# Sulfur Dioxide Based Chemicals REACH Consortium (SDIOC)

Bylaws to the contract for the formation of the SDIOC EEIG

(hereafter 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)<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> OJ L 136 of 29.5.2007

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# PREAMBLE

Whereas the Members are manufacturers, importers or 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) defined by the SDIOC Reach Consortium in Annex 1 of this Agreement, on its own, in preparations or in articles with registered offices in the European Economic Area (EEA).

Whereas the Substances have phase-in status according to Article 3 (20) of the REACH Regulation and each of the Members intend to pre-register 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 provides for extended registration deadlines of phase-in substances if a pre-registration is completed before 1 December 2008.

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:

**Substances:** SDIOC substances 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, including:

manufacturers/ importers/ only representatives 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 and who participate in the Consortium.

**Associates:** Downstream Users as defined in the REACH Regulation/Industry associations/ Manufacturers not established within the European Economic Area/ third parties holding information on the Substance (Data owners), who are not subject to the registration requirements but have an interest in contributing to the achievement of the Purpose as defined in Article II and whose participation in the Consortium has been approved by the Steering Committee as specified in Article III of this Agreement.

**Affiliates:** Any legal entity controlling, controlled by, or under common control with a Regular Member. For these purposes, "control" shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting rights, by contract or otherwise; or (ii) the ownership, directly or indirectly, of 50 % or more of the voting rights.

**Deadlines for registration:** The date by which the Substance should be registered at the latest as specified in Article 23 of the REACH Regulation, as specified in Annex 8.

**Effective date:** the date upon which the last of the Members listed on the front page of this Agreement signs the present Agreement. If one or more Members fail to sign the Agreement within 60 (sixty) days after the date of signature by the first Member, the Agreement shall continue among those Members who signed by said date, which shall then become the Effective Date.

**Lead Registrant:** the Regular Member responsible for coordinating the corresponding Task Force. The Lead Registrant acts within the decisions of a Steering Committee. The Lead Registrant is also responsible for executing, supervising and coordinating, as the case may be, all acts necessary to achieve joint submission of the Core Data for the substance for which the act as Lead Registrant to the Agency on behalf of the respective Members and SIEF members, and comply with the relevant provisions of REACH. Lead Registrants may be potentially replaced by a new regular member if both parties agree on this and the majority *vote* of the Steering Committee is achieved (see Article VII Lead Registrant).

Steering Committee: decision- making body of the Consortium.

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

**Task Forces:** groups of Member's experts established per substance by the Technical Committee to carry out a defined technical task or tasks under the supervision of the corresponding Lead Registrant.

**REACH manager/secretariat:** natural or legal person responsible for daily management of the Consortium, appointed by the SDIOC EEIG and hereby acting within the decisions of the SDIOC EEIG and who has signed an agreement with each individual Consortium Member setting out its tasks and responsibilities and which includes a confidentiality obligation to ensure that it does not misuse any sensitive data it receives.

**Trustee<sup>2</sup>:** An independent third party who in view of the exchange of sensitive individual data, is appointed by the Steering Committee and who is a legal or natural person not directly or indirectly linked to a Member. 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 Effective date ("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.

**Core Data:** 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 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;

<sup>&</sup>lt;sup>2</sup> Trustee: see also Annex 7, 3.3

The scope of the Core Data shall fulfil the requirements of the REACH Regulation applicable to the Regular Member manufacturing or importing within the highest tonnage band of the Substance.

The Core Data also include

- the Chemical Safety Report (CSR) 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, with due regard to the restrictions that Competition Law places on these discussions.
- the Guidance on safe use of the Substance as specified in section 5 of Annex VI of the REACH Regulation.]

Letter of Access: a letter as set out under Annex 5 granting the rights to refer to a Study submitted to the Agency.

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 Core Data for the Substance, based on the highest tonnage band within the Consortium and 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 waivers;

e) Subject to obligations under Art. 30 of REACH Regulation carrying out of 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, 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;

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 defined by the Task Force dealing with the specific Substance. For the purpose of this Agreement, identified uses are limited either to uses common to all interested Members or to uses typically occurring on the market. The list of identified uses will be subject to Steering Committee approval. The list will be kept by the REACH manager/secretariat.

j) Performing a risk assessment according to the scientific principles as agreed by the Technical Committee 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 Core Data for the purpose of Registration to the Agency by the Lead Registrant on behalf of the Members and the EEIG, their Affiliates at least three (3) months before the deadline for registration applicable to the Regular Member(s) within the highest tonnage band, regarding the specific substance in question. In order to have the Core Data submitted on behalf of their Affiliates, the Regular Member concerned notifies the names and addresses of its Affiliates to the REACH manager/secretariat in writing at least thirty (30) days before submission of the Core Data, so the Lead Registrant is able to include the names and addresses in the registration dossier as required in Annex VI Section 1.2 of the REACH Regulation. Each Member may, at his own discretion, decide to opt out from the joint submission.

4. 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. Development of collective comments under the procedure for inclusion of substances in Annex XIV of the REACH Regulation.

6. Where required, preparation of the application for the authorization, pursuant to Title VII of the REACH Regulation, including development of common scientific arguments.

7. Addressing technical and legal issues in relation to the Purpose.

8. Exercising the rights to the Studies in accordance with Articles IV and V of this Agreement.

## **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. REGULAR MEMBERSHIP**

Regular 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.

## **3.** Admission of New Regular Members

- 1. Any application for Regular Membership shall be in writing and shall be sent to the REACH manager/secretariat. The admission of a new Member shall be Subject to the unanimously *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 Regular Membership criteria specified above and has committed to pay the financial contribution referred to below.
- 2. Each new Regular 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) 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 Regular Member shall refund a share of costs only for the Studies he is required to submit within his tonnage band, and

b) 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 2 months. The non admitted applicant may be offered by the Members of the Consortium the access to the Studies or Core data 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 5.
- 4. A new Regular Member shall fully adhere to the terms and conditions set out in this Agreement. Upon accession to the SDIOC EEIG and as of payment of the capital contribution, the new Member shall have the same rights and obligations as any existing Regular Member.

## 4. ASSOCIATES

Associate cooperation shall be open to any Downstream Users as defined in the REACH Regulation/ Industry associations/ Manufacturers not established within the European Economic Areal, third parties holding information on the Substance (Data owners), who are not subject to the registration requirements but have an interest in contributing to the achievement of the Purpose as defined in Article II.

Any Associate Member established outside the European Economic Area must appoint a natural or legal person established in the Community as his representative in the Consortium.

## **5.** Admission of New Associates

- 1. Any application for Associate cooperation shall be in writing and shall be sent to the REACH manager/secretariat. The admission of a new Assotiate shall be subject to the 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 conditions specified above and has committed to pay the financial contribution referred to below.
- 2. Associates shall contribute to the administrative costs incurred by the Members in the context of the Consortium in a fair and transparent proportion determined by the Steering Committee and on an equal share basis and as described in Annex 4.

## **6. 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 100 % 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 one (1) month 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. This also applies to potential financial claims.
- 2. A Member shall be entitled to transfer its rights and obligations under this Agreement under the conditions of § 1 Sec.5 of the EEIG contract: i) to an Affiliate or ii) to a new legal entity in the case of restructuring within a group of companies or the division, demerger or sales of a branch of activities, to the extent that the new entity is or includes a restructured, merged, sold, or demerged entity or branch of activities that is in all respects a functional equivalent of the original Member to this Agreement. To the extent that the Member that sold or demerged a division or branch of activities continues to be subject to registration obligations for any Substance under the REACH Regulation, such Member shall also continue to be a Member.
- 3. In case a Regular Member transfers one or more of its affiliates to another Regular Member and in case the Regular Member who transfers the affiliate would not be any more involved in the production or import of one or more substances, being those substances already produced or imported by the Regular member who buys the affiliate, the Regular Member who transfers the affiliate shall not maintain the obligations associated with the substances in which production or import that member would not be any more involved, namely the obligations related with the costs of studies connected with those substances. It is

understood that after the transfer of its affiliate, the regular Member shall cease to have any rights arising from this Agreement regarding the substances that the Regular member ceases to produce or import.

At the same time, the Regular Member who buys the affiliate shall have no new obligations and support no additional costs if the new affiliate produces or imports substances which that Regular member already produces or imports.

- 4. The consent of the Steering Committee shall not be required in case of an anti-trust authority approved merger, acquisition or group formation of any two or more of the named Members of the Consortium. The Membership shall be transferred to the new legal entity which is the result of the approved merger. The Members shall inform the Steering Committee of any change in writing immediately to update the Affiliated Company's structure. The Members shall be regarded thereof as only one Member concerning the obligations of the cost sharing principles of Article X and Annex 4 and act thereof as only one Member in voting rights.
- 5. The Member shall notify the REACH manager/secretariat by registered letter at least 60 days before the transfer of membership.

## 7. WITHDRAWAL

At any time, a Member can terminate its membership in the Consortium under the conditions of § 17 of the EEIG contract.

#### 8. 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 REACH manager/secretariat 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* 81 *and* 82 of *the EC Treaty* (Annex 2). The defaulting Member shall have the right to present its defence to the Steering Committee before a final decision is taken. The written decision of the Steering Committee shall be immediately (not later than 7 calendar days after the decision is taken) notified to the Member by registered mail and the exclusion shall be *effective* upon the date of receipt of this letter.

#### 9. 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. The exiting Member is entitled to a compensation based on Article 33 of the EEIG regulation.

- 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, except as otherwise agreed by the Steering Committee.
- 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 may 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 10 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. Each Member shall have in place policies and procedures to ensure the confidentiality of Information, and require that its external experts and/or consultants also have such policies and procedures in place to ensure their compliance with these confidentiality obligations.

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 Mernber's Information, as evidenced by documentary records,
- e) becomes subject to disclosure to governmental agency/ authorities with lawful authority to seek such Information.

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. External experts and/or consultants (if bound by a confidentiality agreement) of any Regular Member and their Affiliates 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. 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.

