

Practical Guide on Biocidal Products Regulation

Special Series on Data Sharing - Consortia

ABC

LEGAL NOTICE

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Practical Guide on Biocidal Products Regulation: Special Series on Data Sharing - Consortia

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European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

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PREFACE

This Practical Guide on Consortia explains the role of consortia in the context of the Biocidal Products Regulation (EU) No 528/2012 (the BPR). It is part of a special series of practical guides on data sharing for the BPR, including also an Introduction to the BPR and SME considerations and Practical Guides on Data Sharing and Letters of Access.

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

The Special Series of Practical Guides has been developed by the European Commission in consultation with the European Chemicals Agency (the "Agency") and the Member State Competent Authorities (the "MSCAs"), a sample of SMEs, representative associations, law firms and technical consultancies.

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List Of Abbreviations

The following text conventions are used throughout the Practical Guide.

Standard term / Abbreviation	Explanation
AH	Authorisation holder
AS	Active substance
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)
BPF	Biocidal product family
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)
EU	European Union
LoA	Letter of access
MSCAs	Member State Competent Authorities responsible for the application of the BPR, designated under Article 81 of the BPR
PT	Product Type
R4BP	Register for Biocidal Products
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)
SBP	Same biocidal product
SMEs	Small and Medium Sized Enterprises

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 / Abbreviation	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 active substance	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 "over-the-counter" 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 active substance	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)

Standard term / Abbreviation	Explanation
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 product	In the context of an SBP authorisation, this is the biocidal product or product family which has already been authorised, or for which the application has been made, which the SBP is identical to
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 a consortium in the context of the BPR and why are they set up?

1.1. What?

The word "consortium" is not found anywhere in the BPR but the forming of consortia could constitute a useful tool which could offer possible benefits in the context of product authorisation applications under the BPR. Under the review programme for existing active substances initiated under the Biocidal Products Directive 98/8/EC (the "**BPD**") the predecessor to the BPR several consortia were formed between manufacturers of active substances or biocidal product formulators.

As a preliminary remark, it should be noted that the rules provided under the BPR are different from the ones provided by Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the "**REACH Regulation**"¹). For example, the REACH Regulation includes requirements for pre-registration, participation in a substance information exchange forum (a "**SIEF**") or joint submission of registrations which are not provided under the BPR. This means that principles applicable to consortia under REACH might not apply to consortia under the BPR, especially if established for purposes of product authorisation.

A consortium is a group:

- consisting of more than 2 companies/persons;
- that agrees to work together and to cooperate in order to achieve a common purpose; and
- that agrees to work towards a purpose that is one recognised by the BPR: e.g. seeking the approval of an active substance at European Union (hereafter referred to as "**EU**") level or the preparation of a dossier for product authorisation at EU-wide or EU Member State level.

It is not obligatory, however, to call the group of companies/persons a consortium. Different names can perfectly well be used to refer to the working together of two or more companies/persons including "cooperation agreement", "task force" or "registration group". They all mean the same thing: a group of companies/persons that has decided to work together in order to achieve a common goal under the BPR. For the sake of simplicity, this Practical Guide uses the word consortium.

1.2. The different processes in the BPR for which a consortium could be useful

While the BPR does not include any provisions on consortia, it does provide for concepts such as the biocidal product family (the "**BPF**") or the same biocidal product (the "**SBP**") and indeed, the simplified biocidal product authorisation procedure, which have been developed in order to facilitate the process of applying for product authorisations for companies such as SMEs and to reduce cost and administration issues for both applicants and regulators.

The very nature of the first two concepts at least (BPF and SBP) allows the coming together of like-minded companies/persons. Accordingly, companies/persons seeking a BPF and/or an SBP authorisation may want to consider forming a consortium to get the full benefits from these concepts.

¹ Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396 30.12.2006, p. 1.

In principle, a consortium is not a legal entity. It is simply a grouping of companies/persons connected to each other by the common purpose as established in general by a written agreement or contract between them. A template for such an agreement is given in [Appendix 1](#).

1.3. Legal Structure

Certain consortia may, however, choose to establish themselves as a separate legal entity. Such an entity:

- would have its own legal personality;
- amongst other things, it could be the body to submit the application for product authorisation on behalf of the members or be the authorisation holder (the "AH"); and
- it may have to consider tax implications depending on the legal vehicle it chooses to be set up in; it will have to consider how funds are transferred between members and the consortium vehicle, how invoices are paid, and how third party companies seeking access compensate the consortium, etc.

The choice of legal vehicle could include, e.g. a European Economic Interest Grouping under Council Regulation (EEC) No 2137/85² or a limited liability company. Whatever choice is made, the rules for setting up and drafting the statutes of such a legal entity will usually be provided under national legislation. National legislation will probably also cover the provisions to be included in the legal statutes as well as the procedure for modification or publication. This means that the template consortium agreement should in principle not be used as a basis, but rather as a complement to the required legal statutes. Such matters are beyond the scope of this Practical Guide.

In principle, the choice of establishing a consortium as a legal entity would most often depend on the need to use the consortium as AH or to cater for liability issues involving the members. However, it should also take into consideration the flexibility provided by the national legislation (e.g. in terms of provisions to be included in the legal statutes, procedure for decision-making or acts to be published) and the consequences that the possible dissolution of the consortium could have on the product authorisations.

1.4. Why set up a consortium?

There are two principal reasons why the use of consortia could have possible benefits for product authorisation under the BPR.

Firstly, from the point of view of the company/person affected by the BPR, setting up a consortium allows companies to share costs. Those costs could include:

- The contracting of outside laboratories to conduct new studies;
- The hiring of external technical or legal consultants;
- The day-to-day costs of monitoring and steering the evaluation/authorisation process; and
- Eventually, the payment of authorisation fees to MSCAs or to the Agency.

In effect, the principal attraction of a consortium is that it offers economies-of-scale benefits for its members. This may in particular be important for companies/persons with fewer resources, such as SMEs.

² Council Regulation (EEC) No 2137/85 of 25 July 1985 on the European Economic Interest Grouping (EEIG), OJ L 199 31.7.1985, p.9

Secondly, from the point of view of the regulator, the formation of consortia reduces the risk of (inadvertent) duplicative testing, as well as submission of different dossiers, requiring multiple assessments.

It should be noted that consortia might also have disadvantages, notably in terms of time and costs necessary for setting up and running the consortium, the need to keep some information confidential or possible conflicts between members which should be balanced with the benefits before deciding to set up a consortium (see [section 3](#) below on advantages and disadvantages of establishing or joining a consortium).

2. What are the rules for establishing and running a consortium?

In short, there is no strict set of rules that have to be followed by each and every consortium or consortium member (unless the consortium is a legal entity, in which case the national legislation must be complied with).

In principle, the members of a consortium can include any rule they wish in their consortium agreement, subject to the law³ and, in particular, as long as the rule is in line with, among others, the BPR (e.g. data sharing) and competition law (e.g. non-disclosure of commercially sensitive information, the avoidance of dividing up the market, etc).

If there is one thing that each consortium would benefit from, however, it is that there should be clear rules on how the consortium is to be run and for those rules to be contained in a written document. In order to ensure its smooth running and transparency, therefore, it is recommended that specific provisions in the consortium agreement be included on the following key points. This will also assist in avoiding disputes arising both during the term and operation of the consortium and once the purpose of the consortium has come to an end.

Organisation of the consortium

The greater the number of members, the more practical it will be to establish a decision-making structure, usually involving steering (or executive) and technical committees in order to take decisions. Such committees are not always required, of course, but with different interests being inevitable, it may be that such are necessary. Since the number of members could increase the longer the consortium exists, it is recommended to establish a structure and a decision-making process right from the start. It is, in any event, advisable to have some sort of structure, which could involve a steering committee, technical committee and a consortium manager (internal or external). By having that, the consortium runs less of a risk of losing its direction and it is more likely to achieve the purpose for which it was set up.

