16 July 2011

Updated version for <u>new</u> consortia – 2° registration phase

Consortium Agreement

pursuant to requirements of 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)[1]

The present model consortium agreement has been elaborated by the Cefic Legal Aspects of REACH Issue Team on the basis of REACH requirements, the available guidance, in particular the Guidance on data sharing and the European Law in force.

Please note that this model Agreement 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.

The passages in italic in this Agreement identified as "options" are binding on the Parties only if they have been specifically retained in each case. 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 but when making any decisions it is recommended that these issues should be taken into consideration[2].

Companies are to apply this model at their own risk and Cefic will not accept any warranties resulting from the use of or reliance on this document and its application.

For Cefic and its members: for further clarifications and questions, contact Vincent Navez, Cefic Legal Counsellor. Tel. +32 2 792 75 10 - E-mail: vna@cefic.be

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[1] *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), OJ L 136 of 29.5.2007*

[2] *Adjustments may be necessary in order to comply with the national law applicable according to the Article XIV.*

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Consortium Agreement

Between

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

And

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

And

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

And

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

And

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

As "Members",

Hereinafter individually referred to as a "Member" and collectively referred to as "the Members".

Preamble

Whereas the Members are manufacturers, importers, only representatives as defined in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals **("the REACH Regulation")** of the Substance(s) [*designation of the substance name/ category*] on its own, in preparations or in articles with registered offices in the Economic Area.

Whereas the Substance has phase-in status according to Article 3 (20) of the REACH Regulation and each of the Members [*intends to pre-register or has pre-registered*] the substance individually.

Whereas the REACH Regulation imposes on manufacturers and importers as well as on only representatives an obligation to register the substance as such, in preparation or, under certain conditions, in articles within the prescribed deadlines.

Whereas the REACH Regulation requires, subject to certain exceptions, multiple registrants of the same substance to share certain data and jointly submit part of the registration relating to the substance.

Whereas considering the effort required by regulatory obligations the Members consider it necessary to increase the efficiency of generation of information, to avoid to duplicate work and to reduce associated costs as well as to file a harmonized set of data to the European Chemicals Agency.

Therefore, with a view to fulfilling their regulatory obligations under the REACH Regulation in respect to the Substance, the Members wish to cooperate in form of a consortium **("the Consortium")** open to any other interested third parties subject to the criteria defined hereunder.

THE MEMBERS HAVE AGREED UPON THE FOLLOWING:

Agreement

Article I. Definitions

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

Substance(s): [designation of the name/ category] as specified further in Annex 1 to this Agreement for which the Consortium is created.

Members*:* Members of the Consortium being the above listed initial signatories to this Agreement as well as any other entity which becomes party to this Agreement in the future. The Members are manufacturers, importers, only representatives as defined in the REACH Regulation of the Substance on its own, in preparations or in articles who are subject to the registration requirements pursuant to the REACH Regulation and who participate in the Consortium.

Affiliates: Any legal entity controlling, controlled by, or under common control with a Member or in case of an only representative, the affiliate of the non-EU

manufacturer*,* the affiliate of the legal entity represented. For these purposes, "control" shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of a person, whether through the ownership of voting rights, by contract or otherwise; or (ii) the ownership, directly or indirectly, of [*50 % or more / more than 50%*] of the voting rights or other ownership interest of a person.

Deadlines for Registration*:* The date by which the Substance(s) should be registered at the latest as specified in Article 23 of the REACH Regulation.

Lead Registrant(s): the Member(s), which the other Members (and the SIEF members, upon separate agreement) agree hereto to appoint acting as Lead Registrant as defined under Article 11 (1) REACH, who is responsible for submitting the Joint Registration Dossier to the European Chemicals Agency ("**Agency"**) on behalf of the Members and their Affiliates and on behalf of the members of the SIEF) pursuant to Article 11 (1) of REACH.

Steering Committee: decision-making body of the Consortium.

Chairman: a natural person representative of the Lead Registrant and in case of multiple Lead Registrants, the representative who has been elected subject to vote of the Steering Committee.

Technical Committee: technical consulting body of the Consortium responsible to develop the technical dossier for registration and whose members are nominated by the Steering Committee.

Consortium Manager: natural or legal person responsible for secretariat and/or daily management of the Consortium, appointed by the Steering Committee and hereby acting within the decisions of the Steering Committee.

Trustee: An independent third party who in view of the exchange of sensitive individual data, whose appointment is decided by the Steering Committee and who is a legal or natural person not directly or indirectly linked to a Member or to an Affiliate. A confidentiality agreement will ensure that the Trustee does not misuse any sensitive data (e.g. volumes, customers) it receives. The Trustee must ensure that specific internal procedures effectively protect any Information disclosed to him.

Study: reports, tests or evaluations in written or electronic form, including full study reports, summaries and robust study summaries as defined in the REACH Regulation, relating to intrinsic properties, exposure assessment and risk characterisation of the Substance and as such are of relevance for registration pursuant to Article 10 of the REACH Regulation, in existence before the entry into force of this Agreement **("Existing Study")** or performed after that date **("New Study")**.

Information: Study, other scientific, statistical, commercial or technical data, including but not limited to composition, characteristics, properties and processes and applications, and any information in any form made available to the Members by a Member (including its employees, Affiliates or agents) or any third party, or generated by the Members jointly, pursuant to or in the course of this Agreement. The term Information also comprises information that has been exchanged on the subject matter hereof prior to signing of this Agreement, whether under a preliminary agreement or otherwise.

Joint Registration Dossier: The data that the Members gather, jointly develop and agree to submit to the Agency in order to register the Substance pursuant to Article 11 paragraph 1 paragraph 2 of the REACH Regulation, including the following data:

- Classification and labelling of the Substance pursuant to section 4 of Annex VI of the REACH Regulation;

- Study summaries of the information derived from the application of Annexes VII to XI of the REACH Regulation;

- Robust study summaries of the information derived from the application of Annexes VII to XI, if required in Annex I of the REACH Regulation;

- Proposals for testing where listed in Annexes IX and X of the REACH Regulation;

The scope of the Joint Registration Dossier shall fulfil the requirements of the REACH Regulation applicable to the Member manufacturing or importing within the highest tonnage band of the Substance.

*[**Option I**:*

The Joint Registration Dossier also includes

- *the Chemical Safety Report where required under Article 14 of the REACH Regulation, in the format specified in Annex I of the REACH Regulation including the relevant use and exposure categories.*

- *the Guidance on safe use of the Substance as specified in section 5 of Annex VI of the REACH Regulation.*

***Option II** (if generic CSR but to be submitted individually):*

***Chemical Safety Report (CSR):** the Chapters 3 to 8 of the chemical safety report (CSR) that the Members are required to submit under Article 14 of the REACH Regulation, in the format specified in Annex I of the REACH Regulation that will be prepared outside the Joint Registration Dossier to cover individually the uses of the Members and that will be made available within the consortium.]*

2. Otherwise any definitions specified in the REACH Regulation, in particular in Article 3, shall apply to this Agreement.