# ARTICLE V. OWNERSHIP AND USE OF INFORMATION

1. Within 4 weeks of the entry into effect of this Agreement, or within 4 weeks after joining the Consortium subsequently to the entry into effect of this Agreement, all Members or Associates shall make available to the REACH manager/secretariat a list of their Existing Studies and hard or electronic copy of these Studies for substances of interest to that Company. The REACH manager/secretariat shall make a list of these Studies and shall make the necessary arrangements for the review of these studies by the Technical Committee.

2. Any intellectual property or ownership rights to any existing Information independently developed by a Member or any third party 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 the non-transferable right to use the Information for complying with the requirements pursuant to the REACH Regulation, including the right to refer to the full Study

report, provided that they share in its cost in accordance with the cost allocation method agreed upon under Article X and Annex 4 of this Agreement.

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

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.

In case of admission of new Members usage rights as defined in sentence 2 above shall be granted to new Members by the REACH manager/secretariat who is entitled to do so by the respective Members owning the Study

3. With regard to any new Information generated or developed jointly by the Members or the EEIG pursuant to or in the course of this Agreement, the REACH manager/secretariat shall transfer ownership rights received from the study originator to the EEIG. Subsequent transfer to the Members is possible by the EEIG 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 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 own 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 remaining owners who have financially contributed to the costs thereof unless otherwise agreed by the Members.

In case of admission of new Members, ownership rights shall be granted to the new Member by the EEIG who is entitled to do so by the Members jointly owning the Study.

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.

5. Upon request, Associates and any potential registrants of the Substance, including the applicants for the Regular Membership whose application was refused may be granted a non-exclusive and non-transferable right to use or to refer to the parts or all of the Core Data including to particular Studies to the extent the Members of the Consortium are entitled to do so.

The Steering Committee shall take a decision whether or not to grant such rights and determine the amount of compensation payable in accordance with Article X and Annex 4 by a 75% majority of the Members present or represented without undue delay. The REACH manager/secretariat shall provide the requesting party the proof of cost within four weeks of the decision of the Steering Committee. The REACH manager/secretariat shall issue a Letter of Access (Annex 5) within six weeks of receipt of payment of the compensation.

The terms and conditions of access will be set out in each case specifying the exact scope in accordance with the Letter of Access attached in Annex 5 to this Agreement.

6. 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

#### **2.** BODIES OF THE CONSORTIUM

The bodies of the Consortium will be the Steering Committee and the Technical Committee. 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 Regular 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. Where decisions must be taken on short term, a time-restricted email voting system will operate, according to rules devised by the Steering committee.
- 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 REACH manager/secretariat 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 REACH manager/secretariat shall maintain a list of the representatives per Member Company and the Members shall notify the REACH manager/secretariat of any change in this list without due delay. The representatives shall jointly elect a Chairman for a term of 1 year 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 concerning the following aspects, provided that at least half of its Members are present or represented, shall always be adopted on the basis of a majority vote (75 %) of the Steering Committee unless otherwise set forth in this Agreement:

- Designation of the Lead Registrant per substance,
- Approval of the Core Data to be submitted to the Agency, following recommendation of the Technical Committee;
- Exclusion of a Member;
- Appointment of the Trustee if necessary for compliance with competition law;

- Decisions on the admission to the Consortium of a new Member or Associate and determination of the financial contribution of such new Member or Associate.

Upon unanimous decision, the Steering Committee is entitled to modify Annexes 1-6 to this Agreement. Lists of 1) names and addresses, representatives and tonnage bands of consortium members, 2) Affiliated companies of regular members and 3) Existing studies provided by consortium members are maintained by the REACH manager/secretariat, according to any changes notified to the REACH manager/secretariat by the Member concerned.

A Member shall be excluded from *voting* in the *event* of a conflict of interest, in particular from *voting*, on the exclusion of that Member pursuant to Article III, 8 or on matters in which he has no *vested* interest, including a *vote* on designation, termination or change of the Lead Company, which he is not required to provide for the purpose of registration and in which he does not intend to participate.

Associates are allowed to participate in the meetings of the Steering Committee without any *voting* rights.

- 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 a REACH manager/secretariat, Technical Committee as well as Task Forces where appropriate;
  - Decisions on funding, scope and matters of policy;
  - Directing the Technical Committee;
  - Decisions on working and finance plan and management of financial resources of the Consortium, including budgeting, funding collection and accountancy;
  - Appointment of external consultants to perform technical and scientific tasks;
  - Coordination and supervision of activities of the REACH manager/secretariat;
  - Arbitration in cases of disagreement or disparities within the Technical Committee;
  - Decisions on admission to the Consortium of new Regular or Associate Member and determination of the financial contribution of such new Member;
  - Decision on the exclusion of a Member;
  - Appointment of a Trustee, although the role is normally fulfilled by the REACH manager/secretariat.
- 4. Meetings of the Steering Committee shall be *convened* only as needed and at least once a year to review, on the basis of the technical and financial progress reports of the REACH manager/secretariat 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 REACH manager/secretariat at least 14 days in advance.

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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 REACH manager/secretariat, before the meeting.

- 5. Decisions by the Steering Committee may exceptionally be made in writing, and transmitted by electronic mail, on the initiative of the REACH manager/secretariat. Technical Committee/Task Force/Majority of the Regular Members when a decision cannot be deferred until the following meeting of the Steering Committee but is not sufficiently important to justify an extraordinary meeting of the Steering Committee. Except in urgent cases, replies must be given to the REACH manager/secretariat, within 14 days of the date the written consultation was sent. The absence of the reply within this period shall mean acceptance. Any decision taken by written consultation shall be submitted for confirmation at the subsequent Steering Committee meeting.
- 6. Extraordinary meetings of the Steering Committee will be convened by the REACH manager/secretariat at the request of the majority of the Regular 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. EXECUTIVE COMMITTEE**

The Steering Committee retains the right to appoint an Executive Committee, if needed. Any decision to do this shall include definition of the role, composition and procedures, such as: appointment of members, voting rights and decision-making process, frequency of meetings and accountability to the Steering Committee.

#### **5. TECHNICAL COMMITTEE**

- 1. The Technical Committee shall consist of at least five representatives nominated by the Steering Committee and shall take decisions by 75% majority vote. The representatives may be accompanied by external experts/ consultants in meetings of the Technical Committee. The Members of the Technical Committee shall jointly elect a Chairman who shall organize meetings and report to the Steering Committee.
- 2. The tasks of the Technical Committee shall be directed by the Steering Committee and may include, inter alia, the following:
  - Steering the technical work, within budget approved by the Steering Committee and within the substance/Member Company combinations;
  - Decisions to carry out and act on proposals for testing;
  - Developing work plans;
  - Delegating and directing sub-tasks;
  - Decisions on coordination of and guidance for data collection concerning the Substance;
  - Selecting external consultants, if and when required;

- Approval of test plans proposed by the Lead Registrant;
- Overseeing the progress of contracted work and reporting outcomes/progress/deviations to the Steering Committee;
- Giving input guidance to the REACH manager/secretariat on the value of knowledge developed;
- Estimating financial resources required to comply with REACH requirements;
- Overseeing the preparation of the Core Data 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;
- Forwarding for approval of the Core Data to be submitted for approval to the Steering Committee. Individual lead companies will be responsible for overseeing the progress of the substances for which they are responsible, and for the submission of joint dossier to the Agency; as well as determination of the Information which shall be subject to a request for confidentiality according to Article 119 of the REACH Regulation.
- Approving CSRs, if appropriate; as prepared by the Lead Registrant, in particular collecting and evaluating the uses and exposure scenarios, to the extent allowed by competition law.
- Establishment of Task Forces where appropriate
- 3. The meeting of the Technical Committee shall be convened by the Chairman of the Technical Committee as needed to review the progress relative to the work schedule and the budget. Each Technical Committee shall be attended by the REACH manager/secretariat, who will draft the minutes and provide them to the Steering Committee.

## 6. TASK FORCES

- 1. In order to pursue the Purpose of the Consortium, the Technical Committee may establish Task Forces, whenever necessary, including for the development of Core Data required for each specific Substance covered by the Consortium, or other tasks such as: prepare harmonised classification and labelling, prepare proposals for further testing and data gathering, advise on the selection of external laboratories to conduct the testing programme, supervise performance of the testing programme, advise on potential new Members to join the Task Force.
- 2. The Steering Committee shall approve the scope, composition and budget of the Task Forces in writing.
- 3. Each Task Force shall be chaired by one of its members (the Lead Registrant) appointed for such task by the Steering Committee. The representatives of the Members may be companied by external experts/ consultants in meetings of the Task Forces. The Task Forces may rely on the REACH manager/secretariat to assist in the work which is entrusted to them, provided that the costs involved fall within the budget of the Task Force as approved

by the Steering Committee. The burden of work is importantly shared among other companies with the same substance of interest.