The role of the consortium manager can be important notably in the reporting of the costs, the handling of the budget, the organisation of meetings and dealings with third parties. An external consortium manager can be useful to avoid a possible conflict of interest for a member acting as consortium manager. For purposes of data sharing under the BPR, if the consortium manager acts as the "case owner" in R4BP3 it will be the "data submitter", and accordingly responsible for facilitating contacts between a company/person seeking data access (a "**prospective applicant**") and the data-owning members of the consortium. If the consortium manager is an independent (external) person, he/she can also handle commercially sensitive information which may be needed from the members and ensure compliance with competition law.

³ The national law governing the consortium agreement will be normally stated in the agreement; also the private international law rules may apply. It is beyond the scope of this Practical Guide to explain it in any detail.

Voting rights

Unanimous voting is, in general, the best procedure to take into account the interests of all parties. However, in the case of a consortium, it should be avoided in order to prevent blocking situations caused by a single member.

The risk is clear: one member, whatever its importance, could prove to be an obstacle to the achievement of the purpose for which the consortium has been established. It should be assumed as a matter of principle that a form of majority vote is accepted as representing a reasonable decision which will avoid the situation of one company effectively having a right of veto.

On the flipside of majority voting rules, one must guard against rules which work in favour of certain categories/types of member within the consortium. An alternative could be to apply simple majority voting for most decisions and unanimity voting for important decisions such as decisions on costs above a certain financial value. Other options could also be explored such as a weighted voting system.

Membership

Clear and objective conditions for membership should be provided for, as well as the procedure and the voting rules (e.g. majority voting) to accept new members. A transparent appeal mechanism should also be established where a prospective member is refused membership.

While the BPR provides obligations regarding data sharing and data access, it does not cover what could constitute the membership of a consortium. What this means is that:

- members can decide to open up membership, or restrict it, to certain types and classes of company/person, provided that they comply with applicable competition law rules; and
- they can do so as long as there are rules in place allowing the consortium to provide access to the data it owns under fair, transparent and non-discriminatory conditions and that they make every effort to share the data with third parties which request it for BPR purposes.⁴

Clear, objective provisions on the withdrawal or exclusion of a member should also be included, as well as the consequences, notably on possible reimbursement of membership dues that have already been paid, the rights to use the data and the share of future compensation.

The members should also provide rules in case of legal entity changes, notably due to a merger or acquisition of a member, as well as a transfer of membership rights to another member or to a third party.

All these are conditions that should be unambiguously detailed in an agreement in order to avoid disagreements as far as possible (on which, see [Appendix 1](#)).

Definition of membership costs and cost allocation

Rules should be included on likely future costs, how they will be reported and how the costs will be shared. In principle, the costs should be shared fairly, transparently and non-discriminatorily. It could therefore be decided to share equally the costs between all members (each member paying the same amount). However, other mechanisms of calculating the contributions to be made by each company/person could be considered to reflect the different nature of the member company/person.

For example, sharing costs between an SME and a large/multi-national company could be made by reference to other mechanisms and factors such as the total tonnage of the

⁴ See the Practical Guide on Data Sharing for details on those conditions.

substance/product produced or placed/made available on the EU market by each member company (the confidentiality of such information may need to be ensured by the consortium manager). Whatever the mechanism chosen, the key is to find the one that fairly reflects the different characteristics and capabilities of the different constituents of the membership.

Access to data for third parties

According to Article 63 of the BPR, if a prospective applicant seeks access to data owned by another company/person (a **"data owner"**), both parties must make "every effort" to reach an agreement on the sharing of the data (see section 3.2 of the Practical Guide on Data Sharing). Against that regulatory requirement, the members of a consortium will therefore have to decide how they will ensure, as a consortium, compliance with the every effort obligation.

Calculation of compensation costs

The consortium agreement should include provisions on the establishment of the cost calculation for a letter of access (an **"LoA"**), the procedure for granting an LoA to third parties (i.e. who can issue the LoA, under which conditions, following which procedure and which type of majority voting) and the rule for the sharing of the compensation. If possible, the agreement should also include a template for the LoA and for the data sharing agreement. However, it is important to underline that agreement on data sharing is reached by negotiation. Any prospective applicant seeking access to data owned by the consortium/individual consortium members has the right to challenge any calculation made by the consortium.

Ownership and use of the data

Provisions in the consortium agreement should clearly stipulate who the owner of the dossier and the data in the dossier is, a description of the studies that are owned, and the specific use to which they can be put by the members (e.g. only product authorisation under the BPR, other uses, uses outside the EU, etc). There should also be provisions on whether the rights to use the data are extended to affiliates and customers of the members.

Where existing data owned by one of the consortium's members are included in the dossier, and where these are shared with the other members of the consortium, the rights granted to the other members should be specifically detailed (e.g. is there a right to an LoA or will full-blown ownership be conferred on each member, and, in both cases, for which use?).

Competition law compliance

The members must comply with competition law, which means (amongst other things) that they should not exchange any commercially sensitive information (e.g. information on products, customers, prices, market share, etc), which could have a potentially restrictive effect on open and fair competition.

This obligation is particularly important in case of consortia related to product authorisation because information on products could easily be considered as confidential. In this regard, it should be noted that information which may need to be shared under the BPR, related to uses (or product types), markets (Member States where authorisation is sought) and costs (as part of data sharing compensation) is generally seen as commercially sensitive and will need to be handled with care, possibly through an independent third party. See below at [section 7](#) for more information.

Standard clauses

The agreement should include provisions on budget, books of account, consequences in case of breach or default, assignment, amendment, applicable law and arbitration or jurisdiction.

3. What are the advantages and disadvantages of establishing or joining a consortium?

The advantages of establishing or joining a consortium may include	The disadvantages ⁵ may include:
<p>✓ Pooling resources: clearly this is of most interest to those companies/persons with limited human (expert) resources and therefore time to dedicate to the sometimes onerous tasks that the BPR imposes on companies/persons. Being able to rely on others with that expertise should greatly assist in allowing the company/person to fulfil its BPR obligations.</p>	<p>✗ Potential conflict of members' interests: e.g. issues over ownership and access to existing data, member companies undergoing restructuring or being acquired by third parties, and disagreements on the development of the dossier or the need to conduct new studies.</p>
<p>✓ Avoiding inadvertent duplicative testing as well as submission of different dossiers; there is a reduced risk of making mistakes where, in effect, a second opinion can be obtained from companies/persons which understand the BPR and its legal requirements.</p>	<p>✗ Potential tension between members who are actual or potential competitors, and who are possibly of different sizes.</p>
<p>✓ Cost savings: it stands to reason that costs incurred in generating studies or obtaining legal/technical advice will be greatly reduced if they are shared out over a greater number of companies/persons. This is therefore particularly attractive to those companies (whether SMEs or part of a wider group of companies) with limited financial budgets.</p>	<p>✗ Possible disagreement on the consortium agreement, such as the decision-making structure, the budgeting, the role of the consortium manager, accounting, etc.</p>
<p>✓ Time savings: as above, human resources may be limited for a given company/person and a consortium can assist in shouldering some of the regulatory obligations.</p>	<p>✗ Possible management/administration issues.</p>
<p>✓ Use of knowledge and experience from other companies: as above.</p>	<p>✗ Possible expenses for legal or scientific consultants, or for external secretary or consortium manager, the need for which you may not agree with.</p>

⁵ Note that the application for a single product authorisation in one EU Member State may be more easily undertaken by a company/person acting on its own rather than within a consortium.

<p>✓ Possibility to negotiate lower costs where an LoA is needed for data on an active substance, notably regarding the refund mechanism (which could be applied up-front, since the number of applicants is already known, instead of having to wait for reimbursement at a later stage).</p>	<p>✗ Possible additional expenses and time needed for meetings, calls, etc.</p>
	<p>✗ Possible delays due to the time necessary to set up the consortium, agreeing on the rules, etc.</p>
	<p>✗ Increased need for compliance with competition rules given that competitors (whether actual or potential) will have to meet and discuss issues arising from the consortium's activities.</p>
	<p>✗ Possible increased complexity for data sharing negotiations with third parties</p>

4. What should companies do if they are thinking of setting up/joining a consortium?

4.1. Setting up a consortium

Contact other companies that you know, as a result of publicly available information, have a similar interest in setting up a consortium. Ways of finding out include:

- Reviewing the companies/persons (substance or product suppliers) that are supporting the same active substance/product type combinations in the review programme.
- Reviewing the Article 95 of the BPR list for the companies/persons that are included there by the Agency (see <http://echa.europa.eu/information-on-chemicals/active-substance-suppliers>).
- Discussing with technical consultants or industry organisations (e.g. national associations or EU federations) and asking them to coordinate contacts to avoid any concern with regard to competition law (see below at [section 7](#) for more information).