Article II. Purpose and Objectives

The Members undertake to cooperate and share human and financial resources in order to comply with the requirements of the REACH Regulation **("the Purpose")**. In particular, they undertake to pursue jointly the following objectives:

1. Agreement on the identity and the sameness of the Substance and its regulatory status, as well as on other substances for which the available Information might be relevant for the Substance of interest for the Members.

2. Development of the Joint Registration Dossier for the Substance, including:

a) Gathering and assessing Existing Studies on the Substance individually held by the Members or third parties as well as any data in the public domain (literature, etc.);

b) Identification of data gaps between the Existing Studies gathered pursuant the previous point and the requirements of Annexes VI to XI of the REACH Regulation;

c) Development of read-across approach where possible;

d) Assessment of opportunities for exposure-based adaptations;

e) Subject to obligations under Art. 30 of the REACH Regulation carrying out testing to close the data gaps identified in relation to Annexes VI to VIII of the REACH Regulation taking into account Annex XI;

f) Preparation of study summaries and robust study summaries, if needed and where appropriate;

g) Development of testing proposals as required according to Annexes IX and X of the REACH Regulation taking into account Annex XI;

h) Development of uniform classification and labelling according to the CLP Regulation;

[Optional:

i) Gathering information on use and exposure categories of the Substance, conditions of use and exposure to humans and environment. Identified uses of the Substance to be assessed in the Chemical Safety Report shall be listed by the Consortium Manager. The list shall identify only uses which are commonly known and supported by a majority of the Members with a registration obligation for the specific Substance based on information transmitted and aggregated by a Trustee.

j) Performing a risk assessment according to the scientific principles as agreed by the Technical Committee(s) with the intention to demonstrate safe manufacturing and use of the Substance(s) in the defined application areas [and develop guidance on safe use].

k) Initiating testing where a higher tier risk assessment is needed to demonstrate a safe use in a specific application or specific conditions of use in an application.]

3. Submission of the Joint Registration Dossier for the purpose of Registration to the Agency by the Lead Registrant on behalf, among others, of Members and their Affiliates at least [*two*] months before the deadline for registration applicable to the Member(s) within the highest tonnage band.

4. [Optional but recommended: Continuation of the cooperation contemplated herein during the dossier evaluation according to Title VI of the REACH Regulation, including supervising the performance of the testing proposals as authorized by the Agency.]

5. [Optional: Members who wish to continue their cooperation for the development of collective comments under the procedure for inclusion of substances in Annex XIV of the REACH Regulation and/or for the preparation of the application for the authorization pursuant Title VII of the REACH Regulation, including the development of common scientific arguments under the framework of this Agreement, need to opt for such cooperation. Only

those Members who agreed to cooperate will decide on further separate rules, where deviating from the ones stated in this Agreement, and participate in cost sharing

Article III. Membership:

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 any manufacturer, importer or only representative as defined in the REACH Regulation of the Substance on its own, in preparations or in articles and who are subject to the registration requirements pursuant to the REACH Regulation.

Every only representative shall disclose in writing the number and the identity of the non-EU manufacturer(s) and affiliates it represents. For each non-EU manufacturer represented, the only representative will be considered as a separate member.

3. Admission of new Members

1. Any application for Membership shall be in writing and shall be sent to the Consortium Manager. The admission of a new Member shall be subject to the simple majority vote of the Steering Committee, it being understood that such consent shall not be unreasonably withheld or delayed. The admission shall not be denied if the applicant fulfils the Membership criteria specified above and has committed to pay the financial contribution referred to below.

2. Each new Member shall financially compensate the existing Members for the expenses incurred as well as the accumulated experience and developed knowledge by the existing Members. This compensation shall consist of the following elements:

a) a pro-rated refund determined pursuant to Article X and Annex 4 of this Agreement for the Studies made available or generated jointly under this Agreement by the Members. Unless agreed otherwise, the new Member shall refund a share of costs only for the Studies he is required to submit within his tonnage band, and

b) a non-discriminatory surcharge determined by the Steering Committee based on objective criteria to compensate for administrative and, if appropriate, other expenses incurred by the Members up to the date of admission.

3. Any decision refusing membership shall clearly state the reasons why the membership is not granted. The applicant whose application was turned down has the right to submit its observations in writing to the Steering Committee, which shall review the observations and reply in writing within 3 months. The non admitted applicant may be offered by the Members of the Consortium the access to the Studies or to the Joint Registration Dossier necessary to fulfil his registration requirements in accordance with Article V 5 of this Agreement or may be included in the joint submission of data for the Substance subject to the financial compensation in accordance with Annex 4.

4. Upon signature of a Declaration of Accession attached as Annex 5, a new Member shall

fully adhere to the terms and conditions set out in this Agreement and commits to adhere to the Terms and Conditions set out in any service provider agreements entered into by the Members of the Consortium, including with the Consortium Manager, or entered into by the Consortium Manager acting in its own name and on account of the Members. Upon signature of a Declaration of Accession attached as Annex 5 and as of payment of the due compensation fee, the new Member shall have the same rights and obligations as any existing Member.

4. Transfer of membership

1. A Member shall be entitled to transfer his membership including all its rights and obligations under this Agreement to a third party subject to prior [*xx % majority vote*] of the Steering Committee which shall not be unreasonably withheld or delayed, provided that that third party meets the membership criteria as laid down in Article III 2 of this Agreement. The Steering Committee shall decide within two months of notification; the absence of a decision meaning acceptance. It is understood that after the transfer of its membership the former Member shall cease to have any rights arising from this Agreement. The transfer by a Member of individual rights or obligations arising from his membership to a third party shall not be permitted.

2. The consent of the Steering Committee shall not be required in case of a transfer of Membership to an Affiliate or restructuring within a group of companies or in case of a merger, a division or sale of a branch of activities, to the extent that the merged entity or branch of activities was a Member of the Consortium. The Member shall notify the Consortium Manager by registered letter without undue delay after the event which caused the transfer of membership.

5. Withdrawal

At any time, a Member can terminate its membership in the Consortium if circumstances making the continued membership in the Consortium disproportionate and unjustified have durably occurred for example, if due to circumstances involving the Member, the Member is no longer subject to the REACH registration requirements. Such termination is subject to a three months prior written notice to the Consortium Manager. A Member may terminate this Agreement without cause upon written notice with a notice period of [*xx months/one year*]. In any event, the terminating Member shall fulfill all of its financial obligations up to the date of termination, i.e. until the end of the applicable notice period.