- 4. The tasks of the Task Forces may include, inter alia, the following:
  - Executing approved test plans, or directing the execution of such;
  - Collecting and evaluating the Substance related Information to be shared;
  - Collecting classification and labelling data from all Members and preparing harmonised classification and labelling in accordance with the Global Harmonised System (GHS);
  - Supervising performance of any required testing

# 7. REACH MANAGER/SECRETARIAT

- 1. The REACH manager/secretariat shall be designated as consortium manager by the Steering Committee. The REACH manager/secretariat is accountable to the Steering Committee.
- 2. The REACH manager/secretariat shall be responsible for daily management and shall at all times act in the best interests of the SDIOC EEIG and its Members. For such purposes, the REACH manager/secretariat may make use of own staff or further external service providers. All contracts with further external service providers, including laboratories, to perform technical and scientific tasks, shall, upon prior approval of the Steering Committee, be concluded by the REACH manager/secretariat in its own name and on account of the SDIOC EEIG.
- 3. The REACH manager/secretariat 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:
  - a. Day-to-day management of the Consortium
  - b. Structuring and responsible handling of the Consortium's organisational, administrative and financial matters relating to REACH
  - c. Ensuring compliance with the work programme under the guidance of the Steering Committee in compliance with the Consortium Agreement and the Consortiums' Internal Rules.
- 4. Specific duties
  - a. Establishment of a list of Inorganic Sulfur Substances which require registration together with the tonnage band for each applicant, in order to establish the final data and registration requirements per substance
  - b. Identification of representative samples per substance, for the purpose of experimental testing
  - c. Coordination and supervision of the compilation of all registration dossiers, including:
    - facilitating communication between consultants and Consortium members in collating ancillary documents

- ensuring timely submission of draft documents to each concerned Consortium Member for review/comments
- d. Preparation of work plans and implementation of agreed strategies
- e. Compilation of research, consulting and administrative budgets for each calendar year, as well as overall supervision of budget compliance
- f. Organisation of data collection process and research programmes acc. to agreed strategies, including:
  - supervision over (i) collection and evaluation of all existing data, and (ii) data entry to IUCLID 5
  - coordination of consultancy projects targeted at data gap analyses relating to REACH requirements
  - establishment of strategies to overcome data gaps and development of exp. testing proposals together with the consultants
  - ensuring that adequate chemical safety assessments and chemical safety reports, including hazard assessment and exposure assessments are prepared by the contracted consultants
- g. Organisation and coordination of reporting by the consultants and other involved experts to the steering committee
- h. Organisation of the necessary communication, as follows:
  - reporting to the Steering Committee
  - keeping members updated regarding the current situation
  - organisation and preparation of meetings of the Steering Committee and Consortium Committee, including provision of agendas and recording the minutes of all meetings
- i. Coordination (if applicable) of efforts required for potential authorisation procedures for particular Inorganic Sulfur Substances
- 5. Administrative support including financial matters and accounting
  - the financial administration including accounting will be provided outside of the REACH manager/secretariat, namely by the AXER Partnerschaft in Cologne.
- 6. The REACH manager/secretariat shall, upon prior approval of the Steering Committee, 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 tonnage band.

## 8. 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 REACH manager/secretariat. The REACH manager/secretariat shall act with respect to the third parties in the name and on the account of the EEIG.

# **9. WORKING LANGUAGE**

The working language of the Consortium shall be English.

# ARTICLE VII. LEAD REGISTRANT

1. A Lead Registrant shall be appointed for each substance by the Steering Committee. A Member can refuse to be Lead Registrant for several substances. The decision to either terminate or change the Lead Registrant shall require a majority of 75% of the votes of the Members present or represented at the Steering Committee in line with the provisions laid down in Article VI 3.2 of this Agreement. The Lead Registrant has the right 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.

2. The Lead Registrant, with the assistance of the REACH manager/secretariat and other bodies of the Consortium, shall prepare and submit to the Agency, in the agreement of and on behalf of the EEIG and their Affiliates and other members of the respective SIEFs and in the format specified by the Agency the Core Data for the purpose of registering the substance at least three (3) months before the deadline for registration applicable to the Regular Member(s) within the highest tonnage band.

# 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 [and other Consortium bodies]:
- Participate in the work of the Steering and Technical Committees;
- Fund the agreed work plans and other agreed actions;
- Inform the Chairman of the Steering *Committee* / REACH manager/secretariat of any significant change with respect to legal status or organization;

- Keep the Chairman of the Steering *committee* / REACH manager/secretariat continuously informed of a responsible contact person for the duration of this Agreement which hence leads to an update of the representatives list maintained by the REACH manager/secretariat.

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 81 and 82 EC Treaty (Annex 2) 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 approved 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. Variable costs such as the scientific work involved in the preparation of registration dossiers (i.e. data gap analysis, IUCLID file preparation, development of exposure scenarios, preparation of chemical safety report) will be based on total sulfur dioxide consumption tonnages related to the production of the substances covered by the "consortium" of each individual consortium member including its affiliates. The consumption volumes of sulfur dioxide for this purpose should be based on the average of the three years 2006, 2007 and 2008; these data will be collected in any case during the questionnaire exercise required for the assessment of downstream use profiles for

each substance. Because of confidentiality issues, such data will be collected only when the consortium and a trustee is in place.

- b. 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. Any such costs shall not include any out-of-pocket expenses incurred by the Members, unless approved in advance by the Steering Committee.
- c. Acquisition of rights to Existing Studies valued under conditions specified above provided that the Member needs to submit the Study according to its tonnage band;
- d. 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 according to its tonnage band and provided that no study will be initiated without a budget approved by the Steering Committee;
- e. 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 according to its tonnage band and provided that no study will be initiated without a budget approved by the Steering Committee.
- f. In case the generation of new studies will become necessary, the arising costs shall be paid only by producers of the respective substance, who require these studies to complete the legal requirements for registration. The cost allocation should be based within this sub-group of companies on tonnage band (rounded to the nearest 1,000 tonnes) for producers, or sales in the case of traders; further, only those companies interested in this product can take a decision whether to conduct such studies or not. The production volumes for this purpose should be based on the average of the three years 2006, 2007 and 2008; these data will be collected in any case during the questionnaire exercise required for the assessment of downstream use profiles for each substance. Because of confidentiality issues, such data will be collected only when the consortium and a trustee is in place.

In case the study costs go below a limit of  $\notin$  2000 the arising costs shall be shared equally within the sub-group of companies without consideration of tonnage bands.

- 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 in this article shall be allocated to all Members in accordance with the cost allocation principles under Annex 4.
- 4. 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

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assistance to payer to obtain such Withholding Tax reduction, refund or exemption. Payer shall be entitled to any refund of Withholding Taxes.

- 5. 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.
- 6. The payment settlement will be executed by
  - REACH manager/secretariat acting in its own name but for the account of the Members with regard to administrative and other expenses pursuant to Article X.2.1 a),
  - REACH manager/secretariat acting in its own name but for the account of the interested Members with regard to new studies pursuant to Article X.2.1 c) and d)
  - The owning Member with regard to its existing Studies pursuant to Article X.2.1 b),
  - REACH manager/secretariat acting in its own name but for the account of the Members with regard to the compensation payable by each new Member pursuant to Article III.3.a) and b),
  - REACH manager/secretariat acting in its own name but for the account of the Members with regard to the contribution of new Associate Members pursuant to Article III, 5.2.

# ARTICLE XI. ADMINISTRATION & REPORTING OF COSTS

1. The REACH manager/secretariat 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 quarterly basis.

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

3. Until disbursed pursuant to this Agreement, all the funds of the Consortium shall be maintained by the REACH manager/secretariat in a Consortium specific cost centre approved by the Steering Committee, which preserve the principal while providing a reasonable rate of return. The REACH manager/secretariat 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 REACH manager/secretariat to the cost centre 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. The financial year shall run from 1 January to 31 December of each calendar year.

6. Each year the REACH manager/secretariat shall submit to the Steering Committee for approval the accounts of the past financial year and the budget for the following year.

The Accounts of the Consortium shall be subject to external and independent audit on a yearly basis, by an auditor designated by the Steering Committee, and based on recognized accounting standard procedures. This review shall result in a financial statement to be made available to all the Members that contribute to the budget.

7. When for appropriate reasons the budget agreed by the Steering Committee has to be increased in the course of the financial year, such budget increase shall be subject to prior approval by the Steering Committee at its next meeting.

8. A favourable vote of at least 75 % 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 evidence, methods and techniques known at the time.

2. It is the individual responsibility of each Member to critically 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. No warranty for acceptance of the Study by the Agency is given.

3. 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.

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 shall not be held responsible and liable for delays in the completion and submission of the Joint Registration Dossier, unless caused by gross negligence or wilful misconduct. If a third party asserts a claim against a Member, the other Members shall provide relevant information and support to the extent reasonably possible in defence against such claim.

5. The REACH manager/secretariat acts entirely in its capacity as representative of the EEIG and bears no individual responsibility or liability for its actions taken in this capacity with the exception of gross negligence or wilful misconduct.

## **ARTICLE XIII. DURATION, TERMINATION AND AMENDMENTS TO THE AGREEMENT**

1. This Agreement shall enter into force as from the Effective Date. The Consortium shall be formed for the duration necessary to achieve the Purpose of the Consortium, but not longer than 2022.

Upon achievement of the purpose confirmed in written form by all Members, 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 decision of the Regular 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 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 Consortium's fund. 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 must be in written form 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 CEPANI, shall be applicable. The place of any hearing shall be Germany (Frankfurt) and the language of the arbitration shall be German.

2. This Agreement shall be governed by the laws of Gernany.

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.

1. This Agreement, including the EEIG contract and not beeing in conflict to this, 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.

2. The following Annexes are part of these Bylaws. They must to be executed in line of the EEIG contract and the Bylaws.

# LIST OF ANNEXES:

- 1. SUBSTANCE IDENTIFICATION
- 2. GUIDANCE ON COMPETITION COMPLIANCE
- 3. VALUE OF STUDIES VALUATION RULES
- 4. COST ALLOCATION AND SHARING PRINCIPLES
- 5. LETTER OF ACCESS
- 6. DECLARATION OF ACCESSION
- 7. REGISTRATION DEADLINES
- 8. CONSORTIUM MANAGEMENT SERVICE AGREEMENT

# ANNEX 1

## **Substance Identification**

# **1. SUBSTANCE OVERVIEW**

1. In a controlled process the Consortium Members have identified and agreed upon the following Substances listed in Table 1 to be covered by this Agreement as described in Article 1.1.