A new consortium could be set up with such interested companies/persons, or a sub-group (e.g. for a specific product type) could be created in an existing consortium.

Use the template agreement in [Appendix 1](#) as a good starting point and:

- Agree on the key points;
- Get legal advice to review the consortium agreement;
- Make sure you comply with competition rules;
- Do not disclose any commercially sensitive information to a competitor;
- Try to keep a manageable number of members in order to be fast and efficient but make sure that membership-joining decisions are taken fairly, and according to objective and non-discriminatory reasoning;

- Consider secrecy or non-disclosure agreements in order to engage in discussions for the setting up of a consortium and ensure competition law compliance (see Appendix 3 of the Practical Guide on Data Sharing for a template of one such agreement);
- Consider signing a pre-consortium agreement, including cost-sharing provisions; and
- Consider using an independent third party in order to coordinate all efforts to set up and run the consortium and handle confidential information.

4.2. Joining a consortium

- Enquire whether a consortium has already been set up and find out if the consortium has a contact person (that should be the case if the consortium has been established with a proper structure). Consider joining a consortium as soon as possible after it is established in order to avoid difficulties with claims that may be made by existing members for late membership fees, sharing of costs, etc.;
- Before joining, ask for details about the consortium and for any supporting documents including a non-confidential version of the agreement setting it up;
- Before joining, check if the scope of the consortium covers your requirements (since such information could be considered as confidential, this will probably have to be done through the technical consultant of the consortium or of the applicant, or another independent third party, which could confirm whether the requirements of the applicant are covered or not); and
- Consider confidentiality or non-disclosure agreements in order to engage in membership negotiations and appropriate competition law compliance guidance (see Appendix 3 of the Practical Guide on Data Sharing for a template of one such agreement).

5. The different legal concepts in the BPR which can be used in connection with the setting up of consortia

Preliminary remark: the concept of AH

Article 3(1)(p) of the BPR defines the AH as the person established within the EU who is responsible for the placing on the market of a biocidal product in a particular Member State or in the EU and specified in the authorisation.

This definition does not prevent an independent third party acting in agreement with consortium members (e.g. a consultant) or a consortium established as a legal entity within the EU from being the AH of a product authorisation. Should it be the case, the consortium as AH will be subject to all the relevant obligations in the BPR.

According to Article 17(1) of the BPR, biocidal products will not be made available on the market or used unless authorised in accordance with the BPR. However, the BPR does not make mandatory the placing on the market of authorised products.

Therefore, if an authorisation is granted to a consortium for a single biocidal product or a BPF (with a view to allow consortium members to submit applications for an SBP) and the product(s) covered by the authorisation is/are not placed on the market, the responsibilities of the consortium as AH would be in practice limited to those linked to the lifecycle management of the authorisation (e.g. changes – if any, renewals, annual fees, etc).

Under some circumstances, depending on the specific consortium agreement, consortium members may decide to appoint one of them as “leading member” in order to act as applicant and/or prospective AH.

It should be noted that under R4BP, the “asset owner” is the legal entity that is the “applicant” under the BPR. It can appoint a “case owner” (e.g. a consultant, the manager of the consortium) in order to submit the application on its behalf. The case owner will be responsible for creating the case and following it through its processing, ensuring that invoices are paid, providing any additional information requested by authorities, commenting on any draft evaluation reports or opinions, etc.

For further details, see the Agency's Biocides Submission Manuals.⁶

Biocidal product family: the concept

Under the BPR, a BPF means a group of biocidal products having:

- similar uses;
- the same active substances;
- similar composition with specified variations; and
- similar levels of risk and efficacy.⁷

The BPR allows applications to be made to an MSCA or to the Agency for the authorisation of a BPF. Such an application must explicitly identify the maximum risks to human health, animal health and the environment and the minimum level of efficacy over the whole potential range of products within the BPF.⁸ All products within a BPF are covered by one authorisation under the BPR (each product included in the BPF will have a suffix added to the authorisation number; once the BPF is authorised, only a notification is needed in order to place on the market a new product belonging to the BPF, and which was not explicitly identified in the original authorisation.⁹)

For further details, see the European Commission note for guidance on “*Implementing the new concept of biocidal product families*”¹⁰ and the Agency's Practical Guides on BPR¹¹.

Biocidal Product Families and Consortia

Companies/persons can decide to cooperate to develop a common dossier for authorisation of a BPF, which will cover the relevant products made available on the market by the members of the consortium. In doing so, the following needs to be considered in the context of setting up the consortium:

- Setting up a consortium offers the possibility of having one complete dossier developed and no additional data would have to be submitted individually by the members of the consortium. An application for a BPF could be submitted at EU level or at Member State level (see below).
- Regarding the actual submission itself, the application could be submitted by an external or in-house technical consultant or the consortium manager on behalf of the consortium members (as case owner acting on behalf of the prospective AH), or by the consortium itself if it has a legal entity. The members could also decide

⁶ <http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals>.

⁷ Article 3(1)(s) of the BPR.

⁸ Article 19(6) of the BPR.

⁹ Article 17(6) of the BPR.

¹⁰ CA-Nov14-Doc.5.8 – Final available at <https://circabc.europa.eu/w/browse/df02104b-d5e3-4b11-b960-13a0f08133af>.

¹¹ <http://echa.europa.eu/practical-guides/bpr-practical-guides>.

to apply through a “leading member” nominated by them, which would act as applicant and/or AH of the BPF authorisation.

- If agreed, all biocidal products included in the BPF would be eligible for marketing by all consortium members in all Member States where the authorisation was granted. Therefore, consortium members would in principle be required to share all biocidal product formulations included in the joint BPF which may not always be straightforward given that the consortium members are often competing companies which are unwilling to engage into such far reaching cooperation or because competition law concerns may arise.
- As an alternative, a joint application could be submitted by the consortium (or by a leading member) for the authorisation of a BPF, in connection with individual applications by each member for the authorisation of an SBP of an individual product of the BPF (see the next section on the SBP application).
- Regarding technical equivalence of the active substance source used in a BPF, consortium members might be using different sources, including the one that was originally assessed for the active substance approval and other source(s). Therefore, the members of the consortium will have to select the source to be included in the dossier (one or multiple) and establish technical equivalence through the Agency where necessary.

“Standard” Biocidal product authorisation: the concept

The “Standard” Biocidal product authorisation refers to the situation where an applicant submits an application for the authorisation of a single biocidal product (or several applications for several products) containing the elements referred to in Article 20 of the BPR.

Standard Biocidal product authorisations and Consortia

Consortium members can also decide to cooperate to develop a common core dossier for a single biocidal product authorisation, in particular if the purpose is to obtain a Union authorisation. In doing so, the following needs to be considered in the context of setting up a consortium:

- The content of the common core dossier developed by the consortium will depend on the products concerned and their uses, and will have to be discussed and established amongst the members, perhaps with the assistance of an external or in-house technical consultant.
- Since the authorisation that is granted is product specific, the application for product authorisation can be submitted separately by each member of the consortium and some additional data on the specific product might still be needed. In other words, while the consortium can pool many activities, each member will still need to undergo the formalities involved in submitting an individual application to the MSCA or to the Agency.
- In case of a joint application, the consortium (or a leading member) could also submit an application for a single biocidal product authorisation and be the AH, while the members of the consortium would each apply individually for an SBP authorisation (see below).

SBP Authorisations: the concept

A specific procedure is provided for under the Commission Implementing Regulation (EU) No 414/2013¹² for the authorisation of an SBP.

¹² 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, OJ L 125, 7.5.2013, p. 4

Applications for such authorisations are submitted to the MSCA in which a national authorisation has already been granted (to the same company or another company), or for which an application has been submitted, in respect of a biocidal product with the same properties, or to the Agency where there is a pre-existing Union authorisation for a biocidal product with the same properties, or for which an application has been submitted. An authorisation will be issued under essentially the same terms and conditions.