6. Exclusion

1. Any Member may be excluded from the Consortium, without prejudice to any other rights the Members may have against the defaulting Member, if it does not meet or continue to meet the membership criteria as laid down in Article III or in the event of a serious material breach of this Agreement that has not been repaired within 30 calendar days after formal notice has been sent by the Consortium Manager by registered mail to the Member concerned.

2. The defaulting Member shall be excluded by a decision of the Steering Committee with a majority of two thirds of the votes of the Members present or represented *and on the basis of an objective and documented justification in compliance with Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU)..* The defaulting Member shall have the right to present its defence to the Steering Committee before a final decision is taken. The decision of the Steering Committee shall be immediately notified to the Member by registered mail and the exclusion shall be effective upon the date of receipt of this letter.

7. Consequences of withdrawal and exclusion

1. Subject to paragraph 4 hereunder, withdrawal or exclusion of a Member is without prejudice to the rights and obligations of the Member that is withdrawing or is excluded (hereafter exiting Member) which have accrued up to the date of effective withdrawal or exclusion provided that the exiting Member meets his payment obligations, including all payments related to Studies agreed on, which have arisen during the time of his membership. In particular, the exiting Member shall remain liable for the activities undertaken under this Agreement for the period of his membership. The exiting Member shall have no further rights to any results arising out of this Agreement in respect of which he has not fulfilled his financial contribution. Nevertheless, the exiting Member shall be entitled to compensation and reimbursement, if any, to be collected by the Members of the Consortium (e.g. from new Members who have subsequently joined the Consortium or from SIEF members) for Studies and/or the Joint Registration Dossier developed before cessation of his membership.

2. The other Members shall continue to be entitled to make use of the Information made available by the exiting Member on the conditions specified in this Agreement and provided that that Member has been duly compensated under the conditions defined in this Agreement. Any recoverable damages suffered by the remaining Members as a result of the defaulting Member's actions shall be off set against any compensation payable to the exiting Member.

3. The exiting Member shall have no claims for reimbursement of his financial contribution to the Consortium for the period prior to his effective withdrawing or exclusion.

4. With regard to on-going Studies to which the exiting Member committed, the exiting Member shall financially contribute to all further costs of the Study as well as to all administrative costs incurred until the Study is completed and thereby acquire a joint ownership of the Study.

5. With regard to the Studies, the obligations specified in Article IV of this Agreement shall continue to apply to the exiting Member for a period of twelve (12) years following the initial submission to the Agency by a Member. With regard to all other Information, the obligations specified in Article IV shall continue to apply for a period of *[5/ 10/15]* years after withdrawal or exclusion.

Article IV. Confidentiality

1. The Members shall:

a) treat all Information as confidential and not to disclose it to third parties, unless legal disclosure requirements apply. 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 competent authorities relating to the disclosure of that Information.

   Disclosure of results in Studies as required for legal and/or regulatory purposes including the REACH Regulation, shall only take place by the Members in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed. This restriction does not apply to the Member who has provided the data.

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 Article IV.1 above 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;

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;

c) becomes known to the receiving Member through disclosure by sources other than the disclosing Member, having a right to disclose such Information,

d) was independently developed by the receiving Member without access to the disclosing Member's Information, as evidenced by documentary records,

Specific items of Information shall not fall within any exception merely because they are combined with more general Information falling within any exception. Likewise, any combination of specific items of Information shall not fall within any exception merely because the specific items fall within any exception, but only if the combination itself, and its principles of operation, fall within any exception.

3. Affiliates and external experts and/or consultants of any Member are not regarded as third parties for the purpose of this Article. Each Member assumes full responsibility for compliance by its employees, Affiliates or external experts and/or consultants with the requirements of this Agreement in the respect of any Information received by those employees, Affiliates or external experts from that Member, unless the Affiliate in question is also a party to this Agreement.

4. Non-EU manufacturers represented by an only representative who is Member of this Consortium are not regarded as third party for the purpose of this Article. Each Member that is an only representative assumes full responsibility for compliance by the non-EU manufacturer it represents with the requirements of this Agreement in the respect of any Information received by that non-EU manufacturer from that Member.

5. In the event of non-compliance with the obligations set out in this Article the Members whose Information is disclosed shall have the remedies available under the applicable law notwithstanding the stipulations contained in this Agreement, notably Article XII. *[Optional: Each Member acknowledges that damage alone would not be an adequate remedy for any material breach of this Agreement and agrees that the other Member shall be entitled to the remedies of injunction, specific performance or other equitable relief, or conservatory relief or measures. Such remedy shall be in addition and not in lieu or limitation of other remedies available. Failure by a Member in exercising any right, power or privilege hereunder shall not act as a waiver, nor shall any single or partial exercise thereof preclude any further exercise of any right, power or privilege].*

6. These confidentiality provisions shall survive the term of this Agreement, and any Member who leaves the Consortium of it own accord or otherwise continues to be bound to these provisions.

Article V. Ownership and use of Information

1. Within [*xx weeks*] of the entry into effect of this Agreement, or within [*xx week*] after joining the Consortium subsequently to the entry into effect of this Agreement, all Members shall make available to the Consortium Manager a list of their Existing Studies and a hard or electronic copy of either the robust study summaries or the full reports of these Studies. The Consortium Manager shall make a list of these Studies and shall make the necessary arrangements for the review of these studies by the Technical *[/Steering*] Committee(s).

2. Any intellectual property or ownership rights to any existing Information independently developed by a Member and made available to the Members in accordance with this Agreement shall remain unaffected by this Agreement. The other Members shall have for an indefinite period of time a non-exclusive, non-transferable and non-terminable right to use the Information for [*REACH purposes only / any regulatory purposes*], including the right to refer to the full Study report [*and only for the Substances / and including for REACH read-across purposes*], provided that they share in its cost in accordance with the cost allocation method agreed upon under section X and Annex 4 of this Agreement.

[Optional:

The Study made available by a Member or a third party to other Members may not be sub-licensed or otherwise made available to third parties without prior written approval of the Member who provided the Study.

The Member who provided a Study to other Members may extend, at a cost or free of charge, the right to other Members to use or refer to the Study for other purposes.

Existing Studies which are owned by several Members or by one or several Members and one or several third parties can only be made available to the other Members with the prior written approval of all owners unless otherwise agreed among the owners of the Study.]

3. 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 X and Annex 4 of this Agreement. Each of the joint owners shall obtain a copy of the full Study report. The Information referred to in the first sentence may be used by the Members who have contributed to the costs thereof for *[REACH purposes only / any regulatory purposes]* and shall not for the period of 12 years from the date of initial submission to the Agency be sold, licensed or otherwise made available to third parties by any Member without prior written approval of [*all/ majority of 2/3 / other*] remaining owners who have financially contributed to the costs thereof unless otherwise agreed by the Members.

4. Affiliates of a Member shall have a royalty-free right on Information referred to in paragraph 2 and 3 provided that the relevant Member to which they are affiliated has contributed to the costs thereof in accordance with the cost allocation method set out in Article X and Annex 4 of this Agreement.