No.	Compound name from EC inventory	Molecular formula	CAS No.	EC Number	Producers, designated lead registrant in bold letters	Legal classification	Highest tonnage band per member [t]	Registr. deadline
Sulfites and hydrogensulfites								
1	sodium sulfite	Na <sub>2</sub> SO <sub>3</sub>	7757- 83-7	231-821-4	ESSECO, BASF		Above 1,000	Dec. 2010
2	potassium sulfite	$K_2SO_3$	10117- 38-1	233-321-1	<b>ESSECO</b> , BASF, CWK		Above 1,000	Dec. 2010
3	sodium hydrogen- sulfite	NaHSO3	7631- 90-5	231-548-0	<b>GRILLO</b> , BASF, ESSECO, TIB	Xn R22 : Harmful if swallowed. R31 : Contact with acids liberates toxic gas.	Above 1,000	Dec. 2010
4	ammonium hydrogen- sulfite	NH <sub>4</sub> HSO <sub>3</sub>	10192- 30-0	233-469-7	ESSECO, TIB, CWK		Above 1,000	Dec. 2010
5	magnesium dihydrogen disulfite	Mg(HSO <sub>3</sub> ) <sub>2</sub>	13774- 25-9	237-403-8	ESSECO		Above 100	Jun. 2013
Disulfit	tes							
6	disodium disulfite	Na <sub>2</sub> S <sub>2</sub> O <sub>5</sub>	7681- 57-4	231-673-0	<b>GRILLO,</b> BASF, ESSECO	Xn, Xi R22 : Harmful if swallowed R31 : Contact with acids liberates toxic gas R41 : Risk of serious damage to eyes	Above 1,000	Dec. 2010
7	dipotassium disulfite	$K_2S_2O_5$	16731- 55-8	240-795-3	BASF, ESSECO		Above 1,000	Dec. 2010
Dithionite								
8	sodium dithionite	Na <sub>2</sub> S <sub>2</sub> O <sub>4</sub>	7775- 14-6	231-890-0	BASF, BRÜGGEMAN N, <b>SILOX</b>	Xn R7 : May cause fire. R22 : Harmful if swallowed. R31 : Contact with acids liberates toxic gas.	Above 1,000	Dec. 2010
Thiosulfates								
9	ammonium thiosulfate	$(NH_4)_2S_2O_3$	7783- 18-8	231-982-0	ESSECO, TIB, CWK		Above 1,000	Dec. 2010
10	sodium thiosulfate	$Na_2S_2O_3$	7772- 98-7	231-867-5	CWK, ESSECO		Above 1,000	Dec. 2010
11	potassium thiosulfate	$K_2S_2O_3$	10294- 66-3	233-666-8	ESSECO, CWK		Above 1,000	Dec. 2010

Table 1. Overview of the substances to be covered by this agreement

# **2. CATEGORIES**

1. The Consortium has defined categories for the Substances falling under the Agreement. Four (4) simple categories have been defined, based on the similar chemistries of the substances. These categories mayor may not define how the substances may be grouped in Task Forces.

# **3. SUBSTANCE SAMENESS CHECKING PROCEDURE**

- 1. The Consortium will use the Substance sameness checking procedure, in accordance with the 80% rule described in the Guidance for identification and naming of substances in REACH, with the following purpose:
  - a. To agree upon the Substance sameness per Substance listed in the Substance overview between the Consortium Members (Table 2);
  - b. In an equivalent process, to check and agree upon the Substance sameness per Substance listed in the Substance overview for new Consortium Members;
  - c. To be offered to the SIEF as Substance sameness checking procedure during the pre-SIEF by the SIEF Formation Facilitator (as introduced in the Guidance for Data Sharing).
- 2. As main driver in the Substance sameness checking procedure, the Consortium has agreed upon a Substance Identification Profile (SIP) per substance that contains:
  - a. The set of Substance Identification Parameters that is considered to be sufficient to identify the Substance for the purpose of the Joint Submission dossier and appropriate to fall under the legal definition of a substance in REACH. The Guidance for identification and naming of substances under REACH is used as much as possible;
  - b. The verification procedure contains the analytical methods and procedure to be used to check unambiguously if a Substance fulfils the parameters as agreed in the SIP;
  - c. The approval procedure, whereby each Individual Member has to sign a Statement that his Substance is in line with the SIP. The Statement includes the possibility *I* need to include the verification procedure by a Third party to verify the Substance to fulfil the SIP. The results of the Verification will be added to the Statement.
- 3. The REACH manager/secretariat organizes the drafting, approval and maintenance of the SIP per Substance in the Consortium. The SIP's prepared need to fulfil the under point 2 mentioned elements in a scientifically and legally justifiable way and to take maximal on board the individual needs of the Members. The preparation and agreement process on the SIP per Substance might result in the need to split the SIEF or merge different SIEF's into one. Splitting and merging of the SIP can only be done with a majority voting procedure in the Steering Committee.
- 4. Once the SIP's are approved, the REACH manager/secretariat organizes the approval procedure (with or without Verification) by all the existing Members as well as for any New Member in the future. The most recent status of the SIP's and Approval procedure is

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maintained in an overview by the REACH manager/secretariat that can be shared with the Consortium Members as agreed.

- 5. Per Substance it is agreed if and how the Consortium will contribute to the Sameness checking process in the SIEF. The default scenario is that per Substance a Consortium Member will offer to the relevant SIEF to be the SIEF Formation Facilitator (SFF) and in that role he will offer the Sameness checking procedure and SIP worked out in the Consortium as base for the Sameness checking process in the SIEF. If appropriate, Substance sameness checking procedure and tools might be modified in the discussions within the SIEF. If relevant and in consultation with all Members, the procedure and tools are supposed to be aligned with the approved Sameness Checking Process in the SIEF.
- 6. The Member will inform the REACH manager/secretariat if they have new information possibly relevant to update the SIP. This will be processed by the REACH manager/secretariat in line with the Maintenance procedure agreed.
- 7. The Member will inform the REACH manager/secretariat if their Substance is changed in such a way that it might no longer be aligned with the SIP. The possible consequences will be discussed and agreed upon with the Member in consultation of the relevant Consortium bodies.
- 8. The REACH manager/secretariat will organize the maintenance of the SIP per substance in an agreed update process of the SIP within the Consortium. This process might include another approval process amongst the Members if considered to be relevant.
- 9. The REACH manager/secretariat will organize that a new Member who accepted the Consortium Agreement will be subject to the same Verification and Approval procedure using the most recent version of the SIP as conducted with the existing Regular Members.
- 10. The REACH manager/secretariat will archive all Statements (with or without Verification). Any Regular Member can have access to the archived Statements for verification purposes after the Member in question has given permission.

#### Table 2. Sameness of substance

Substance*	Purity (mass %)	Impurity 1 (mass %)	Impurity 2 (mass %)	Impurity 3 (mass %)	Impurity 4 (mass %)	Impurity 5 (mass %)	Impurity 6 (mass %)	Impurity 7 (mass %)	Impurities classified for CMR properties
Sodium sulfite Na <sub>2</sub> SO <sub>3</sub>	94-100	Na₂SO₄ <4	Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub> <0.02	Cl⁻ <0.1	Heavy/trace metals <0.002				no
Potassium sulfite K <sub>2</sub> SO <sub>3</sub>	44-46	K₂SO₄ <0.5	S <sub>2</sub> O <sub>3</sub> <sup>2-</sup> <0.03	KCI <0.05	Heavy/trace metals <0.002				no
Ammonium hydrogensulfite NH₄HSO₃	<b>50-72</b> aq. solution	(NH <sub>4</sub> ) <sub>2</sub> SO <sub>3</sub> <10	(NH <sub>4</sub> ) <sub>2</sub> SO <sub>4</sub> <2.5	(NH <sub>4</sub> ) <sub>2</sub> S <sub>2</sub> O <sub>3</sub> <0.2	Heavy/trace metals <0.001				no
Magnesium hydrogensulfite Mg(HSO <sub>3</sub> ) <sub>2</sub>	<b>26.5-31.5</b> aq. solution	MgSO₄ <2.5	Heavy/trace metals <0.01						no
Sodium hydrogensulfite NaHSO₃	<b>19-43</b> aq. solution	Na₂SO₃ <2	Na₂SO₄ <5	Cl <sup>-</sup> <0.1	Fe <0.005	Heavy/trace metals <0.005			no
Sodium metabisulfite Na <sub>2</sub> S <sub>2</sub> O <sub>5</sub>	90-100	Na₂SO₃ <2	Na₂SO₄ <5	S <sub>2</sub> O <sub>3</sub> <sup>2-</sup> <0.06	Cl <sup>-</sup> <0.1	Heavy/trace metals <0.005			no
Potassium metabisulfite K <sub>2</sub> S <sub>2</sub> O <sub>5</sub>	96-100	K₂SO₃ <2	K₂SO₄ <4	S <sub>2</sub> O <sub>3</sub> <sup>2-</sup> <0.15	Na⁺ <2	Cl <sup>-</sup> <0.5	Heavy/tra ce metals <0.002		no
Sodium dithionite Na <sub>2</sub> S <sub>2</sub> O <sub>4</sub>	88-92	Na₂S₂O₅ <6	Na₂S₂O₃ <0.6	Na₂CO₃ <3.5	Na₂SO₄ <3	HMTA** <0.3	Methanol <0.5	Na₂S <0.2	no
Ammonium thiosulfate (NH <sub>4</sub> ) <sub>2</sub> S <sub>2</sub> O <sub>3</sub>	55-61 (aq. Sol) >98 solid	(NH <sub>4</sub> ) <sub>2</sub> SO <sub>3</sub> <4.5 <1	(NH <sub>4</sub> ) <sub>2</sub> SO <sub>4</sub> <1 	Cl <sup>-</sup> <0.5	Heavy/trace metals <0.001				no
Sodium thiosulfate Na <sub>2</sub> S <sub>2</sub> O <sub>3</sub>	97-100	Na₂SO₃ <2.5	Na₂SO₄ <1	CI <sup>-</sup> <0.1	Heavy/trace metals <0.002				no
Potassium thiosulfate K <sub>2</sub> S <sub>2</sub> O <sub>3</sub>	46-51.5	K <sub>2</sub> SO <sub>3</sub> <4	K₂SO₄ <0.5	Heavy/trace metals <0.001					no

\*Identification, classification/labeling: see table 1; \*\*Hexamethylene tetramine

# ANNEX 2

#### Guidance on competition compliance

# CODE OF CONDUCT

I.