This procedure can only be used for a product (the "**same product**") which is identical to another biocidal product or product family (the "**related reference product**") that has been or is in the process of being authorised, aside from differences that amount to administrative changes.¹³ Authorisations of a same product or of a related reference product can be changed or cancelled independently of each other.

For further details, see the Agency's Practical Guides on the BPR.¹⁴

SBP Authorisations and Consortia

As mentioned above, applications for SBP authorisations could be used by the members of a consortium within the context of a joint application submitted by the consortium or a leading member for authorisation of a BPF or a single biocidal product.

Regarding the BPF in particular, the consortium (as a legal entity) could submit an application for a BPF (at national or EU level), through the consultant or consortium manager, and at the same time, each member, individually or through the consultant/consortium manager, would submit an application for an SBP, either for a same BPF or for an SBP of an individual product of a BPF.¹⁵ This alternative would allow each member to obtain an authorisation for its own product(s) and would avoid having to rely on the AH, especially in the event of a possible dissolution of a consortium.

It should be noted that in case of a SBP application, an LoA should be obtained to all the data supporting the authorisation of the related reference product (for an individual product of a BPF, the LoA should cover the data relevant for that individual product only). This means that, if the consortium (as a legal entity) obtained an LoA to the complete active substance dossier from a participant in the review programme or an alternative supplier, it would also need to have obtained the right to sub-license the access to the complete active substance dossier to the consortium members in order to be allowed to give them an LoA for their individual SBP applications.

The procedures for each type of authorisation: BPF, standard and SBP

The application for authorisation of a single biocidal product or a BPF can be submitted according to the procedure for a standard Member State authorisation, mutual recognition in sequence, mutual recognition in parallel, simplified authorisation or Union authorisation.

For further details, see the Agency's Practical Guides on BPR.¹⁶

The choice between applying for authorisation at EU level or at national level will usually depend on the number of Member States of interest where the members of the consortium want to obtain authorisations for their products, the relevant product type(s) concerned, the properties of the active substance(s) (the "**AS**") contained in the products, the

¹³ e.g. an amendment of an existing authorisation of a purely administrative nature involving no change to the properties or efficacy of the biocidal product or BPF, such as the name of the biocidal product, certain changes in the manufacturer's identity or in manufacturing location or process.

¹⁴ <http://echa.europa.eu/practical-guides/bpr-practical-guides>.

¹⁵ For further information see the Commission Note for guidance on "Submission of joint applications for the authorisation of a BPF in connection with individual applications under the SBP Regulation", discussed at the 58th meeting of representatives of the MSCAs the implementation of the BPR, CA-Nov14.Doc.5.9

¹⁶ <http://echa.europa.eu/practical-guides/bpr-practical-guides>.

conditions of use of the products across the EU and the costs linked to the regulatory lifecycle management of the authorisations (e.g. authorisation fees, annual fees, etc.).

However, it should be noted that an application for an SBP should follow the same procedure as the related reference product. This means that if a BPF has been authorised at EU level, through a Union authorisation, an application for an SBP of an individual product of a BPF cannot be submitted to a Member State with a view to obtaining a national authorisation (and vice versa).¹⁷

6. Practical issues

The following are possible practical issues that could arise and that will need to be dealt with by the members of the consortium:

- Scope and duration of the consortium should be clearly established;
- Different membership categories (e.g. full member, associate member, or category 1 and category 2 members) representing different voting rights and/or costs contribution levels are possible but should be carefully worked out further to clear and objective criteria;
- All decision-making processes and voting mechanisms should be clear and transparent;
- Conditions for membership and conditions for granting access to data have to be fair and transparent and based on objective criteria, applied in a non-discriminatory way;
- A venue for meetings should be established; agendas should be set and circulated in advance of all meetings (by the Manager or other person appointed to undertake such administrative tasks) with minutes taken by an appointed person, again for subsequent circulation and approval;
- Clear rules should be established up-front on how to deal with applications for data sharing and membership;
- Clear rules should be established up-front on how to deal with contacts and discussions with regulatory authorities;
- Members should decide how the application should be submitted, by whom, and who should be the AH. In principle, an application could be submitted by the consortium as a legal entity, the technical consultant or consortium manager (on behalf of the members), the lead member (on behalf of the members) or each member individually;
- Rules should ensure flexibility to allow for quick input and reaction from members in order to meet deadlines (e.g. information exchange with the technical consultant);
- Unanimous voting should be avoided;
- Lengthy procedures should be avoided;
- Members should consider appointing a lead company and in this case provide clear rules on its tasks, responsibility and liability;
- Members should consider appointing a knowledgeable representative within their company, possibly having the power of decision, as well as an alternative representative;

¹⁷ At the time of writing this guide, discussions were initiated to make it also possible to apply for a SBP authorisation at Member State level, from a biocidal product or biocidal product family authorised at EU level.

- Members should decide how payments will be made (e.g. by the consortium as a legal entity, by the consortium manager/secretary/treasurer from the consortium account, by each member (split invoices), or by one member on behalf of the others);
- Rules should be established for the handling and re-distribution of funds which the consortium will receive either from membership fees or through the sale of LoAs. Taking into account that these funds may need to be deposited in escrow accounts, VAT rules may be applicable. Bear in mind that a consortium cannot be a profit-making exercise for the members;
- In case studies must be conducted by the consortium, the owner of the data should be clearly identified (e.g. whether it is the consortium itself or the consortium members);
- In case the consortium members need to obtain an LoA to the AS data, and the LoA is granted to the consortium itself, they should make sure that the consortium is allowed to give access to the AS data to the consortium members for their own individual applications or, where relevant, to third parties (e.g. an SME not being a consortium member); and
- In case the consortium members need to be included in the list of suppliers published by ECHA in accordance with Article 95 of the BPR, it should be noted that the submissions should be made individually by each member of the Consortium and that a fee will be charged per submission.¹⁸

7. Competition law issues

Compliance with competition law is a requirement regardless of the nature of your business. The aim of competition law is essentially to ensure that there is sufficient competition in terms of pricing, quality, quantity, etc, of services and products on the marketplace, all of which are considered ultimately to be of benefit to the customer/consumer.

It is not the place for this Practical Guide to explain the ins and outs of competition law as it is applied under Articles 101 and 102 of the Treaty on the Functioning of the European Union. Suffice it to say that competition law fully applies to all activities undertaken by companies/persons or associations of companies/persons under the BPR and, therefore, also to the formation and operation of consortia.

The fact of forming a consortium is a legitimate exercise under the BPR. It is, however, the way that the coming together of the relevant companies/persons takes place, and the subsequent operations of the consortia, that could raise concerns.

So what are those concerns?¹⁹ There are two principal ones, and they are addressed in turn.

First: Sharing of Information

Potential or actual competitors cannot in the main – share information that is confidential to them where that information is commercially sensitive. Put differently, such

¹⁸ See the Agency's *"Guidance on active substances and suppliers (Article 95 list)"*, Version 2.0, December 2014, Section 3.1.7:

<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation?panel=vol5partB#vol5partB>.

¹⁹ The European Commission has adopted detailed *"Guidelines on the Applicability of Article 101 TFEU to horizontal co-operation agreements"*, OJ C 11, 14.1.2011, p. 1, which readers should refer to.

companies/persons cannot give any information of whatever quality or size about their recent, current and future commercial strategy to a competitor without running the risk of infringing competition law.

The situations in which companies/persons may have to share information if they are to set up or join consortia under the BPR are as follows:

Establishing which companies/persons wish to set up a consortium for a BPR purpose

Clearly, companies/persons looking to set up a consortium need to approach other like-minded companies/persons. The process of doing that means potentially discovering the commercial intentions of a competitor, and that could raise concerns under competition law. Accordingly, below are some "dos and don'ts" guidance which may be of assistance.