In case the Member is an only representative, the Affiliates of the company/ies it represents shall have the same rights provided the only representative has contributed to the costs thereof in accordance with the cost allocation method set out in Article X and Annex 4 of this Agreement.

5. Cost allocation method between the Members agreed upon under article X and Annex 4 of this Agreement shall be implemented at the latest [*x*] days after the corresponding

registration deadline under the REACH Regulation. If the corresponding payment has not been made by the due date, except in cases of a bona fide dispute over the amount due, the rights mentioned under this Article will be void ab initio, ie being considered as never been granted.

6. Upon request, any potential registrant of the Substance, including the applicants for the Membership whose application was refused may be granted [*via a SIEF agreement based on the Cefic model and drafted according to the same principles*] a non-exclusive and non-transferable right to use or to refer to the parts or all of the Joint Registration Dossier including to particular Studies to the extent the Members of the Consortium are entitled to do so.

In that regard, the Lead Registrant is granted by the other Members of the Consortium, when being the owner(s) and/or the subjects authorized to grant the rights to use the (robust) studies summaries and to refer to the full study reports, the rights to act under the SIEF agreement in the name and on behalf of all Members of the Consortium.

7. Neither this Agreement nor any disclosure of Information shall be deemed by implication or otherwise to vest in one Member any present or future rights in any patents, trade secrets or property rights in data belonging to another Member and no licence is granted except as explicitly stated in this Agreement.

Article VI. Organisation

1. Legal personality

This Agreement or 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 neither independent of its Members nor under its own name. Each Member appoints the Consortium Manager to act in the Consortium Manager's own name but on account of all Members concerned.

2. Committees

The bodies of the Consortium will be the Steering Committee and the Technical Committee(s).

In addition, in order to fulfill 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

1. 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.

2. The Steering Committee shall consist of one representative per Member (the **"representatives**"). Substitutes for representatives may also be appointed. Replacements of

representatives, proxies or substitutes shall be possible and shall be communicated in writing or electronically to the Consortium Manager who shall promptly advise the other Steering Committee members of the change. The representatives may be accompanied by external experts/consultants in meetings of the Steering Committee. The Chairman is the representative of the Lead Registrant. In case of multiple Lead Registrants within the Consortium, the representatives shall jointly elect a Chairman for a term of [1 year or more] and may elect a deputy Chairman.

Each Member is entitled to one vote in the Steering Committee. Decisions of the Steering Committee shall be taken by a simple majority of the voting representatives unless otherwise provided for in this Agreement. [*Decisions can be taken by the Steering Committee if at least half of its Members are present or represented/Decisions taken by the Steering Committee do not require any presence quorum*].

For an only representative as Member and in accordance with article III.2, the Consortium Manager will be informed of the number of non-EU manufacturers being represented by the only representative. For the purpose of equal voting, each non-EU manufacturer and its affiliates will have one vote and the total amount of votes of non-EU manufacturers will be allocated to the only representative.

Decisions of the Steering Committee can equally be adopted during a face-to-face meeting, a conference call or in writing, including email. In this latter case, a Member's failure to respond means approval of the decisions subject to approval, when no response is provided within a certain time to be defined on a case by case basis by the Steering Committee.

Upon unanimous decision, the Steering Committee is entitled to modify any provisions and Annexes to this Agreement.

A Member shall be excluded from voting in the event of a vote on the exclusion of that Member pursuant to Article III 5 or on matters in which he has no vested interest, including a vote on testing proposals which he is not required to provide for the purpose of registration and in which he does not intend to participate.

3. 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 inter alia the following:

   - Appointment of the Consortium Manager;

   - Decisions on funding, scope and matters of policy;

   - Appointment and directing the Technical Committee(s);

   - Decisions to carry out and on proposals for testing;

   - Decisions on working and finance plan and management of financial resources of the Consortium, including budgeting, funding collection and accountancy;

   - Decision on the appointment of external consultants to perform technical and scientific tasks;

   - Establishment of ad hoc task forces and/or an executive committee and its respective operational rules, whenever necessary, including for the development of Joint Registration Dossier required for each specific Substance covered by the Consortium [*or for the development of an application for Authorisation*];

- Approval of the Joint Registration Dossier to be submitted jointly to the Agency;

- Coordination and supervision of activities of the Consortium Manager and the Lead Registrant(s);

- Arbitration in cases of disagreement or disparities within the Technical Committee(s);

- Adoption of the technical decisions when there is no Technical Committee in place in the Consortium.

4. Meetings of the Steering Committee shall be convened as deemed necessary to review, on the basis of the technical and financial progress reports of the Consortium Manager and the progress relative to the work schedule and the budget.

Notice of each Steering Committee meeting and the agenda shall be transmitted to each Member by the Consortium Manager at least 7 days in advance.

No decision can be taken on an item which does not appear on the circulated agenda.

A Member who is prevented from attending may be represented only by another Member. One Member, however, may not represent more than [*one*] other Member. The written proxy shall be presented to the Consortium Manager, before the meeting.

5. Extraordinary meetings of the Steering Committee will be convened by the Consortium Manager at the request of the majority of the Members wherever the agreed deadlines or estimated budget are overrun or when other extraordinary circumstances occur. The Members of the Consortium shall have the opportunity on that occasion to consider their participation in the Consortium based on documented reasons.

4. Technical Committee(s)

1. The Technical Committee(s) shall consist of representatives by the Members and shall take decisions by [*unanimous / 2/3 / simple majority]* vote. The Members of the Technical Committee(s) shall jointly elect a Chairman for each Technical Committee who shall organise meetings and report to the Steering Committee.

2. The tasks of the Technical Committee(s) shall be directed by the Steering Committee and may include, inter alia, the following:

- Steering the technical work;

- Developing work plans;

- Delegating and directing sub-tasks;

- Selecting external consultants, if and when required and subject to approval of the Steering Committee;

- Proposing test plans to the Steering Committee;

- Executing approved test plans;

- Overseeing the progress – reporting deviations to the Steering Committee;

- Collecting and evaluating the Substance related Information to be shared;

- Giving input/ guidance to the Consortium Manager on the value of knowledge developed;

- Estimating financial resources required to comply with REACH requirements;

- Preparing the Joint Registration Dossier for registration, including the determination of data gaps, waivers and surrogate data as well as completion of data gaps in compliance with the legal requirements laid down by the REACH Regulation regarding data sharing;

- Collecting classification and labelling data from all Members and preparing harmonised classification and labelling in accordance with the GHS;

- Supervising performance of the testing;

- *[Option: Preparing CSR, if appropriate; in particular collecting and evaluating the uses and exposure scenarios.]*

5. Consortium Manager

Option 1 (external manager):
1. The appointment of the Consortium Manager is decided by the Steering Committee. He signs a separate agreement with each individual Consortium Member setting out the tasks and responsibilities listed below including a confidentiality obligation to ensure that it does not misuse any sensitive data it receives.