The Members shall not make any agreements concerning coordination of conduct which restrict or affect competition within the meaning of Article 81, EC Treaty and shall also observe the prohibition of abusing a dominant market position pursuant to Article 82, EC Treaty:

#### Article 81, EC Treaty

[Prohibition of agreements and practices distorting competition]

- 1. The following shall be prohibited and is incompatible with the Common Market: all agreements between undertakings, decisions of associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the Common Market, and, in particular, those which:
  - (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
  - (b) limit or control production, markets, technical development, or investment;
  - (c) share markets or sources of supply;
  - (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
  - (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.
- 2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.
- 3. The provisions of Para. (1) may, however, be declared inapplicable in the case of:
  - any agreement or category of agreements between undertakings,
  - any decision or category of decisions by associations of undertakings,
  - any concerted practice or category of concerted practices, which ontributes to improving the production or distribution of goods or to romoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:

- (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;
- (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

#### Article 82, EC Treaty

[Prohibition of abuse of a dominant position within the Common Market]

Any abuse by one or more undertakings of a dominant position within the Common Market or in a substantial part of it shall be prohibited as incompatible with the Common Market in so far as it may affect trade between Member States.

Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (a) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

#### II.

The Members shall act in compliance with the following checklist:

DO	DON'T			
Application of competition law Arts. 81 and 82, EC Treaty may be applicable to the foundation and activities of a Consortium.	Do not assume that conflicts with competition law are excluded simply by the fact that the Consortium complies with the provisions of REACH.			
Consultation in Matters of Competition LawAn in-house lawyer, the company compliance officer or an external legal	Do not assume that the Code of Conduct deals with all competition law issues exhaustively. Essentially, compliance with Arts. 81 and 82, EC Treaty and other relevant competition laws is usually			

counsel should be consulted and should attend the meetings whenever there are uncertainties relating to compliance with competition law. All Consortium meetings and discussions under this Agreement, which are not in compliance with the Code of Conduct, shall be stopped until an antitrust counsel is involved.	reviewed on the basis of market impact in each individual case. This Code may, therefore, be regarded only as a source of general conduct recommendations.
Activities under the Agreement Activities under this Agreement must be restricted to the initially defined goals and purposes of the Agreement, in particular activities shall be limited to the circulated agenda circulated prior to the meetings in question.	<ul> <li>Pursuant to Articles 81 and 82, EC Treaty the following activities, <u>inter alia</u>, are prohibited under the terms of this Agreement:</li> <li>Coming to arrangements on prices, markets and customers (<u>see</u>, Article 81, Para. 1 (a) to (e) EC Treaty);</li> <li>Jointly limit or control production, technical developments or investments;</li> <li>Joint boycotting of other companies;</li> <li>Unjustified unequal treatment of trade partners;</li> <li>The abusive exploitation of a dominant market position.</li> </ul>
Exchange of Confidential Information An external trustee or consultant shall be involved for the exchange of confidential information, if required.	<ul> <li>The exchange of confidential information concerning market behaviour is not admissible between the Members, specifically as it relates to:</li> <li>production capacities,</li> <li>production or sales volumes,</li> <li>import volumes,</li> <li>market shares,</li> <li>price policy,</li> <li>distribution and marketing terms,</li> <li>marketing strategies,</li> <li>information regarding supplier relationships,</li> <li>production technology,</li> <li>investments,</li> <li>etc.</li> </ul>

Documentation on cooperation	
Prepare agendas and keep minutes of all meetings, which detail the subject of the meeting.	
Whenever there are uncertainties or concerns with respect to EC competition law under this Agreement, have the contents of the agendas and minutes be reviewed by an in- house legal expert or the compliance officer of your company prior to sending them to all Members to the Agreement.	

#### Value of studies - valuation rules

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, iii) contributed by non consortium members to the consortium.

a) The aforementioned reports 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 a high quality report 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 (if available). The robust summary may also be integrated into the IUCLID data set.
- 1.2. The quality of the reports (taking into account the adequacy, relevance and reliability) is determined by the Technical Committee, or experts commissioned by the latter, in accordance with the Klimisch et al.3 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. If there are discrepancies between the REACH Guidance on data sharing and the globally accepted OECD guidance on Klimisch rating, the OECD guidance will prevail.
- 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.

<sup>&</sup>lt;sup>3</sup> H.-I. K1imisch, 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)

# **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, unless otherwise agreed, 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.
- 2.3 The expenses for preliminary testing and Substance testing are calculated according to the FLEISCHER list.<sup>4</sup>
- 2.4. For each relevant study per end point, the final replacement value will be determined by default by using the replacement values coming from the FLEISCHER list (Annex 3, 2.3). If necessary and agreed upon in the Consortium, additional costs can be included for the additional analysis steps to take. E.g. 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 provision5 of the procedure or method
  - Costs per analysis
  - Number of analyses performed

If necessary and agreed upon in the Consortium, a different final replacement value can be allocated to a certain study (must be justifiable with documented evidence of costs). In the end, the individual positions are to be presented and justified with sufficient plausibility.

- 2.5. If the Consortium has worked on the Chemical Safety Report (CSR) as part of the joint submission, it has to agree upon if and under what conditions to share the CSR to other requesters that want to have access rights to that CSR for their Registration. The value of the CSR development is based on all costs made by the Consortium dedicated to the development and acceptance of the CSR between the Members. The decision to share the CSR, the specific criteria for sharing and the justifiable value and relevant correction and deduction factors will be agreed upon in the Steering Committee and made available to the data exchange service described in Annex 4, 3.
- 2.6. The Consortium agrees to work with the following correction factors that will be used to transparently increase the actual replacement value per end point if the following conditions are met. The correction factor will be based on the final replacement value

<sup>&</sup>lt;sup>4</sup> Fleischer, M., *Journal of Business Chemistry*, 4, **2007**, 96-114.

<sup>&</sup>lt;sup>5</sup> Provision of analytical procedure or method includes the measures required for testing a method known from the literature for compatibility with the intended use.

agreed upon as described in Annex 3, 2.4. More than one correction factor can be applicable for a certain study value:

- a. Plus balanced Administration % for all Consortium Members and non-Members. The actual Administration % relates to the final replacement value agreed upon as described in Annex 3, 2.4 (worked out in table 1);
- b. **Plus** additional balanced Administration % for IUCLID 5 robust summaries for non Consortium Members. This is set to 30% of the balanced Administration fee as described in Annex 3, 2.6 a (worked out in table 1);
- c. Corrections due to other factors can be evaluated only on a case-by-case basis and will need to be accepted by 75% majority voting in the Technical Committee, upon proposal of the relevant Task Force.
- 2.7. The Consortium agrees to work with the following deduction factors that will be used to transparently reduce the actual replacement value per end point if the following conditions are met. The deduction factor will be based on the final replacement value agreed upon as described in Annex 3, 2.4. More than one deduction factor can be applicable for a certain study value:
  - a. Minus 20% for a Klimisch 2 study for all Consortium Members and non-Members;
  - b. 500 € for a Klimisch 3 or 4 study for all Consortium Members and non Members. However, on a case by case situation, the Technical Committee can suggest to include Klimisch 3 & 4 studies if they significantly contributed in the filling of a data gap (e.g. by weighted evidence). The deduction factor must be determined on a case by case basis;
  - c. Minus 50% for just a letter of Access for REACH Restricted usage by a non Consortium Member (no transfer of the actual study report and study data);
  - d. Minus 30% for just a letter of Access for all usages<sup>6</sup> by a non Consortium Member (no transfer of the actual study report or study data);
  - e. Deductions due to other factors can be evaluated only on a case-by-case basis and will need to be accepted by major voting in the Technical Committee.
- 2.8. The current value of a given report is comprised of the final replacement value for studies (Annex 3, 2.4) and for the Chemical Safety Report (Annex 3, 2.5) corrected to include for the applicable correction factors (Annex 3, 2.6) and deduction factors (Annex 3, 2.7) related to the relevant use of the data.
- 2.9. The REACH manager/secretariat will centrally store and maintain an overview of all relevant studies and the relevant details like the ownership as well as the results from the

<sup>&</sup>lt;sup>6</sup> All usages mean usage of the study results in any legal framework (e.g. for TSCA, MIT, etc) or registration system (e.g. REACH registration; biocides, etc.).

scientific evaluation and financial valuation as input for the data cost allocation and sharing principles described in Annex 4.

	Correction	factor 2.6.a)	Correction factor 2.6.b)	
Study value (€)	Adm %	Adm (€)	Additional Adm % for Robust Summaries	Additional Adm (€) Robust Summaries
3000	25	750	7.5	225
5000	20	1000	6	300
20000	15	3000	4.5	900
50000	10	5000	3	1500
100000	7	7000	2.1	2100
200000	5	10000	1.5	3000
300000	4.2	12600	1.25	3750

Table 1. Surcharge to the total study value for administrative expenses according to Annex 3, 2.5.

## Cost allocation and sharing principles

In line with Article X and XI of the present agreement, this Annex describes the detailed cost allocation and sharing principles for all Consortium expenses to be shared amongst Members and other stakeholders (if appropriate).

The first section describes the different Consortium management costs and how to share those fairly over the Members it concerns. The second section describes the cost allocation and compensation rules for studies owned/generated by the Consortium to complete and to have access to the studies relevant for the individual Registration dossiers. The third section describes the data exchange service of studies owned by the Consortium to non Members and how the costs are compensated to the data owners and other Members.

How those main cost allocation and sharing principles affect Associate Members and new Consortium Members is worked out in detail in section 4 and 5 respectively. Finally, section 6 describes the funding principles of the Consortium organizing that there is a healthy cash flow to make sure that the Consortium can conduct the necessary activities to meet its purpose.