DO	DO NOT
✓ Review the companies/persons (substance or product suppliers) that are supporting the same active substance/product type combinations in the review programme	✗ Cold-call a company/person or contact a company/person you know well and ask what their intentions are
✓ Review the Article 95 BPR List for the companies/persons that are included there by the Agency	✗ Ask for, or offer, any information about your intentions beyond what is necessary to establish whether they wish to set up a consortium for a BPR purpose
✓ Discuss with technical consultants or industry organisations and ask them to coordinate contacts without revealing the identities of interested companies/persons until such time as a non-disclosure agreement is signed by each party (see Appendix 3 of the Practical Guide on Data Sharing for a template of one such agreement)	
✓ Approach those companies/persons identified with a request limited to asking about their intentions under the BPR	
✓ Ensure that all approaches are documented, even where done by telephone or in a conversation	
✓ Reject – and be seen to reject – any information that is given to you by the other company/person which you believe could be confidential and commercially sensitive	

Information discussed at consortium meetings/during consortium activities

Once the consortium is set up, all discussions/conversations/meetings/decisions, etc, that take place must be limited to the legitimate purpose for which the consortium exists. It is inappropriate to discuss prices or customer terms and conditions or costs or investment plans or other commercial intentions regarding how or where you are selling or going to sell your product. The discussions, etc, must be tightly aligned with the BPR purpose.

That said, it is clear that once the consortium is established, certain information that competitors would otherwise not have revealed to one another may need to be revealed in

order for the consortium to be able to function. For example, where the mechanism used to calculate each member’s cost contribution is based on the volume of the product placed on the EU market by each member, it is inevitable that – regardless of the precautions that are taken – a greater degree of transparency than that which existed beforehand will result. While that may be inevitable, the members will have to take all necessary precautions to ensure that the risk of transparency is reduced to the minimum. So, for example, any volume data should be aggregated; they should relate to old data (more than two years’ old) and, if presented to the wider group, the figures should not be attributable to any member. The information provided by the members could also be handled by an independent third party such as a trustee.

Below are dos and don’ts guidance which may be of some assistance.

DO	DO NOT
✓ Draft agendas for all meetings and stick to them; and draft and circulate the minutes to all members	✗ Attend any meetings without an agenda
✓ Accurately document all meetings, conversations, decisions, etc	✗ Allow members to speak off agenda
✓ Consider using an independent third party to collect commercially sensitive information (such as volume sales) where that is objectively required for the consortium to operate; have the data aggregated; and try to make sure that they are “old”, not current and certainly never future predictions	✗ Discuss any information other than information which is necessary for the purpose for which the consortium has been established
✓ Reject – and be seen to reject – any unilateral announcement, however made, by a member where that reveals commercially sensitive information	

Membership Criteria

Consortium membership may give rise to certain exclusionary concerns when the consortium has access to particular testing data, commercial resources and other materials that cannot be duplicated readily by other competitors.

In that situation, members of a consortium need to be careful as to how they treat other companies/persons which wish to join as a (late-coming) member. If such third parties are not treated in a transparent, objectively justifiable manner, the consortium runs a risk of being accused of infringing competition law. The basis of that accusation would be, for example, that the consortium is preventing the third party from having access to something which is necessary for its entry or continued presence on the given market.

Accordingly, it is important for the consortium to ensure the following:

- Membership rules should be sufficiently flexible in order to allow new members to join at a later date under the same conditions as existing members; if the same conditions do not apply, an objective justification must be found (for example, risk premium, interest adjustment, etc).
- Conditions and the procedure for membership applications should be clearly provided, avoiding unanimity voting, and they should be subject to a credible appeal process where the application is rejected at the first attempt.

- In principle, all members should share the costs for the development of the dossier and the registration equally, unless there is an objective justification for treating specific members differently. Reference is made to [section 2](#) above on suggestions as to alternatives to a simple *pro rata* split.

Miscellaneous Points

- Collective bargaining: there is nothing under competition law that prevents consortia negotiating access on behalf of all of its members from a data owner (which itself could be a consortium). Such represents economies of scale savings, apart from anything else. The key, from a competition law point of view, is to ensure that the discussions occur between designated parties (so a representative of the consortium), both parties possibly being subject to confidentiality/non-disclosure agreements. That way, already the circulation of use to which any information gleaned can be put is restricted. However, data owners must treat all applicants equally, which means that the members will not be able to benefit from specific deductions due to the fact that several companies are applying for data access at the same time.
- Liability: all members of the consortium are individually liable should a competition law infringement be established. Even those neutral officers who are appointed to assist in running the consortium, for example, may be personally liable for any anti-competitive decision ultimately taken by the consortium.

8. Summary of BPR consortia Dos and Don'ts

DO	DO NOT
✓ Do ensure that a comprehensive and detailed written agreement is in place establishing the consortium	✗ Share confidential information with the other members
✓ Provide clear rules for decision-making	✗ Make a distinction amongst members based on their membership in another association or consortium
✓ Treat all prospective applicants (for membership or data sharing) equally – apply the same rules to everyone, unless objectively justified	✗ Refuse membership without objective justification
✓ Establish clear and fair rules for calculation of compensation for membership and LoA fees	✗ Accept too many members if not practically feasible (still on the basis of objective criteria)
✓ Define the rights for each member on the data jointly developed	✗ Duplicate vertebrate data
✓ If you restrict membership, offer access to your data in a fair, transparent and non-discriminatory way	✗ Apply unanimity voting
✓ Make every effort to reach an agreement on data sharing in case a request is made by a third party	✗ Apply lengthy procedures, notably for information exchange with the technical consultant or decisions related to the dossier and strategy
✓ Share all vertebrate data	✗ Discriminate between members and/or

	third parties by applying different costs or fees without objective justification
✓ Provide for an agreed dispute resolution procedure, e.g. arbitration or national courts	✗ Apply unfair costs or fees which are not objectively justified
✓ Provide conditions and procedure for membership	
✓ Appoint a dedicated and knowledgeable representative	
✓ Decide how the application will be submitted and by whom	

9. Frequently asked questions on consortia

What is a consortium? (see [section 1.1](#))

A consortium is a gathering of more than two companies/persons with the aim of achieving a common goal. Most often a consortium is no more than a contract between the members (referred to as, e.g. task force agreement, memorandum of understanding, operating rules) but it can also take the form of a legal entity separate from the members (for example, a European Economic Interest Grouping).

Is it a legal term? (see [section 1.1](#))

No. The word consortium is chosen for this Practical Guide because it is the word commonly chosen by industry when more than 2 companies/persons come together to achieve a common goal under the BPR. Other terms such as cooperation agreement, task force and registration group are just as legitimate.

What is the greatest benefit of being part of a consortium? (see [section 1.4](#))

For companies/persons, it is the savings made in spreading the costs of generating tests/studies, hiring technical consultants/other consultants, etc, across a number of like-minded companies/persons. For the relevant regulatory authorities, consortia reduce the likelihood of duplicative testing and of multiple assessments.

Name some of the other advantages (see [section 1.4](#) and [section 3](#))

In effect, it is a question of economies of scale:

- Human resource/time savings (the workload can be shared);
- Pooling of expertise/sharing of knowledge; and
- Depending on the type of consortium, the ability to collectively defend a position.

What is the biggest downside to being part of a consortium? (see [section 3](#))

There is always going to be potential for the consortium to work only as fast as its slowest member; so lack of flexibility and adaptability may be a hindrance.

Name some of the other disadvantages (see [section 3](#))

In effect, it may be a question of relationships between member companies/persons:

- There may be tension between members, in particular where they are actual or potential competitors; there may be intractable divergences of opinion which take up a lot of management and external consultant time to resolve;
- It may take a long time to set up the consortium and get it up and running; and

- By bringing companies/persons together, there is an increased risk of competition law non-compliance if members are not fully aware of their rights and obligations in that regard.

What form does a consortium have to take? (see [section 1.2](#) and [section 1.3](#))

None. This is an issue for the members to decide. It can range from an *ad hoc* grouping with no strict rules (not recommended) to a clearly delineated agreement between members with defined roles, structures, liability, membership rules, etc, (which is recommended) to a fully-fledged separate legal entity with its own legal personality (and rights and obligations).

What rules do consortia have to abide by? (see [section 2](#))

EU and Member State competition law applies regardless of the form of consortium chosen. All members must abide by competition law at all times.

The consortium (depending on its activities) must also abide by the BPR's provisions. If the consortium is a legal entity, the rules of the Member State under whose laws the legal entity has been established must be complied with as well.