***Option 2 (company member of the consortium)*:**
1. The Consortium Manager is appointed by the Steering Committee among the Members of the Consortium.

The Consortium Manager is accountable to the Steering Committee.

2. The Consortium Manager shall be responsible for daily management and [*optional: 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:

- Proposing the working and finance plan;

- Organising and convening meetings, distribution of agenda and making minutes, archiving, and distribution of information;

- Keeping archives for a minimum period of twelve years and notifying the Members before the archive will be disposed of;

- *Optional and conditional (only when Consortium Manager is external)* Handling as independent third party of sensitive individual Information (production volumes, capacities, markets etc), acting therefore as Trustee where required;

- Supervising the external consultants and experts;

- Following up on progress in the technical activities of the Consortium and reporting on the technical and financial aspects;

- Providing technical and administrative support for the Technical Committee(s);

- Coordinating and providing guidance for data collection concerning the Substance(s);

- Performing sub-tasks as agreed by the Technical Committee(s);

- Processing of purchase orders/contracts for studies/work in line with the approved test plans;

- Handling financial matters and being responsible for the accounting, including budgeting, invoicing, keeping track of costs/value of information;

- Keeping an updated list of Members, including Affiliate(s) of the Members, and their representatives, and an updated list of Existing and New Studies. These lists shall be made available to the Members on simple request and free of charge;

- Communicating to organisations, associations and potential new Members.

3. The Consortium Manager shall, 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 account of the Members who are required to submit the Study according to their registration requirements. Only the Members who are required to submit the Study shall be listed as parties to the agreement and shall be liable for the expenses incurred.

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 Members, with the relevant provisions of REACH in this respect. [*Optional: In particular, the Member grants a limited power of attorney to the Consortium Manager to sign the SIEF agreement, whenever necessary, and any Letters of Access issued as confirmation to third parties for hand on behalf of the Lead Registrant(s) as representative of the members of the Consortium*].

6. Representation and activities in relation to third parties

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

7. Working language

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

Article VII. Lead Registrant

1. The Lead Registrant(s) shall be designated by the Steering Committee; the Lead Registrant shall accept such designation. The Lead Registrant is accountable to the Steering Committee.

2. If appointed as the Lead Registrant in the relevant SIEF, the Lead Registrant, with the assistance of the Consortium Manager and other Committees of the Consortium, shall prepare and submit to the Agency, in the agreement of and on behalf of the Consortium Members and their Affiliates and other members of the respective SIEF, and in the format specified by the Agency the Joint Registration Dossier [*optional: Chemical safety Report/ Guidance on safe use*] for the purpose of registering the substance at least two months before the deadline for registration applicable to the Member(s) within the highest tonnage band.

The Lead Registrant shall make available the Technical Dossier in IUCLID format, i5z file or updated formats (i.e. data referred to in Article 11 (1) paragraph 2 [optional - if CSR is included in joint submission: *and paragraph 4*] REACH that have to be submitted in the joint submission) [and when applicable the CSR as defined according to Article I of this Agreement], to the other Members of the Consortium, provided that they share the costs in accordance with the cost allocation method agreed upon under Section X and Annex 4 of this Agreement.

The Lead Registrant(s) shall pay its/their fee as invoiced by the Agency after submission of the Joint Registration Dossier without undue delay. The Lead Registrant(s) shall further inform without undue delay the other Members of the Consortium of the creation of the joint submission object in REACH-IT and shall provide the valid security token number and the name of the joint submission.

3 The Lead Registrant(s) shall forward in writing to the Consortium Manager, within 5 calendar days, any communication received either from the Agency or a Member State or any other authority regarding the joint submission.

4. The Lead Registrant(s) shall if so requested and approved by the majority of the Steering Committee participating in the joint submission for the Substance concerned, appeal any adverse decisions of the Agency or the Member States relating to the jointly submitted registration dossier.

5. The decision to either terminate or change the Lead Registrant(s) shall require a majority of two thirds (2/3) of the votes of the Members present or represented at the Steering Committee notwithstanding the right of the Registrant(s) to resign upon written notice to the Steering Committee with a notice period of six months. Such resignation, however, is only admissible if not endangering the Purpose of the Consortium.

The Lead Registrant has the right to terminate its functions as lead registrant under the cumulative conditions that:
-it has been validly replaced in its functions within the Consortium (and the SIEF);
-its assignee has accepted to be bound by the obligations of the Lead Registrant; and
-accessorily, the SIEF members have been notified about such replacement.

Article VIII. 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:

- Observe and comply with the provisions of this Agreement;
- Timely provide any available Information, including Existing Studies, on the Substance(s), [*optional: its applications and areas of use]* to the extent necessary for the Purpose;
- Allocate human and financial resources to the Steering and Technical Committees or to the Executive committee or other Task Forces having been established and relevant for the particular Member*;*
- Participate in the work of the Steering and Technical Committees;
- Fund the agreed work plans and other agreed actions;
- Inform the Consortium Manager of any significant change with respect to legal status or organization, in particular the names, addresses, representatives, affiliated companies and tonnage bands of Consortium Members.
- Keep the Chairman of the Steering Committee and the Consortium Manager continuously informed of a responsible contact person for the duration of this Agreement.

2. Each Member is responsible for observing its rights and obligations pursuant to the REACH Regulation, 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 information that is to be submitted to the Agency within the registration dossier in due time by each Member as well as any information communicated by the Members to customers, suppliers and other third parties, such as Safety Data Sheets.

Article IX. Competition law compliance

1. 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 (TFEU) as well as any applicable national laws. The Members explicitly agree to observe Cefic REACH competition law compliance guidance attached as Annex 2 to this Agreement.

2. Should it become apparent at any time that this Agreement, any provision of this Agreement, or any activity or decision of the Members of the Consortium, can have a potentially restrictive effect on open and fair competition, in breach of any statutory provision, each Member to this Agreement shall take immediate steps to remedy that situation.

Article X. Definition of costs and cost allocation

1. Valuation of Existing Studies

The value of Existing Studies made available by the 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 3.

2. Cost sharing principles

1. The following costs shall be shared between the Members:

a) Administrative expenses reasonably incurred by the management of the Consortium, including secretarial services, management of confidential data or external experts which have been approved by the Steering Committee. In case of multiple Technical Committees the administrative expenses shall be allocated to the individual Technical Committees and Members shall only participate in cost sharing for the Technical Committees they are members of. Any such costs shall not include any out-of-pocket expenses incurred by the Members unless approved in advance by the Steering Committee.

b) Acquisition of rights to Existing Studies valued under conditions specified above provided that the Member needs to submit the Study;

c) Costs for new Studies to be jointly developed according to Annexes VI to VIII of the REACH Regulation, provided that the Member needs to submit the Study and provided that no study will be initiated without a budget approved by the Steering Committee;

d) Costs for New Studies to be jointly developed pursuant to the evaluation of testing proposals by the Agency, provided that the Member needs to submit the Study and provided that no study will be initiated without the costs being approved by the Steering Committee.

taking into account that unless they would have an interest in acquiring additional Studies for other or future purpose, only the Members of the Consortium requiring Studies for their registration will need to share the related costs of the Studies, given that members of the Consortium are only required to pay for Studies they need and for the directly related administrative expenses.