# 1. THE CONSORTIUM MANAGEMENT COSTS

Related to Article X, 2.1 a), the following consortium management costs can be distinguished:

- a) The generic Consortium operational costs (relevant for all members) covering all administrative expenses incurred by the management of the Consortium, including consortium management, financial management, data exchange service, secretarial services and support and external experts or company experts on behalf of the consortium;
- b) The specific Consortium operational costs (relevant for specific members; e.g. of a specific taskforce or sub-consortium) covering all administrative expenses incurred by managing the specific parts of the Consortium, including consortium management, financial management, data exchange service, secretarial services and support as expenses for external experts or company experts (if appropriate);
- c) The historical Consortium costs, conducted by some founding members as part of the formation of the Consortium up to the moment the Consortium became operational, with a clear identifiable and justifiable added value for the Consortium to meet its purpose and a proven record of historical costs;
- d) The historical pre-consortium costs, conducted by some founding members before the Consortium was formed or became operational (e.g. from the founding association members), with clear identifiable and justifiable added value for the Consortium to meet its purpose and a proven record of historical costs.

The Consortium management costs (approved by the Steering Committee) will be shared between the Members using the following cost sharing principles:

a) The generic Consortium operational costs will be shared equally over all Regular Members;

- b) The specific Consortium operational costs will be shared equally over all Regular Members involved in the specific Consortium activities;
- c) The historical Consortium costs will be turned into an additional fee for the one time Consortium entry fee for new Members that relates to the average annual contribution of the existing Regular Members. After approval of the additional fee by the Steering Committee, this additional fee will be required for all new Regular Members as part of Their one time Consortium entry fee;
- d) The historical pre-consortium costs will be turned into an additional fee for the one time Consortium entry fee that after approval by the Steering Committee will be required for all existing or new Regular Members that have not contributed to the historical pre-consortium costs.

For the purpose of cost sharing, a Regular Member and its affiliates count together as one share. For an Only Representative as Regular Member, a separate action will be taken by the REACH manager/secretariat to identify and agree upon the number of non-EU Manufacturers being represented by the Only Representative. For the purpose of equal cost sharing each non-EU Manufacturer and its affiliates will count for one and the combined share will be allocated to the Only Representative.

Equal cost sharing will mean splitting the costs in an equal share over the number of stakeholders involved.

The REACH manager/secretariat will keep record of all Consortium management costs, the Consortium entry fee and organize the proper invoicing of all relevant parts to the Members in line with the funding principles agreed (Annex 4, 6).

# 2. THE COST ALLOCATION AND COMPENSATION OF STUDIES WITHIN THE CONSORTIUM

Draft Cost Allocation Key for existing studies

# 1. General

- a) The cost allocation key serves the fair allocation of costs of Studies, test data and other information required for the REACH registration among the Members.
- b) Cost allocations can be calculated for all Studies to end points for which information is required according to Annexes VII to X, REACH.
- c) A Member can normally submit only one report per end point for a cost allocation. If the Member has several redundant reports at the same end point, they can be used for securing the key Study. For non-redundant reports, the REACH manager/secretariat makes the decision whether and to what extent they can be included in the cost allocation.
- d) For Studies which are not required pursuant to Annex VII to X, REACH or Studies which relate to issues for which no standard protocol is available, the REACH manager/secretariat decides whether or not such Studies are to be included in the Registration Dossier and in cost allocation.

## 2. Value of the Reports for Exclusive REACH Use

- a) The current value of a Study determined in accordance with the rules of financial valuation of Studies, test data and other information (Annex 3 of this Agreement) serves as the measuring base for cost allocation and compensation.
- b) Since other Members than Owners shall only be granted the right to use the Studies for the purpose of Substance registration pursuant to REACH, those Members are eligible for reduction of 30 % relative to the current value of the Study. Any usage of the Studies for other purposes requires a separate bilateral agreement by the Owners.

## **3.** Cost Allocation among the Members

- a) The Members share equally the costs of all Studies, test data and other information that they are required to submit to satisfy the registration requirements of all Substances listed in Annex 1 of this Agreement according to the highest applicable tonnage band.
- b) By contribution of a report of category (1) "reliable without restriction", the prorated share of a full Member is considered as paid for the relevant end point. This applies to all Members who contribute reports of equal value. The cost allocation is carried out by the remaining Members.
- c) If Studies from category (1) "reliable without restriction" and (2) "reliable with restrictions" are available at the same end point, the key Study shall be used for cost allocation calculation. The party supplying a Study of a lesser value contributes to cost allocation according to the value difference, calculated for the Study according to Annex 3 of this Agreement.
- d) If a Study from category (1) "reliable without restriction" is not in existence, but only one or several reports from (2) "reliable with restrictions" are available, the key Study shall be used for the calculation of the cost allocation.

## 4. Compensation

- a) The total compensation results from the total sum of contributions to be paid by Members.
- b) The total amount of the compensation is divided among the Owners according to the value determined for the respective Study under Annex 3 of this Agreement.

## 5. Entry of a New Member

- a) Each new Member upon entry pays a share of the costs according to Article III, 2. of this Agreement. The share covers the contribution to costs of Studies, test data and other information as well as the general costs incurred by the Consortium to date.
- b) The financial contribution paid by new Members for the Studies, test data and other information is determined in accordance with the same criteria as those of the other Members.

c) If a new Member enters the Consortium following the submission of the Registration Dossier, the new Member must pay the share for all Studies, test data and other information contained in the Registration. A cost allocation is only possible for the Studies of the new Member which are subsequently requested by the authorities.

## 6. Third Parties (Non-Consortium Members)

- a) Third parties subject to registration requirements but who are not (and will not be) Members, <u>e. g.</u>, as in the case of rejection of an applicant as a full Member, may be (via the REACH manager/secretariat) integrated into the submission of the Joint Registration Dossier and be granted the right to refer to Studies, test data and other information – <u>e. g.</u>, waiving argumentations, reasoning of testing proposals – of the Consortium. Concerning data already registered, such rights are granted through issuance of a Letter of Access (model in Annex 5 of this Agreement).
- b) The cost share of the third party for the submission of the Joint Registration Dossier and for the provision of rights to use will be fixed by the Steering Committee analogously to the regulation in Annex 4, 2.5 whereas the third parties are only required to share the costs for the substance listed in Annex 1 which they are going to register.
- c) The consideration obtained for granting rights to use the Studies generated by the Consortium is allocated at equal shares to the third parties with 30% deduction of the study value due to the limited referral right only for REACH use.

Related to Article X, 2.1.b), 2.1.c), and 2.1.d) the following data sharing processes can be distinguished within the Consortium with its own cost sharing characteristics:

- a) Sharing of existing data owned by one Consortium Member (data owner) within the Consortium. Unless otherwise agreed with the data owner, all Regular Members will have access right to the data in electronic form for the REACH Registration usage only after fulfilling its cost compensation requirements in line with the funding principles described in Annex 4, 6.3;
- b) Sharing of existing data owned by a non Consortium Member (e.g. requested from a SIEF Member) within the Consortium. If appointed to be relevant for the Registration dossier, the REACH manager/secretariat will organize on behalf of the Consortium with the data owner the practical arrangements to get access to the study for all relevant Regular Members of the Consortium now and in the future (see Annex 4, 3) and the conditions to fulfil the financial compensation to the data owner. The REACH manager/secretariat will fulfil on behalf of the Consortium the financial requirements to the data owner within the agreed limits of the procedure approved by the Steering Committee. Unless otherwise agreed with the data owner, all Regular Members will have access right to the data in electronic form for the REACH Registration usage only after fulfilling the cost compensation requirements to the Consortium in line with the funding principles described in Annex 4, 6.3;
- c) Generation of new data by and for the Consortium to be used within the Consortium to complete the Registration dossier before submission or pursuant to the evaluation of testing proposals by the Agency. Unless otherwise agreed within the Consortium, all Regular Members will become owner of the study, receive a copy of the full study report and have access right to the data in electronic form for all usages (including the Registration under

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REACH) after fulfilling its cost compensation requirements in line with the funding principles described in Annex 4, 6.3. However, subsequent sharing of these data outside of the Consortium must be agreed by all joint-owners, and on the understanding that compensation received will be equally shared amongst the study owners.

All data from these processes are subject to a scientific evaluation ('Klimisch rating') and financial valuation process ('study value in euro's') as described in Annex 3 and centrally stored and maintained by the REACH manager/secretariat. This will form the necessary input for the cost allocation and compensation mechanism that is setup in line with Annex 5 of the REACH Guidance on data sharing with the following principles:

- 1. Per Regular Member, the final cost compensation will be calculated per relevant end point for his Registration. This means that each Regular Member will have to inform the REACH manager/secretariat what studies he needs access to and on the timing of access in line with the funding principles described in Annex 4, 6. The final cost compensation and subsequent access rights will be organized only for the agreed end points per Regular Member;
- 2. Per end point with a key study appointed<sup>7</sup>, the highest study value for cost sharing will be determined. By default this is the value of the agreed key study or any equivalent study with a same (or higher)<sup>8</sup> Klimisch rating but a higher study value;
- 3. Per end point the average financial contribution per Regular Member will be calculated by a simple quotient of the highest study value for cost sharing to the number of Regular Members that need access to the study;
- 4. Per end point, the financial contribution per individual Member will be determined:

Members with an equivalent study of the same Klimisch rating will have to pay an allowance of  $500 \notin$  to get access to the key study:

Financial contribution = € 500,-

Members with a Klimisch 2 study whereby the selected key study is a Klimisch 1 study will contribute a relative amount of the average financial contribution:

(Average financial contribution)' <u>«highest study value) - (value Klimisch 2 study))</u> (highest study value)

Members with a Klimisch 3 or 4 study or no studies will have to pay the average financial contribution:

Financial contribution = (average financial contribution described in Annex 4, 2.3)

<sup>&</sup>lt;sup>7</sup> The key study to be Included in the Registration dossier will be selected by the company expert(s) of the Lead Registrant or outsourced experts in the process agreed within the Consortium. The REACH manager/secretariat will

Registrant or outsourced experts in the process agreed within the Consortium. The REACH manager/secretariat will register the agreed key study and determine the most expensive study of equivalent quality for the cost sharing mechanism.

<sup>&</sup>lt;sup>8</sup> It is assumed that normally the selected key study by default always will be of the highest Ktimisch rating. However, If for what ever reason the experts decide (with sufficient justification) that the key study will be of a lower Klimisch rating, this cannot have impact on the cost allocation and compensation mechanism. By determination the highest study value for cost compensation, the study value it selves cannot become a selection criterion to appoint the most appropriate key study.