Other than that, the consortium's members are free to decide how the consortium should be run, in terms of number of meetings, quorum for attendance, hiring of consultants, membership rules, etc.

What opportunities are there to set up a consortium in the context of the BPR? (see [section 1.2](#) and [section 5](#))

Consortia can be set up under the BPR for a variety of purposes, amongst others, as a vehicle allowing members to jointly work on and apply for a biocidal product (family) authorisation (where relevant, in connection with SBP applications) and, in doing so, realise cost savings and economies of scale.

Can a consortium approach a data owner on behalf of all members to negotiate access to data for all the members? (see [section 7](#))

Yes, as a rule it is possible to engage in collective bargaining for members of a consortium but ultimately, if successful, each member will need to obtain an individual LoA or sign an individual data sharing agreement (where needed). For Article 95 purposes, individual submissions to the Agency are required.

Can a consortium negotiate as data owner if it receives requests to do so from prospective applicants? (see [section 2](#) and [section 5](#))

Yes, this is possible and happens quite often.

Can a consortium itself grant an LoA to prospective applicants? (see [section 2](#) and [section 5](#))

Yes, the consortium (established as a legal entity) acting as representative of the data owner(s) can sign an LoA, either to consortium members or third parties (e.g. an SME that is not member of the consortium).

Can a consultant act as an applicant either for joint or individual applications? (see [section 5](#))

Yes, this is possible and, again, common practice in many consortia. It also helps the members to abide by competition law.

Can a consultant to the consortium be the AH? (see [section 5](#))

Albeit not directly provided in the BPR, nothing prevents an independent third party acting in agreement with the consortium members (for example, a consultant) from being the AH of a biocidal product authorisation. In such a situation, he would act "on behalf of" or pursuant to a mandate of the consortium members.

Can a consortium be an AH? (see [section 5](#))

The same answer applies here: nothing in the BPR prevents a consortium established as a legal entity from being the AH of a biocidal product authorisation if it is set up as a legal entity by the members for that purpose. In this case, the consortium itself will need to be the beneficiary of any LoA it relies on.

What responsibilities, under the BPR, could a consortium have as AH? (see [section 5](#))

Where the consortium is a legal entity, it will have the same rights and obligations as any other AH (e.g. obligation for notification of unexpected or adverse effects, etc). However, where the products are not placed on the market, these responsibilities would be limited in practice to the regulatory maintenance of the products authorisation (e.g. changes, if any, renewals, annual fees, etc).

Can a consortium have a single active substance supplier? (see [section 5](#))

This can be the case, but must not necessarily be so. For competition law and freedom of contract reasons, members to a consortium should be free to source their active substances as they want and as fits their needs. Therefore, practically speaking, it seems rather unlikely that all members will have one and the same source. The downside of having multiple sources, however, is that members will need to establish the technical equivalence of their sources, within the context of, for example, a joint BPF or SBP authorisation. This requires the involvement of the Agency and payment of a fee.

Appendix 1. Template product consortium agreement



NOTE to the reader: Appendix 1 has four Annexes.

Skeleton Outline for a Biocidal Product Consortium Agreement

Under the BPR

The present outline for a consortium agreement has been drafted on the basis of BPR requirements.

This outline is by no means intended to be mandatory or prescriptive. It should rather serve primarily as a guideline or prompt for discussion in order to ensure that all interested parties address a range of aspects when considering consortia formation.

Ultimately, it is for a group of companies to assess the appropriateness of the provisions on a case-by-case basis and decide what elements they wish to adopt (and at what level), also in consideration of the relevant national contract law (which will vary depending on the choice of law agreed by the parties).

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

Consortium Agreement

Between

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

And

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

And

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

Hereinafter individually referred to as a “**Member**” and collectively referred to as the “**Members**”.

Preamble

The Preamble sets the scene and places the agreement in context. It is usually a list of descriptions. It may cover some or all of the following points: the approval status of the substance; a reference to the principle that biocidal products may not be made available on the market or used unless authorized; a reference to the parties as wishing to avoid duplicating efforts.

The following are examples of phrases which may be relevant:

- Whereas the Members are manufacturers or suppliers of biocidal products containing the active substance [Substance];
- Whereas the Substance has been approved under the Biocidal Products Regulation (EU) No 528/2012 (the “**BPR**”) by Commission Implementing Regulation [reference], with date of approval of [Date], and has been included in the Union list of approved active substances;

- Whereas the BPR provides that biocidal products shall not be made available on the market or used unless authorised in accordance with the BPR;
- Whereas an application for authorisation must be submitted by [date] to the European Chemicals Agency (the “**Agency**”) or to a Member State Competent Authority (an “**MSCA**”) in order to keep the product on the market;
- Whereas considering the effort required by regulatory obligations the Members consider it necessary to increase the efficiency of generation of information, to avoid duplication of work and to reduce associated costs as well as to submit a harmonised set of data to the Agency or the MSCA;
- Whereas the Members agree not to disclose, or discuss or exchange with one another or any parties to which their discussions and/or cooperation may be subsequently extended, any competitive or otherwise sensitive market information; and
- Whereas the Members agree to share data and costs in a fair, transparent and non-discriminatory way.
- Therefore, with a view to fulfilling their regulatory obligations under the BPR in respect to the biocidal products containing the Substance, the Members wish to cooperate in the form of a consortium (a “**Consortium**”) subject to the criteria defined hereunder.

THE MEMBERS HAVE AGREED UPON THE FOLLOWING:

AGREEMENT

Article I. Definitions

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

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

Affiliate / Applicant / Chairman / Consortium Manager / Customer / Data Submitter / Deadline for Application / Information or Data / Joint Product Authorisation Dossier / Members / Product(s) / Steering Committee / Study / Substance(s) / Technical Consultant / Territory / Trustee (etc)

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

Article II. Purpose and Objectives

The following are proposed as examples of the type of purposes and objectives that a consortium can be established for; they are neither an exhaustive nor a required list

1. The Members undertake to cooperate and share human and financial resources in order to comply with the requirements of the BPR for product authorisation (the “**Purpose**”). In particular, they undertake to pursue jointly the following objectives:
 - a. Development of the Joint Product Authorisation Dossier for the Products, including:
 - i. Gathering and assessing Existing Studies on the Substance or the Product individually held by the Members or third parties as well as any data in the public domain.
 - ii. Identification of data gaps between the Existing Studies gathered pursuant to the previous point and the requirements of Article 20 of the BPR.

- iii. Development of read-across approach where possible.
- iv. Carrying out testing to close the data gaps identified in relation to Article 20 of the BPR.
- v. Gathering information on use and exposure of the Products.
- vi. Performing a risk assessment.
- vii. Submission of the Joint Product Authorisation Dossier to [the Agency / the MSCA *delete as appropriate*] by [*complete*] on behalf of the Members before the Deadline for Application – or – The individual submission of the application for authorisation shall be done individually by each Member for its Products.
- viii. Agreement on the establishment of technical equivalence, if needed and required by the BPR, and submission of the request(s) to the Agency for the establishment of the technical equivalence of the Substance, according to Article 54 of the BPR.
- ix. Continuation of the cooperation contemplated herein during the evaluation of the application.
- x. Continuation of the cooperation contemplated herein after authorisation of the Products.

Article III. Membership

Membership criteria must be open, objectively justified and non-discriminatory

1. General

Membership shall be open to any applicant who fulfils the membership criteria and is committed to pay the financial contribution as laid down in this Article.

2. Membership

Membership shall be open to manufacturers and suppliers of biocidal products containing the Substance [*optional: and used for Product Type X*] and who are subject to the authorisation requirements pursuant to the BPR.

