non-disclosure agreement can be used to protect confidential information of **Company A and B** disclosed during negotiations, while the deposit can be used as an advance of the Article 95 LoA cost.

Company B is happy to sign the non-disclosure agreement (the template for which is found in the Practical Guide on Data Sharing) as it is a two-way document with reciprocal obligations. Both parties are therefore protected, both in terms of the confidentiality of information disclosed during the negotiations and because contractually both parties have agreed not to use the information for any other non-BPR purpose.

Company B, however, refuses to lodge a deposit. It is technically an SME and its current cash flow situation is delicate. It also notes that the Practical Guide on Data Sharing specifically says that a deposit is not a prerequisite for data sharing and refusal to lodge a deposit will not mean that it has not used every effort.

6th Interaction

Company A sets up an online secure data room in order that **Company B** can review the studies on Sandsoap. Thereafter negotiations follow on the data compensation price. These are conducted by email, teleconference and, on occasion, in a face-to-face meeting. As agreed,

whenever a meeting is held, a note is taken alternately by the companies and circulated as soon as possible afterwards for comment/approval.

Company A explains in detail how it has calculated its costs and discusses these further with **Company B**.

Further, as **Company B** has a right under the BPR to “cherry-pick” which studies it wants access to, it reduces the number of studies to be included in the proposed LoA; this obviously reduces the data compensation cost.

At the same time as negotiations take place on the data compensation price, **Company A and B** also negotiate on the text of the data sharing agreement which is intended to contain the parties' agreement of the conditions under which the intended LoA would be granted. Both parties know that technical equivalence is not a prerequisite for data sharing; therefore in order to protect itself, **Company A** insists on the inclusion of a warranty in the draft data sharing agreement such that **Company A** does not warrant that the data access granted to **Company B** will be acceptable to any regulatory authority to which the LoA is submitted or that any application based on the LoA will be successful.

Possible Outcomes

- Successful negotiations: both parties agree a data sharing agreement and the LoA is issued accordingly.
- Referral of case to data sharing complaint procedure of the Agency – access granted. **Company B** notifies **Company A** of its intention to refer the case to the Agency; lodges a share of the costs for the data concerned in **Company A's** bank account; and then initiates the data sharing complaint procedure with the Agency by filling out the web form and providing their documentary evidence of their efforts made in the negotiations. Then the Agency also contacts **Company A**, and requests them to send in their proof of every effort within ten working days and advises both parties to continue to negotiate pending any decision from the Agency. Once all the files are received, the Agency issues a decision within 60 days. **Company B** has made every effort to come to a

data sharing agreement. However, the Agency believes that [Company A](#) has for some time sought to delay and frustrate the negotiations; has given unreasonable deadlines such as five working days within which to clarify the data access request; and has not substantiated its data compensation cost despite repeated requests to do so from [Company B](#). Further, [Company B](#) has not received a response to its latest offer; negotiations have effectively broken down. The decision is positive and the Agency allows [Company B](#) to refer to the requested vertebrate data relating to the Sandsoap dossier as well as the requested toxicological, ecotoxicological and environmental fate and behaviour studies after the receipt of the proof of payment. The data compensation price can still be agreed between [Company A and B](#), but no agreement is forthcoming and [Company A](#) brings a case before a national court in order to determine the cost compensation amount.

- Same as above, but companies come to a voluntary agreement during/after the Agency's assessment of the case.
- Referral of case to data sharing complaint procedure of the Agency – access not granted. [Company B](#) follows the procedure outlined in the above paragraph. The Agency then deliberates on the every effort of both parties. [Company A](#) has made every effort whereas [Company B](#) has not. [Company B](#) has, among other things, not challenged alleged delays in [Company A's](#) correspondence; not been consistent in the data it requires and has kept changing its request; and has commenced the dispute procedure while negotiations with [Company A](#) are clearly ongoing and at a relatively premature stage. The Agency issues a decision not granting the prospective applicant permission to refer and requests both parties to continue to make every effort as the data sharing obligation still applies to them both. The parties therefore continue negotiations and the share of the costs lodged by [Company B](#) in [Company A's](#) bank account, remains lodged with [Company A](#).

[Note: in any of the above described scenarios where the Agency issues a decision, the parties can refer the case to the Agency's Board of Appeal].

Annex 5

COMPENSATION CALCULATION FACTORS

Compensation Costs Claim include...		Possible Increments/Decrements include...
<p>Laboratory Costs</p> <p>The basis of any costs calculation should be a choice between (i) the costs actually borne by the participant/data owner at the time they were incurred or (ii) replacement costs established objectively</p>		<p>Example Decrement:</p> <ul style="list-style-type: none"> ➤ The prospective applicant will wish to contribute less to the costs if its request is for limited access. The reduction should be calculated by reference to an objective criterion such as Eurostat data. <p>Example Increment:</p> <ul style="list-style-type: none"> ➤ Inflation and interest may be sought to be added to the actual costs but will need to be fully justified
<p>Fees paid during review programme</p> <p>Fees and related costs incurred by the data submitter in the BPD/BPR review programme of an existing or new active substance, may form part of the compensation calculation</p>		<p>Example Decrement:</p> <ul style="list-style-type: none"> ➤ Limited access only sought: as above at (1) ➤ If the prospective applicant is seeking access to only one test/study, it can argue that it should not pay for a relative portion of the overall administrative fees paid by the data owner in defence of its

Compensation Costs Claim include...		Possible Increments/Decrements include...
		<p>dossier</p> <ul style="list-style-type: none"> ➤ In so far as this is part of the data submitter’s own application, the prospective applicant should not participate in these costs if it will have to pay similar costs itself during its subsequent application <p>Example Increment:</p> <ul style="list-style-type: none"> ➤ As above, inflation/interest may be sought but will need to be fully justified
<p>Third Party Fees</p> <ul style="list-style-type: none"> ➤ Legal fees (e.g. in hosting the group, drafting the agreement between them) ➤ Technical consultancy fees ➤ General administrative fees associated with running a group of companies (e.g. a consortium) ➤ An overall handling fee 		<p>Example Decrement:</p> <p>Limited access only sought: as at (1) above</p> <p>Example Increment:</p> <p>As above at (1), inflation and interest may be sought but will need to be fully justified</p>

Compensation Costs Claim include...		Possible Increments/Decrements include...
covering administrative and legal formalities		
<p>Internal work costs</p> <p>Fees and costs incurred internally by the data owner including:</p> <ul style="list-style-type: none"> ➤ “Sweat equity” costs meaning the effort put into the generation of the test/study by the data owner and/or his staff ➤ Travel expenses ➤ Man-day calculations based on hierarchical staff values 		<p>Possible Decrement:</p> <p>Limited access only sought: as at (1) above</p>
<p>Risk factor costs</p> <p>A risk factor may be sought to be applied to the overall cost calculation, when the participant in the review programme is an SME</p>		<p>Example Decrement:</p> <p>Limited access only sought: as at (1) above</p>