However, when some of the Klimisch 3 or 4 studies are of value for read-across or QSARS to fill a data gap, these studies can be included in the cost allocation and compensation mechanism as well:

(Average financial contribution)' <u>«highest study value) - (value Klimlsch 3 or 4 study)</u>) (highest study value)

5. Per end point, the financial compensation per individual Member<sup>9</sup> will be determined:

Members owning the key study or equivalent studies of the same (or higher) Klimisch rating will be entitled to receive part of the total amount of financial contributions as financial compensation:

(Total amount of financial contributions) \* (highest study value) (Total sum of study values of all relevant studies)

Members with a Klimisch 2 study whereby the selected key study is a Klimisch 1 will be entitled to receive a reduced part of the total amount of financial contributions as financial compensation:

(Total amount of financial contributions) \* (value Klimisch 2 study) (Total sum of study values of all relevant studies)

Members with a Klimisch 3 or 4 study or no studies will not be entitled to receive part of the total amount of financial compensations as financial compensation:

Financial compensation =€ 0,-· (zero euro)

However, if it is agreed that some Klimisch 3 or 4 studies contribute to fill a data gap, the data owners will be entitled to receive part of the total amount of financial contributions as financial compensation:

(Total amount offinancial contributions) \* <u>(value Klimisch 3 or 4 study)</u> (Total sum of study values of all relevant studies)

- 6. Per end point, the final cost compensation per individual Member is the balance of the individual financial contribution (Annex 4, 2.4) minus the individual cost compensation (Annex 4, 2.5).
- 7. The REACH manager/secretariat will implement the data exchange service as described, organize the access rights for a fair, transparent and non-discriminatory cost allocation and compensation (financial clearing house). Therefore it keeps record of the total of all final cost compensation (Annex 4, 2.6) and invoicing status for all relevant end points in a data balance sheet per Member. These data balance sheet are dynamic, since the individual final cost compensation share will be influenced by the introduction of new relevant studies, Regular Members or data requests as described in Annex 4, 3. The Regular Member will only have access right to the data in question after fulfilling its financial data compensation requirements in line with the funding principles described in Annex 4, 6.

# 3. THE COST COMPENSATION MECHANISM OF CONSORTIUM STUDIES FOR NON-MEMBERS

<sup>&</sup>lt;sup>9</sup> The total amount of the financial contributions of the individual Members will be shared in a weighted balance over all Regular Members that have relevant studies for the same end point (meaning Klimlsch 1 or 2 or If agreed to be relevant to fill a data gap also Klimisch 3 or 4).

All existing data owned by a Consortium Member, new data generated and owned by the Consortium Members and even data used in the dossier owned by non Consortium Members are unless otherwise agreed with the data owner subject of the data exchange service of the REACH manager/secretariat as agreed upon in this Annex, with the following characteristics:

- a) Access to individual data owned by the Consortium (e.g. newly generated studies) or by individual Consortium Members (e.g. existing data) and subject to data exchange for a financial compensation to non-Consortium Members (e.g. requested by other SIEF Members; including for the purpose of read across). Unless otherwise agreed in the Consortium, any SIEF Member (including for read across purposes) can get a letter of access to be entitled for the usage agreed (by default this access is restricted to REACH Registration only) after fulfilling its cost compensation requirements agreed upon.
- b) Access to a full dossier for a certain tonnage band covered by the Registration of the Consortium for a non-Consortium Member. Unless otherwise agreed in the Consortium, any potential Registrant (not being a Consortium Member) can get a letter of access and electronic data to be entitled for the usage of the full Registration dossier for its Registration under REACH after fulfilling its cost compensation requirements agreed upon.

On behalf of the Consortium, the REACH manager/secretariat will organize the data exchange service for new and existing data of the Consortium towards non-Consortium Members by the following main principles:

- 1. Only data with approval from the data owner and/or the Consortium can be offered to other non-Consortium Members for a financial compensation. The REACH manager/secretariat will store these approvals, organizes the availability of the data and appropriate letters of access and uses the prices calculated based on Annex 3;
- 2. When becoming applicable, the price for a full dossier will be drafted as combination of the total value of the dossier (including the appropriate correction and deduction factors of Annex 3) and the following standard: non-members who want to use our end dossier as (to be) submitted to ECHA will pay a fee equal to a Regular member's share in the total costs incurred over the past 3 years p l u s an advantage compensation of 50 %. The dossier will be transferred just for the purpose of registration. No IPR (Intellectual Property Rights) will be transferred or granted. The actual price will be approved in the Steering Committee. Where the dossier contains data of non Consortium Members, separate agreements will be organized with the data owners to be entitled to sell on their behalf access to their data and how they will get their part of the compensation. If there remains data in a full dossier that needs separate arrangements with a data owner, this will be clearly communicated and will need to be given follow-up by the requester of the full file;
- 3. The REACH manager/secretariat will organize the platform for other SIEF Members to request data and standard follow-up procedure:
  - If the data cannot be shared via the data exchange service of the REACH manager/secretariat (e.g. the data is not yet available; the data owner wants to organize the data sharing differently; etc.) the data requester gets a specific answer;
  - If the data can be shared, the data requester will get a standard proposal specifying the deliverables including the price, invoicing and data distribution procedure to follow;

- After receiving an approval of the proposal, the REACH manager/secretariat will send an invoice;
- The appropriate letter of access and electronic data if appropriate will only be distributed after the invoice has been paid;
- 4. The REACH manager/secretariat will keep track on all data access requests and their followup status and keep track on all financial compensations being paid.
- 5. the REACH manager/secretariat will organize the sharing of the financial compensations received via the data exchange service over the Regular Members and other stakeholders involved (e.g. data owner outside the Consortium) in line with the funding principles agreed (Annex 4, 6).

# 4. Associate Members

Associate Members will not be required to contribute to the operational Consortium costs specified under Annex 4, 1.

In its approval process of any Associate Member to join the Consortium (Article III, 5), in line with the funding principles agreed (Annex 4, 6) the annual Consortium fee will be determined that will be a fair part of the Consortium entry fee applicable in that moment of time (related to what the Associate Member will bring and get from its Membership of the Consortium).

The REACH manager/secretariat will collect the annual Consortium fee for new Associate Members within one month after signing the Consortium Agreement and for existing Associate Members in January of each subsequent year.

The Associate Member being a data owner will be included in the cost allocation and compensation mechanism for his studies (if being used by the Consortium).

# 5. MEMBERS WHO JOIN THE CONSORTIUM AFTER ITS INCEPTION

New companies joining the Consortium as Regular Member after its inception as described in Article III, 3 shall be required to fulfil the financial contributions being prepared by the REACH manager/secretariat as a dedicated proposal. The proposal will consist of the following components:

- 1. To compensate the Consortium for the historical costs made (Annex 4, 1), in line with the funding principles described in Annex 4, 6 a onetime Consortium entry fee needs to be paid within one month after signing the Consortium Agreement;
- 2. To join the activities for that year, in line with the funding principles described in Annex 4, 6, a provision (being the annual provision corrected for the costs made in previous quarters) needs to be paid, within one month after signing the Consortium Agreement;
- 3. To get access to the relevant data for his Registration dossier, the REACH manager/secretariat will prepare a dedicated data balance sheet for the new Regular Member after consultation what data is needed by the new Regular Member and if applicable what data will be contributed by the new Regular Member (if not already covered and still applicable). This new data balance sheet will follow the invoicing procedure described in Annex 4, 6.3.

The REACH manager/secretariat will organize the approval of the proposal drafted for the new Regular Member as agreed with the Steering Committee and organize the follow-up with the new Regular Member.

After signing the declaration of Accession and fulfilling of the financial requirements described in the approved proposal, the new Regular Member will be full partner in the Consortium Activities and be treated accordingly.

# **6.** FUNDING PRINCIPLES

- 1. The main funding principle is based on an annual provision required to be paid by all Regular Members at the beginning of each year until the time of submission of the Registration dossiers:
  - 1.1. The annual provision is based on a best guess estimation of the budget for:
  - the Consortium management costs as described in Annex 4, 1;
  - the Newly to be generated data for that year (if relevant). This part of the provision will be included on the data compensation balance sheet per Member;
  - the support of contracted Technical service provider(s);
  - If relevant, the annual provision will be corrected for budget not spent in the previous year and can be corrected using part of the financial buffer already been formed.
  - 1.2. The annual provision for the first year will be drafted by the REACH manager/secretariat in the first month after start of the Consortium and approved by the Steering Committee within 2 months<sup>10</sup>;
  - 1.3. The annual provision for every coming year will be drafted by the REACH manager/secretariat in September and approved by the Steering Committee in October;
  - 1.4. The annual provisions for Regular Members will be collected within 3 Months after the start of the Consortium and in January of every coming year;
  - 1.5. When a new Regular Member enters the Consortium, the annual provision will be recalculated for n+1 Members:
    - The new Regular Member needs to pay this recalculated annual Provision minus any costs made in any previous quarter (as agreed via the quarterly financial assessments described in Annex 4, 6.5);
    - All existing Regular Members will get the difference between their annual provision paid and the recalculated annual provision on their balance sheet to be compensated in the fourth quarterly financial assessment (Annex 4, 6.5)

<sup>&</sup>lt;sup>10</sup> The EBRC proposal, approved by the Members by signing the Consortium Management Service Agreement with EBRC, does contain all relevant data to directly generate the invoice for the annual provision of the first year. Therefore, instead of the mentioned 3 months in Annex 4, 6.1.4, this will be done one month after signing the Consortium Management Service Agreement.