3. Criteria for membership

The following points can be considered and appropriate provisions added:

- a. Criteria and procedure for admission of new Members, including cost allocation [see Annex IV]
- b. Transfer of membership
- c. Withdrawal of membership
- d. Exclusion of members
- e. Appeal mechanisms for exclusions
- f. Consequences of withdrawal and exclusion

Article IV. Confidentiality

This is an example of a generic clause that can be found in many different types of agreements

1. The Members shall:
 - a. Treat all Information as confidential and not disclose it to third parties, unless legal disclosure requirements require that disclosure. Each Member shall advise immediately the other Members in writing of any disclosure or misuse by any

- Member or a third party of Information, as well as of any request by relevant regulatory authorities relating to the disclosure of that Information.
- b. Use the Information only for the Purpose or otherwise as permitted under or in accordance with this Agreement.
 - c. Disseminate the Information to their employees, Affiliates or external experts and/or consultants only on a need to know basis and only to the extent absolutely necessary for the Purpose or otherwise as permitted under or in accordance with this Agreement if those are contractually or otherwise obliged to keep the Information confidential.
2. The obligations specified in the preceding article shall not apply to Information for which the receiving Member can reasonably demonstrate that such Information:
- a. was known to the receiving Member on a non-confidential basis prior to its disclosure pursuant to this Agreement; or
 - b. 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 Member; or
 - c. becomes known to the receiving Member through disclosure by sources other than the disclosing Member, having a right to disclose such Information; or
 - d. was independently developed by the receiving Member without access to the disclosing Member's Information, as evidenced by documentary records.
3. These confidentiality provisions shall survive the term of this Agreement, and any Member who leaves the Consortium of its own accord or otherwise continues to be bound to these provisions.

Article V. Ownership and use of Information

Below are examples of the type of ownership and use rights that Members to the consortium can agree to; again they are neither required nor prescriptive; it is up to the Members to decide between themselves the extent of shared rights

1. New Studies

- a. Any Information generated or developed jointly by the Members in accordance with this Agreement shall be owned jointly by the Members provided that the individual Members have contributed to the costs thereof in accordance with the cost allocation method set out in Article [] and Annex III of this Agreement. Each of the joint owners shall obtain a copy of the full Study report.
- b. *Provide rules on the use of the New Studies by the Members (e.g. for which use, in which territory) and by their Affiliates and customers*

2. Existing Studies

- a. *Provide rules on the reporting and selecting of relevant Existing Studies owned by Members and on the rights provided to the other Members (e.g. letter of access or ownership, for which use, in which territory) and to their Affiliates and customer*

3. Third parties

- a. Upon request, any prospective applicant may be granted [*via a data sharing agreement*] a non-exclusive [*and transferable/non-transferable*] right to use or to refer to part or all of the Joint Product Authorisation Dossier including to particular Studies in accordance with Article [] of this Agreement.

- b. [*The Consortium Manager/the Data Submitter*] is granted by the Members of the Consortium, the rights to act in data sharing negotiation in the name and on behalf of all Members of the Consortium.

Article VI. Third party requests for access to Existing and New Studies under the BPR

Provide rules on the procedure for the handling of requests for data sharing from third parties, including the role of the Consortium Manager, on the procedure for the granting of the Letter of Access [see Annex II] and on the conditions to be offered to third parties [see Annex IV]

Article VII. Organisation

Depending on how the Members agree to structure themselves, some or all of the clauses below may assist.

1. Legal personality

This Agreement and the cooperation contemplated herein shall not constitute, or be deemed to constitute a legal entity or partnership between the Members nor make a Member the agent or representative of another Member unless expressly stated otherwise. In its external relations, the Consortium will not act independently of its Members or under its own name. Where a Consortium Manager is appointed by the Members, each Member agrees that the Consortium Manager will act in its own name on behalf of all Members concerned.

Only where a consortium is proposed as prospective AH of a product authorisation will it need to have a legal entity within the EU

2. Committees

Depending on how the Members agree to organise the consortium, the following committee structure may be helpful.

The bodies of the Consortium will be the Steering Committee and the Technical Committee. In order to fulfil the Purpose, the Steering Committee shall be empowered to set up any necessary committees, groups and task forces, the composition, mandate, duration and rules of which shall be determined by the Steering Committee in accordance with the rules specified hereunder.

3. Steering Committee

- a. The Consortium shall operate through a Steering Committee which will exercise overall direction and control over the Consortium. The Members shall meet in the Steering Committee in person, by telephone or video conference in order to take decisions on the overall organisation and activities of the Consortium.
- b. The Members of the Steering Committee shall jointly elect a Chairman who shall provide support to the Consortium Manager for organising meetings and taking minutes.
- c. *Include rules on the decision-making process, voting rights, convening of meetings, preparation of agenda and attendance of meetings.*
- d. The Steering Committee shall have all powers and make all decisions necessary to ensure that the Purpose is achieved. The tasks of the Steering Committee may include the following: [*complete with list of tasks*].

4. Technical Committee

- a. The Technical Committee shall consist of representatives of the Members and shall take decisions by [*unanimous/2/3/simple majority*] vote. The Members of

the Technical Committee shall jointly elect a Chairman who shall organise meetings and report to the Steering Committee.

- b. The tasks of the Technical Committee shall be directed by the Steering Committee and may include, inter alia, the following: [*complete with list of tasks*].

5. Consortium Manager

- a. *Option 1 (external manager)*: the appointment of the Consortium Manager is decided by the Steering Committee. The Consortium Manager signs a separate agreement with each individual Consortium Member setting out the tasks and responsibilities listed below including a confidentiality obligation to ensure that he does not misuse any sensitive data he receives.
- b. *Option 2 (company member of the consortium)*: the Consortium Manager is appointed by the Steering Committee among the Members of the Consortium. The Consortium Manager is accountable to the Steering Committee.
- c. The Consortium Manager shall be responsible for daily management and external representation of the Members of the Consortium. The Consortium Manager shall conduct all normal business of the Consortium, to the exclusion of strategic activities exclusively attributed to the Steering Committee, and shall in this regard deal particularly with the following: [*complete with list of tasks, for example these could include responsibility for handling requests made by Third Parties for access to the Information or for membership, including holding the escrow account where funds resulting from such requests will be deposited*].
- d. The Consortium Manager, upon prior approval of the Steering Committee, may sign all contracts with external consultants, experts, including the laboratories, to perform technical and scientific tasks, in its own name but on the account of the Members.
- e. The Consortium Manager is empowered to represent the Members for all acts necessary to achieve the Purpose, unless stated otherwise in this Agreement, and shall fully and timely comply, on behalf of the Members, with the relevant provisions of the BPR in this respect.

6. Treasurer

The Steering Committee may decide to elect a Treasurer in order to maintain the financial books and records of the Consortium, which shall be open to inspection by any Member.

7. Confidential information

The Technical Consultant, the Consortium Manager, as the case may be, shall collect any information that must be submitted by the Members for the purposes of this Agreement. Such information may include the lists of company-specific information held by individual Members (including any summary information and protocols), the average annual quantities of Products placed on the market by each Member, the specifications on their product types of interest and other sensitive market information. The Technical Consultant, the Consortium Manager shall at all times maintain the confidentiality of this information, also *vis-à-vis* the other Members, and only disclose it to relevant regulatory authorities to the extent this is required for the Purpose.

8. Representation and activities in relation to third parties

No contractual commitments with third parties in relation to the Purpose of this Agreement shall be entered into by any Member on behalf of the other Members of the Consortium without the prior approval of the Steering Committee. The Consortium shall be represented with respect to the third parties by the Consortium Manager.

9. Working language

The working language of the Consortium shall be [*English*].

Article VIII. Definition of costs and cost allocation

Cost sharing in a consortium can be complex and requires a good understanding by all; some or all of the clauses below may assist

1. Valuation of Existing Studies

The value of Existing Studies made available by a Member to other Members shall be determined by the Steering Committee on the basis of an evaluation of the scientific quality, adequacy and relevance in relation to the achievement of the Purpose, in accordance with rules laid down in Annex III.