2. Other costs incurred by the Members in the context of this Agreement shall not be compensated unless agreed by the Steering Committee.

3. Expenses referred to under 2. 1a) shall be allocated to the Members equally, among all Members of the Consortium when these administrative expenses are common or among the specific Members that register the related Substance(s) when the expenses are directly related to some specific Substance(s) only.

4. The expenses referred to under 2.1 b), c) and d) shall be allocated to Members in accordance with the cost allocation principles under Annex 4.

5. 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 of 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.

6. Indirect Taxes, including but not limited to Value Added Tax (VAT), Goods and Service Tax (GST), Service Tax, 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 purposes of indirect taxation.

Article XI. Administration & Reporting of costs

1. The Consortium Manager shall administer and keep records of all expenses incurred including allocation and cost-splitting as well as credits and present a costs overview to the Steering Committee on a monthly / quarterly basis.

2. The Consortium Manager shall administer invoices and the compensation payable to Members or from the Members based on their respective verification. The Consortium Manager shall keep records of the full value of the data obtained/generated.

3. Until disbursed pursuant to this Agreement, all the financial contributions made by the Members of the Consortium shall be maintained by the Consortium Manager in a Consortium specific cost centre approved by the Steering Committee, which preserve the principal while providing a reasonable rate of return. The Consortium Manager shall be responsible for making any disbursement relevant for the activities of the Consortium, subject to prior approval of the expense by the Steering Committee. All earnings shall be credited by the Consortium Manager to the cost centre common to the Members of the Consortium.

4. The Steering Committee shall base decisions on contributions and payments on the principle that provided Information shall be assessed and incurred costs shall be split in a fair, transparent and non discriminatory way.

5. Each year the Consortium Manager shall submit to the Steering Committee for approval the expenses of the past financial year and the finance plan for the following year.

Upon request of a Member [*and at its own expenses*], the Accounts of the Consortium may be subject to external and independent audit by an auditor designated by the Steering Committee...

6. When for appropriate reasons the finance plan agreed by the Steering Committee has to be increased, such finance plan increase shall be subject to prior approval by the Steering Committee at its next meeting.

7. A favourable vote of at least two-thirds (2/3) of the Members present or represented shall be required for all decisions concerning 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 Party having submitted a study which has been used in the Joint Registration 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 Party, these studies do not infringe on the rights, in particular, but without limitation, intellectual property rights, of any third party and (iii) that this Party has not received a claim or notice of any alleged infringement.

3. It is the individual responsibility of each Party to critically assess the Information that is generated or that is made available. Each Party assumes the full responsibility for its own use of the Information so developed or received. No warranty for acceptance by the Agency of the Joint Registration Dossier or any data it contains is given.

4. None of the Parties, including the Lead Registrant, shall be held liable for any direct, indirect or consequential loss or damage incurred by any Party in connection with the activities contemplated in this Agreement, unless caused by gross negligence or wilful misconduct. In particular, the Lead Registrant(s) shall not be held responsible and liable for delays in the submission of the Joint Registration Dossier, unless caused by gross negligence or wilful misconduct..

5. The Member who submits a Study to other Members will indemnify them in respect of any claims for unauthorised use or breach of the intellectual property rights of any third party relating to that Study.

6. Each Member shall be liable vis-a-vis third parties within the scope of its responsibility. The other Members of the Consortium shall support to the extent possible and reasonable, any Member against whom a liability claim has been made by a third party in its defence against such claim.

Article XIII. Duration, termination and amendments to the Agreement

1. This Agreement shall enter into force as from [../../..] The Consortium shall be formed for the duration necessary to achieve the Purpose or at the date corresponding to [*e.g. at the registration deadline for members with a lower tonnage band/ at the deadline for the authorities to evaluate the registration dossier/…..*].

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.

2. This Article and the provisions relating to the protection of confidentiality (Article IV), ownership and use of Information (Article V), dispute resolution and applicable law (Article XIV) and limitation of the liability (Article XII) shall survive the termination of this Agreement. With regard to the Studies, the obligations specified in Article IV of this Agreement shall survive for a period of twelve (12) years following the initial submission to the Agency by a Member. With regard to all other Information, the obligations specified in Article IV shall survive for a period of *[e.g. 3/5]* years after dissolution.

3. 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 cost centre. 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.

4. Amendments to this Agreement (which includes its Annexes) must be subject to a written amendment signed by any Member to be effective.

Article XIV. Dispute resolution and applicable law

1. The Members shall first attempt to settle amicably any dispute arising out of this Agreement.

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.

Should such amicable settlement fail, the dispute shall be resolved by arbitration, ousting jurisdiction by ordinary courts, by a panel of three arbitrators. Each party to the dispute will nominate one arbitrator. These two arbitrators will then designate a third arbitrator who will also act as chairman. The arbitration decision shall be binding on the parties. The arbitration rules of the [*e.g. CEPANI, ICC*] shall be applicable. The place of any hearing shall be .[*e.g. Brussels*] and the language of the arbitration shall be English.

2. This Agreement shall be governed by the laws of [*e.g. Belgium*].

3. 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.

4. 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	**For and on behalf of**
XXXXXXXX	**XXXXXXXXXXX**
Signature:_____	Signature:_____
Name:	Name:
Title:	Title:
Date:	Date:

For and on behalf of

XXXXXXXX

Signature:_____

Name:

Title:

Date:

For and on behalf of

XXXXXXX

Signature:_____

Name:

Title:

Date:

List of Annexes:

1. Substance identification

2. Guidance on competition compliance

3. Value of studies – valuation rules

4. Cost allocation

5. Model Declaration of Accession

Annex 1

Substance identification

The Substance(s) covered by this Agreement is/are following:

[*define as precisely as possible each category of the substance, each substance, including impurity and where necessary production process*]

[*provide all the information required by REACH Regulation to identify the substance, including IUPAC name, CAS, etc*]

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Annex 2

Guidance on competition compliance

Cefic REACH
guidance DO & DON'T

Annex 3

Value of studies – valuation rules

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

REACH requires that the data submitted in the registration is "relevant and has sufficient quality to fulfil the requirements" (Step 3 in Annex VI on information requirements). Pursuant to Article 13 paragraphs 3 and 4:

- the test methods to generate information on intrinsic properties of substances should be in accordance with the test methods laid down in Council Regulation EC/440/2008 or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate
- the ecotox and tox tests and analyses shall be carried out in compliance with the principles of good laboratory practice (Directive 2004/10) or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609 if applicable.