- 1.6. The total amount of the annual provisions amongst Regular Members needs to be sufficient for the Consortium to finance all its planned operational activities for that year.
- 2. An additional funding principle is in the form of the onetime Consortium entry fee for new Regular Members and the annual Consortium fee for Associate Members.
  - 2.1. To compensate the Consortium for historical costs (Annex 4, 1.c) the one time Consortium entry fee in the first quarter of the first year will be equal to the annual provision; after that the onetime Consortium fee will equal to the actually made costs of all preceding quarters since the start of the Consortium (determined figure at the quarterly financial assessments; Annex 4, 6.5). These onetime Consortium entry fees will be collected by the REACH manager/secretariat as described in Annex 4, 4 and added to the financial buffer (Annex 4,4);
  - 2.2. To compensate for historical pre-Consortium costs (Annex 4, 1.d), each new Regular Member has to pay an additional one time Consortium entry fee of 20% of the justifiable costs with proven record of costs made. These onetime Consortium entry fees will be collected by the REACH manager/secretariat as described in Annex 4, 4 and be returned as an equally share to the relevant Members via their fourth quarterly assessment at the end of each year;
  - 2.3. To contribute to the Consortium management costs, the annual Consortium entry fee for Associate Members is set by default at 10 % of the Consortium entry fee for historical costs determined as described in Annex 4, 6.2.1. These annual Consortium fee will be collected by the REACH manager/secretariat as described in Annex 4, 5 and added to the financial buffer (Annex 4, 4);
  - 2.4. The Consortium entry fees and annual Consortium fee for Associate Members need to be approved by the Steering Committee and made available to whom it concerns.
- 3. Per Member a data balance sheet for the data compensation requirements per relevant substance will be kept up to date that includes:
  - 3.1. Per relevant end point the final cost compensation for access right to the agreed data within the Consortium is maintained (Annex 4, 2);
  - 3.2. Per newly developed test on behalf of the Consortium, the annual provision part (Annex 4, 6.1) and the actual costs made (Annex 4, 2) will be taken into consideration to the actual financial compensation to be paid;
  - 3.3. Per Consortium study being requested by and invoiced to a non-Member (Annex 4, 3).the incoming money will be first allocated to the data owner or data owners in an equal share to the maximal amount of 2 times the study value (actual study value for the data owner with documented proof or otherwise the study value from the Catalogue; see Annex 3). The additional remaining money coming in after having compensated all data owners will be added to the financial buffer;
  - 3.4. Per Consortium dossier being requested and invoiced to a non Member (see point 3), the incoming money will be added in an equal share to the data balance sheets of all Regular Members (after corrections if relevant for money to be returned to data owners).

- 3.5. The REACH manager/secretariat will invoice the final data compensation for the relevant studies and include the invoicing status on the balance sheet in the following scenario's:
  - Once the Registration dossier has been completed and approved to meet the first Registration deadline, the data balance sheets for all Members will be frozen and invoiced versus paid out to all Members that requested access to the data to meet the first deadline (depending on the balance). The Regular Members that fulfilled their financial requirements will get access to the data for their Registration dossier and can be included in the joint submission. The frozen data balance sheets (after completion of the invoicing status) will be archived and from there further maintained (to include new data and/or data requests) for as long as the Consortium remains active;
  - If a Regular Member decides to get access of some or all data at another moment in time, the additional admin costs to prepare such an in-between
  - invoicing and updating of the data balance sheet will be to his expenses;
  - If a Regular Member decides to leave the Consortium in line with the termination clauses of the Consortium Agreement at an earlier moment in time, his data balance sheet will be frozen and invoiced or paid out. The final data balance sheet for the Member leaving the Consortium will be archived but no longer be maintained.
  - With the Steering Committee the procedure will be agreed how to continue the data exchange service on behalf of the Consortium after the invoicing for the first Registration deadline has been conducted. This will include how and when to invoice the remaining data balance sheets of the Regular Members that have a Registration requirement later in time and did not request to join the first deadline. It also includes how to deal with new data requests from the ECHA to be developed by the Consortium (if relevant) and how to continue the data sharing (point 3) to new Registrants.
- 4. The Consortium will develop a financial buffer by incoming money from the following activities:
  - 4.1. Collection of the onetime Consortium entry fees amongst new Regular Members described in Annex 4, 6.2;
  - 4.2. Collection of the annual Consortium fees amongst Associate Members described in Annex 4, 6.2;
  - 4.3. Additional remaining money coming from the invoiced access to Consortium studies or Consortium dossiers by non Consortium members (see point 6.3.3);

If appropriate and approved by the Steering Committee, part of the financial buffer can be used to lower the annual provision for the coming year or to solve in between budget problems.

- 5. A quarterly financial assessment (debit and credit per individual Member) will be prepared with an overview of the costs made and review if the annual allocated budget is still sufficient.
  - 5.1. Each quarterly assessment will be input for the updated Consortium entry fee (Annex 4, 2.1);

- 5.2. The third quarterly assessment will be input for the calculated Annual provision for next year (Annex 4, 1.3);
- 5.3. The fourth quarterly assessment will be used to specify any positive balance to be returned to the account of the Member;
- 5.4. If necessary, additional budget in line with the cost allocation and sharing principles can be requested. However, this needs upfront approval of the Steering Committee.
- 6. At termination of the Consortium, a final balance will be made of all costs made (or still to be made during termination) and the Consortium incomes via the different routes (annual provisions of Members, Consortium entry fees, data balance sheets):
  - 6.1. If there is a positive balance, this will be returned to all Regular Members present in the consortium at the time of termination proportionally to their financial contribution to the Consortium in time;
  - 6.2. If there is a negative balance, the extra costs will be shared amongst Regular Members in line with the regular cost sharing principles agreed.

# Letter of Access<sup>11</sup>

Letter of Access for the registration of the substance [insert the name of the substance to be registered] under REACH Regulation

By this letter, the Members of the Consortium<sup>12</sup> on the registration of the substance REACH (hereafter referred to as "the Consortium") agree that the data, studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments specified in detail below owned by Members of the Consortium and submitted by the Consortium in support of the registration under REACH on

Substance [insert the EC No., CAS No, and exact name of the *substance to be registered*]

(hereinafter *collectively* referred to as the "Registration Dossier"), may be referred

by Applicant: *Company* 

in order to support Applicant's registration of the above mentioned substance under REACH.

The Dossier covers documents as listed in the Attachment to this Letter of Access.

It is agreed that:

1. The right to refer is restricted only for the registration purpose as specified above.

- 2. The right of refer is solely granted in favour of *Company including its affiliates* and is not transferable to any other entity or person.
- \_\_\_\_\_ is not authorised to receive any copies 3. Company \_ authorised to inspect of the Dossier nor is *Company* or view the Dossier or any related specific document in whole or in part.<sup>13</sup>
- 4. This Letter of Access shall in no event be construed as granting *Company* any property rights whatsoever in the Dossier.

Signature: Authorized Representative of the Consortium

<sup>&</sup>lt;sup>11</sup> www.cesio2004.de

<sup>&</sup>lt;sup>12</sup> At the date of issue of this Letter of Access the members of the consortium are: [insert names of the members of the consortium} the latter

<sup>&</sup>lt;sup>13</sup> Depending on the contract between the Consortium and Company\_

may receive the results and/or summaries/robust summaries of studies directly from the Consortium.

Consortium Management Service Agreement

## CONTRACT AGREEMENT

"Sulfur Dioxide Based Chemicals REACH Consortium manager/secretariat"

This contract agreement is made and entered into on 01.04.2009 by and between

## **EBRC Consulting GmbH**

a company organised under the laws of Germany, having its registered office located at

Raffaelstr. 4, D-30177 Hannover, Germany,

hereinafter referred to as "EBRC"

AND

## Sulfur Dioxide Based Chemicals REACH Consortium

an association organised under the laws of Germany, having its registered office located at

Hannover (Germany),

hereinafter referred to as the "Sulfur Dioxide Based Chemicals REACH Consortium" or as the "client"

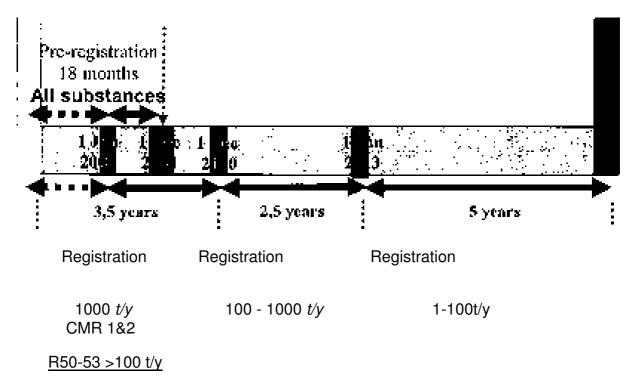
## For full agreement, please contact us!

# **Registration deadlines (article 23 REACH)**

# Pre-registartion & Registration timetable for phase - in substances

# 1 June 2007: REACH entered into force

1 Jun 2018



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# Sulfur Dioxide based Chemicals REACH consortium (SDIOC)



Hannover, 18 March 2009

#### Agreement on

#### REACH scientific consulting activities for inorganic sulfur chemicals

Dear Sirs,

By agreement with the group of industrial producers of inorganic sulfur compounds, please find attached our working document, in which we have identified three separate phases of the project:

- Phase I: data gathering, quality and relevance screening, and compilation of a data gap analysis report with testing proposals (if required)

- Phase II: IUCLID 5.0 compilation

- Phase III: PNEC/DNEL derivation, HH and ENV exposure data gathering, and finally CSA and CSR generation.

Please kindly acknowledge that this is an outline proposal only, which is at this point in time intended for your initial orientating purposes. Once further details on availability of data, as well as production volumes, number of producing and consuming sites and the extent of downstream user and consumer

#### SDIOC Agreement 01.10.2009

scenarios is known, we can update this proposal to specifically meet the then expected requirements. We also wish to note explicitly that this proposal entails a cooperation with our partners ARCHE, who would be responsible for the environmental part of the project.

Please also note that we have made corrections to points 1.1. (interested companies) and 1.2 (candidate lead registrants) in comparison to our previous document version.

Yours sincerely,

#### **EBRC Consulting GmbH**

Dr. R. V. Battersby

#### For full agreement, please contact us!