2. Cost sharing principles

- a. The following costs shall be shared between the Members: *[complete with list of costs to be shared by Members, e.g. administrative expenses, compensation for Existing Studies, costs of New Studies, etc]*.
- b. Other costs incurred by the Members in the context of this Agreement shall not be compensated unless agreed by the Steering Committee.
- c. The costs referred to at (a) above shall be allocated to the Members equally, among all Members of the Consortium, unless otherwise decided by the Steering Committee.
- d. All payments due hereunder shall be net payments, i.e. free of any bank or transfer charges or similar charges and without deduction of any taxes, levies or other dues payable. If payer is required to withhold any tax or to make any other deduction from any such payments, then the said payments shall be increased to the extent necessary to ensure that, after making the required deduction or withholding, payee receives and retains (free from any liability in respect of any such deduction or withholding) a net sum equal to the sum which it would have received and so retained had no such deduction or withholding been made or required to be made (gross-up amount). If upon application of the beneficiary any withholding tax can be reduced, or refunded, or an exemption from withholding tax is granted, payer shall file on behalf of payee for such reduction, refund or exemption. Payee shall render any assistance to payer to obtain such withholding tax reduction, refund or exemption. Payer shall be entitled to any refund of withholding taxes.
- d. Indirect Taxes, including but not limited to Value Added Tax (VAT), Goods and Service Tax (GST), Service Tax, and Business Tax, as applicable pursuant to the relevant tax law, shall be borne by payer. However, payer is entitled to withhold any payment of indirect taxes unless payee has provided payer with a sufficient invoice for the purposes of indirect taxation.

Article IX. Individual obligations

1. The Members undertake to make all reasonable efforts to ensure the appropriate and timely achievement of the Purpose. In particular, each Member shall:
 - a. Observe and comply with the provisions of this Agreement;
[complete]
2. Each Member is responsible for observing its rights and obligations pursuant to the BPR, in as much as these rights and obligations are not observed by the Members of the Consortium in accordance with this Agreement. This applies, in particular, to *[complete]*.

The following Articles X onwards are standard type clauses that can be found in many different types of agreement

Article X. Competition law compliance

The Members acknowledge that any activities carried out under this Agreement have to be carried out in full compliance with EU competition law, in particular but not limited to Articles 101 and 102 of the Treaty on the Functioning of the European Union as well as any applicable national laws. The Members explicitly agree to observe the competition law compliance policy provided in Annex I to this Agreement.

Article XI. Administration & Reporting of costs, billing and books of account

Provide rules for the keeping of records or expenses and credits, administration and payment of invoices, preparation of budget, handling of consortium account, handling of disbursements, handling of books of account, reimbursement to Members and voting majority for decisions on financial matters

Article XII. Limitation of liability

1. The Members shall undertake their Purpose-related activities specified hereunder in good faith and according to all applicable laws and regulations, and they shall use all reasonable endeavours to ensure the best possible results based on the information, methods and techniques known at the time.
2. Each Member having submitted a study which has been used in the Joint Product Authorisation Dossier represents to the others: (i) that it is the rightful owner or grantee of the study(ies) and free to grant rights therein; (ii) that, to the knowledge of this Member, these studies do not infringe on the rights, in particular, but without limitation, intellectual property rights, of any third party; and (iii) that this Member has not received a claim or notice of any alleged infringement.
3. It is the individual responsibility of each Member to assess the Information that is generated or that is made available. Each Member assumes the full responsibility for its own use of the Information so developed or received.

Consider adding other provisions on liability, in particular where the consortium is the AH of a product authorisation

Article XIII. Assignment

A Member may assign its Membership in the Consortium. A Member may not transfer a partial interest in the Consortium. An assignment shall not be effective until the assignee agrees in writing to assume the responsibilities of the assignor in accordance with this Agreement.

Article XIV. Duration, termination and amendments to the Agreement

1. This Agreement shall enter into force as from [*date*]. The Consortium shall be formed for the duration necessary to achieve the Purpose, or until the period of data protection applying to the Information and the Studies in the Joint Product Authorisation Dossier has come to an end, in accordance with Article 60 and Article 95 of the BPR, unless otherwise decided by the Steering Committee.
2. Upon achievement of the Purpose the Consortium can be terminated by a majority decision of the Steering Committee. Prior to that date, the Consortium may only be dissolved by a [*unanimous/2/3/majority vote*] decision of the Members.
3. This Article and the provisions relating to the protection of confidentiality (Article []), ownership and use of Information (Article []), dispute resolution and applicable law

(Article []) and limitation of liability (Article []) shall survive the termination of this Agreement.

4. Upon termination of the Consortium and after payment of all obligations of any kind to or by the Members, the [*Steering Committee*] shall decide on the method of liquidation and the distribution of the earnings still on the Consortium's account. Before dissolution or termination of the Consortium all remaining joint and severable rights and obligations of the Members resulting from this Agreement shall be settled.
5. Amendments to this Agreement (which includes its Annexes) must be subject to a written amendment signed by all Members to be effective.

Article XV. Dispute resolution and applicable law

1. The Members shall first attempt to settle amicably any dispute arising out of this Agreement.
2. If differences remain, each Member shall have the right to submit its observations in writing to the [*Steering Committee*], which shall have to reply in writing stating the reasons for the decision within 3 months.
3. Should such amicable settlement fail, the dispute shall be resolved by [*arbitration/jurisdiction by ordinary courts*]. The place of any hearing shall be [*complete*].
4. This Agreement shall be governed by the laws of [*include the name of the country*].
5. 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.
6. This Agreement constitutes the entire agreement and supersedes all other prior agreements and understandings, both written and oral, between the Members with respect to the subject matter hereof.

This Agreement may be executed in any number of counterparts each of which when executed and delivered will be an original, but all of the counterparts together will together constitute one and the same agreement.

For and on behalf of

Signature: _____

Name:

Title:

Date:

For and on behalf of

Signature: _____

Name:

Title:

Date:

For and on behalf of

Signature: _____

Name:

Title:

Date:

Annex I Competition Law Compliance Policy

In order to avoid any violation of competition law and/or regulations, the Members, (*the Steering Committee representatives*), (*the Consortium Manager*) and (*the Technical Consultant*) agree that the following activities shall be avoided:

Discussion or exchange of information concerning:

- company pricing policies and customer credit terms;
- production costs, capacity and sales volumes;
- plans for production, distribution and marketing;
- changes in industry production;
- transportation rates, zone prices and freight equalization;
- company bids on new and existing contracts, company procedures for responding to bid invitations;
- marketing plans and strategies; and
- information about raw material suppliers.

The Members further agree to:

- acknowledge the policy before each [*Steering Committee*] meeting;
- inform other company personnel involved in the work of the Consortium about the rules of antitrust policy;
- limit all discussions during meetings to the topics on the agreed agenda;
- protest immediately should the discussion or any meeting activity appear to fall within the scope of the above mentioned activities to be avoided; and
- maintain a good record of all meetings.

Annex II Letter of Access Template

Refer to template Letter of Access in the Practical Guide on Letters of Access

Annex III Value of studies – valuation rules



NOTE to the reader:

This is an example only. Other guidance on valuation of studies can be obtained from the Practical Guide on Data Sharing.

The Members shall decide on financial valuation rules of existing Studies pursuant to the BPR requirements.

The value of a Study should in principle be based on the costs actually borne by the data owner at the time they were incurred [*replacement costs are another valid option –see Practical Guide on Data Sharing*]. The laboratory costs should be vouched according to invoices and proof of payment of the invoice.

Where the costs cannot be vouched because the specific invoicing documentation is missing or the data are relatively old, or if the data were generated in-house, an agreement shall be reached on the estimated replacement value. The following factors shall be taken into account:

- the same test would have to be considered (notwithstanding advances in scientific progress over the years);
- the same type and quality of laboratory would have to be considered;
- the average of three independent quotations should be used; and
- a third party should, as far as possible, be asked to conduct the assessment of replacement costs.

Annex IV Cost allocation



NOTE to the reader:

This is an example only. Other guidance on cost calculation can be obtained from the Practical Guide on Data Sharing.

The BPR requires that costs for data should be shared in a fair, transparent and non-discriminatory way. In the absence of specific rules, the Members are free to select any cost allocation and compensation mechanism that they consider fair, transparent and non-discriminatory.

In principle, costs for data shall be shared equally, based on the number of parties involved.

The overall admission contribution by new Members, shall be calculated taking account of the following:

[complete with elements to be included in the cost calculation, e.g. costs for existing data, costs for new data, administrative expenses, consultancy fees, etc – for guidance, see Practical Guide on Data Sharing]

The above overall admission contribution by new Members shall be the basis for an offer of a LoA made to a Third Party on request for a BPR purpose, without prejudice to Article 63 of the BPR.

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU

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