The responsibility for the quality of data remains always with the registrant. In this context it should be noted that in case of joint submission several potential registrants of the same substance should jointly decide on the key studies to be included in the lead registrant's file. If the potential registrant does not agree with this selection, he has the possibility to opt out upon valid justification according to article 11.3 REACH, e.g. if he considers the data of insufficient quality or on the contrary if he finds that selected data are of unnecessarily high standard (and too costly) at least for his application (see page 81 of ECHA Guidance on data sharing).

The choice of the evaluation rules and the responsibility for this choice will remain with the Members of the Consortium.

ECHA Guidance on data sharing takes as a basis Klimisch rating[3] (adequacy, relevance and reliability). The valuation rules described below have been based on ECHA Guidance on data sharing recommendations and rules previously developed in practice[4]:

[3] H.-J. Klimisch, M. Andreae, and U. Tillmann, A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data, Regulatory Toxicology and Pharmacology 25, 1-5 (1997)
[4] www.cesio2004.de

The following rules apply for the valuation of the studies, test data and other information i) contributed by consortium members to the consortium, ii) generated or established by the consortium, which together with the aforementioned information are made available to new parties.

a) The aforementioned studies are initially evaluated with respect to their scientific value. In a second step, their financial value is calculated through the use of various mark-ups and deductions.

b) The object of the valuation is to ensure that adequate compensation is paid to the report owner for the provision of preliminary services and that the recipients' requirement for high quality information is satisfied.

1. Scientific Evaluation

1.1. For reports, which are contributed by individual members of the consortium, the supplier provides the consortium with the report itself and existing and available summaries in the form of an IUCLID data set and a robust summary. The robust summary may also be integrated into the IUCLID data set.

1.2. The quality of the reports is determined by the Technical Committee, or experts commissioned by the latter, in accordance with the Klimisch et al. method by classifying the report into one of the following categories: (1) reliable without restriction, (2) reliable with restrictions, (3) not reliable, (4) not assignable.

1.3. The allocation to the four categories must be accompanied by appropriate substantiation in accordance with the requirements described in the chapter "Documentation of reliability categories in data sheets (IUCLID)" of the Klimisch et al. publication.

1.4. The quality of the robust summaries and IUCLID datasets is determined by the Technical Committee, or experts commissioned by the latter.

1.5. If the documents (IUCLID data set and/or robust summary) submitted by a party supplying a report are not in conformity with the state of the art or missing the Technical Committee or experts commissioned by the latter, should develop a robust summary and an IUCLID update.

1.6. Also studies, for which no standard protocol exists, e.g., exposure studies, must be documented by an IUCLID data set and a robust summary, and are also to be evaluated under the Klimisch et al. method.

2. Financial Valuation

2.1. From a scientific viewpoint, reports in category (1) “reliable without restriction" and (2) “reliable with restrictions" qualify for financial compensation, whereas reports in categories (3) “not reliable" and (4) “not assignable" are deselected from the subsequent procedure. This does not mean that the information contained in reports from the latter two categories is classified as useless. Rather, the owners are asked to make such information available free of charge.

2.2. The assessment basis for determination of the financial value of a given report is the replacement value of the report as of the valuation date. Included in this value are expenses for setting up the test ,e.g.:

- Preliminary testing for determining test concentrations
- Substance testing according to the standard protocol
- Development of suitable analytical methods
- Supplementary analyses
  i) Substance characterization
  ii) Stability in test medium
  iii) Concentration in test medium
- Administrative expenses, e.g.:
  i) Processing and professional support by the commissioning party
  ii) Travel expenses
  iii) Archival of the test substance and raw data
  iv) Preparation of IUCLID data set and robust summary.
- The calculation only includes expenses, which are documented by verifiable documentation or, if such documentation is not available, expenses that can be justified with sufficient plausibility.

2.3. The expenses for preliminary testing and substance testing according to the standard protocol are calculated as the arithmetic average of the prices charged by the following three European testing institutes according to their price lists:

- Testing Institute A
- Testing Institute B
- Testing Institute C

If a price for a certain test is not available from any of the above institutes a price will be asked from another institute as decided by the Technical Committee.

The relevant end point is subjected to the customary standard procedures valid as at the valuation date. Special conditions, such as those granted when commissioning larger contingents, are not taken into account.

2.4. In cases of testing for inherent substance properties, the limitation (2) "reliable with restriction" arises mostly from the fact that the study was conducted at a date prior to the introduction of the GLP standards. The deduction is determined from the difference presented in the price lists of institutes or to be inquired there.

2.5. Deductions due to other deficiencies can be evaluated only on a case-by-case basis. The total deduction should not exceed 20% of the price of the standard test The following should serve as a guidance:

- Non-GLP, a reduction with 20%
- A study classified as a Klimisch 2 study due to deficiencies which could have been overcome with a reasonable effort should have its value reduced with up to 20%.

2.6. For surveys, which are not supported by any standard test protocols, the party supplying the report should provide a document with an overview of the process steps, including the expenses and the time required (working days, costs per working day), such as:

- Development of study concept
- Exploratory studies
- Performance of the study
- Analyses
- Expenses for further contractors
- Administrative costs (see 2.9).

The individual positions are to be presented and justified with sufficient plausibility.

2.7. The calculation of expenses for substance analysis, for which no market prices are available, requires the following information from the party supplying the report for each analytical procedure:

- Brief description of the procedure or method, including the limit of detection

- Estimated costs for the development or provision[5] of the procedure or method
- Costs per analysis
- Number of analyses performed
- The development and provision costs can also be included in the costs for each analysis.

2.8. Robust summaries contributed by the supplier or developed by experts commissioned by the Technical Committee(s) should be compensated by 30% of the value of the admin costs according to 2.9.

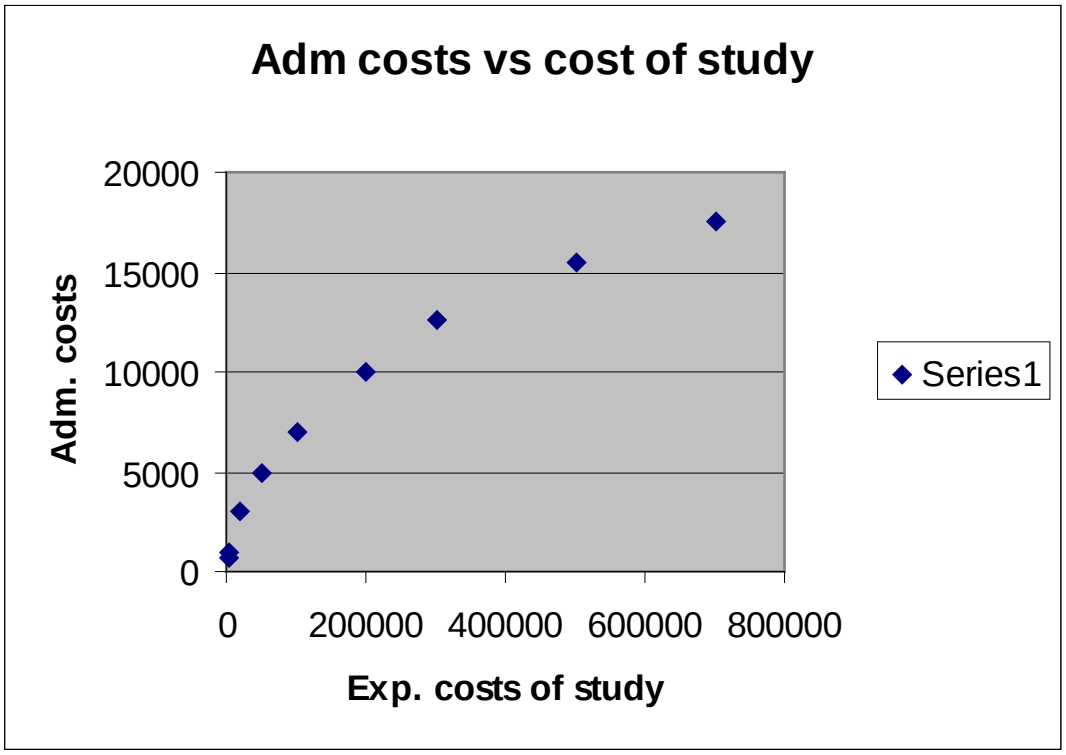
2.9. A surcharge to the sum total of experimental costs (substance testing and analysis) is charged for administrative expenses (processing, monitoring and professional support by the commissioning party, travel expenses, archival of the test substance and raw data). The surcharge depends on the experimental value of the study according to Attachment 3b. In the case of significant amounts in excess of the above surcharge, the expenses are to be substantiated and documented individually.

2.10. The decision to conduct a study involves the risk that the study results could adversely affect or prevent future substance marketing; hence, the individual member contributing a report to the consortium was exposed to the risk that the investments made in the study are of minor or no benefit. The other members of the consortium, new parties or parties wishing to acquire a specific study are not exposed to this risk since they already know the study result. Therefore, the contributing member(s) is granted a fixed surcharge of 30% of experimental costs.

2.11. The current value of a given report is comprised of the experimental and administrative expenses, as well as the risk premium specified above.

[5] Provision of analytical procedure or method includes the measures required for testing a method known from the literature for compatibility with the intended use.

Surcharge to the total experimental costs for administrative expenses according to 2.9.



Study value	Adm	Adm %
3000	750	25.00%
5000	1000	20.00%
20000	3000	15.00%
50000	5000	10.00%
100000	7000	7.00%
200000	10000	5.00%
300000	12600	4.20%

Annex 4

Cost allocation

The REACH Regulation requires that costs for existing 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. ECHA Guidance on data sharing indicates that the possible mechanism may include:

1. Sharing data equally, based on the number of parties involved;
2. Proportionally, based on production or sales volume or otherwise;
3. Alternative mechanism using part of the above models in different mode.

For more detailed guidance please refer to the section on cost sharing in ECHA Guidance on data sharing and its Annex 5 for comprehensive cost sharing examples.

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

i) Compensation for the resources necessary for the examination of the new member's application, in the form of an application fee;

ii) Compensation for the time and efforts incurred by the existing members for the formation and functioning of the consortium (amount fixed ex aequo et bono)

iii) Compensation to owners of existing data taken into consideration for the identification of the data to be included in the Joint Registration Dossier

iv) Compensation for new data developed by the consortium

v) Compensation for risk taken in developing new studies (risk premium)

vi) Compensation for the administrative expenses to date it is entering the Consortium;

vii) Compensation for the expenses related to the technical work and the development of the Joint Registration Dossier for the year it is entering the Consortium;

viii) Compensation for the lack of return of funds allocated in the past by the members to the development of new data

ix) An interest adjustment for some of the above compensations (e.g. equivalent to the annual average interest rate as per the London Interbank Offered Rate (LIBOR).

Equal sharing within Volume Bands:

The following calculation describes a case where there are 2 studies available in a SIEF with 4 participants.

- The first (Study 1) contains physical chemical data which is required by all four SIEF participants.

- The second (Study 2) contains exposure assessment data which is only required by potential registrants in the >100t and >1000t volume bands.

We assume in this case the owner of Study 1 is SIEF Participant A and the owner of Study 2 is a third party which does not have any obligation to register the substance under REACH. The value of the study 1 has been calculated to be 20,000 € and the value of Study 2 has been calculated to be 100,000 €.

In order to demonstrate the volume impact of the SIEF participants, the following set of illustrative volume band factors is introduced.

SIEF participant A has a volume > 1000 tonnes, SIEF participant B has a volume between 100-1000 tonnes, SIEF participant C and D have volume bands 1-100 tonnes.

	Volume Range	**Required studies**
Company A	>1000	1 + 2
Company B	100 - 1000	1 + 2
Company C	1 – 100	1
Company D	1 – 100	1

Using the principle of equal cost sharing within volume bands, allocations are as follows:

Participant	Volume (ktonnes)	Contribution to Study 1	Contribution to Study 2 (K€)	Total Contribution
A	> 1000	-15	50	35
B	100 - 1000	5	50	55
C	1 - 100	5	0	5
D	1 - 100	5	0	5
Totals		0	100	100

Annex 5

Model Declaration of Accession

The Company:

Name
Address/ seat of incorporation
Represented by

Hereby declares that wishes to join as Member the present Consortium Agreement pursuant to REACH legislation, dealing with the Substance(s) and thereby recognizes by signing this Declaration of Accession that it is bound by the terms and conditions set out in the consortium agreement as of [*date*].duly signed by the parties listed in the attachment to this declaration (the "Consortium Agreement").

The Company thereby recognizes by signing this Declaration of Accession that, as of [*insert date i.e. the date from which this new joiner is bound*], it is bound by the terms and conditions set out in the Consortium Agreement applying to a Member, and by any service provider agreements entered into by the Members of the Consortium or by the Consortium Manager of the Consortium acting in its own name and on account of the Members.

[*Affiliates*], [*Exclusive Toll Manufacturers and*] external experts/consultants of the Company are not regarded as third parties for the purpose of Confidentiality obligations under such agreements and are bound by confidentiality agreements/obligations with the Company covering the same level and scope of confidentiality.

The application of the terms and conditions of the Consortium Agreement means that the company will obtain the unlimited rights and obligations of a Member of the Consortium upon payment of the amounts as defined in Section [….] of the Consortium Agreement.

Date
Signature