

Agreement

**for the Formation of a REACH Consortium for lime substances
pursuant to REACH Requirements**

(‘REACH Lime Consortium’)

Version only intended for information purpose.

**Should you wish to join the consortium, please
contact EULA aisbl to enquire about the procedure.**

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REACH LIME CONSORTIUM AGREEMENT

This Consortium Agreement (hereinafter, the “Agreement”) is made and executed on _____ 2009, by and between:

_____, a company established under the laws of _____ with a registered office in _____, hereby represented by its duly appointed legal representative;

_____, a company established under the laws of _____ with a registered office in _____, hereby represented by its duly appointed legal representative;

_____, a company established under the laws of _____ with a registered office in _____, hereby represented by its duly appointed legal representative;

_____, a company established under the laws of _____ with a registered office in _____, hereby represented by its duly appointed legal representative;

_____, a company established under the laws of _____ with a registered office in _____, hereby represented by its duly appointed legal representative;

Hereinafter collectively referred to as “Parties” or “Members”, and each a “Party” or “Member”

Section I. Preamble

WHEREAS, the Members to this Agreement are manufacturers, importers, only representatives, data holders, downstream users and/or Third Party Representatives (as defined below), of the substances listed and identified in Appendix 1 hereto (hereinafter referred to as the “Substances”); with a registered company (i.e., a legal entity) established in the territory of the European Union;

WHEREAS, pursuant to Regulation (EC) 1907/2006 of the European Parliament and of the Council (hereinafter referred to as “REACH”), manufacturers and importers are subject to an obligation to register the relevant Substance within the deadlines referred to in Article 23 of REACH, provided that they have pre-registered these substances before 1 December 2008;

WHEREAS, the Substances have phase-in status according to Article 3(20) of REACH and have been pre-registered;

WHEREAS, pursuant to Article 29 of REACH, the manufacturers, importers, only representatives and data holders of this Agreement are also participants in the Substance Information Exchange Forum (SIEF) with respect to the Substances;

WHEREAS, SIEF may be a starting point for a suitable platform for participants to organize among themselves the mandatory joint submission of data, as provided for in Article 11 of REACH, including as an option the exchange of the data needed to perform the Chemical Safety Assessment (CSA) and drafting the Chemical Safety Report (CSR);

WHEREAS, REACH expressly encourages and aims to facilitate the sharing and joint submission of data by multiple registrants (Articles 11 and 19) for registration purposes; and WHEREAS, the Members of this Agreement agree to share existing vertebrate animals data and develop jointly any missing vertebrate studies that is needed for the Registration of the Substances under REACH, taking into account the provisions set out in the ECHA guidance document concerning the sharing of vertebrate animals data;

WHEREAS, the Parties to this Agreement hereby wish to form a consortium in order to facilitate the sharing and joint submission of data relating to the Substances for the purposes of REACH (the “Consortium”);

WHEREAS, cost allocation under this Agreement should be proportionate and reflect the Members’ respective tonnage categories, resulting in lower costs for manufacturers and importers of lower tonnages; and WHEREAS, the Members’ voting rights should also be proportionate and reflect cost allocation and related tonnage categories;

WHEREAS, the parties agree that a Trustee should be appointed to handle sensitive information;

WHEREAS, the Members agree to conduct their activities in a fair, transparent and non-discriminatory way, and in full compliance with applicable competition laws.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties agree as follows:

Section II: Fundamentals

1. Definitions

The definitions in Article 3 of REACH apply in addition to:

- (1) *Regular Member*: a manufacturer, importer or only representative, who is subject to a registration requirement according to REACH and who is a signatory of this agreement. A Regular Member can be represented in the Consortium by a third party, i.e. a natural or legal person (e.g., an affiliate or a trade association) acting on behalf of one or more other legal entities or natural persons pursuant to a written mandate to lawfully represent these legal entities and provided that the list of the legal entities or natural persons it represents is communicated to the Coordinator.
- (2) *Associate Member*: a downstream user within the meaning of Article 3(13) of REACH or a data holder whose participation in the Consortium has been accepted by the Regular Members. An Associate Member can be represented in the Consortium by a third party, i.e., a natural or legal person (e.g., an affiliate or a trade association) acting on behalf of one or more other legal entities or natural persons pursuant to a written mandate to lawfully represent these legal entities or natural persons and provided that the list of the legal entities it represents is communicated to the Coordinator.
- (3) *Affiliate*: any legal entity controlling, controlled by, or under the common control of 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 person, 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 or other ownership interest of a legal person. Affiliates must be notified to the Coordinator who will maintain a list of the name.
- (4) *Steering Committee*: the committee of the Consortium which is authorised to make decisions on behalf of the Consortium. The Steering Committee will consist of one representative of each Regular Member.
- (5) *Third Party Representative*: a natural or legal person appointed by a manufacturer, importer or only representative pursuant to Article 4 of REACH.

- (6) *Lead Registrant*: a manufacturer, importer, only representative, or their third party representative which, pursuant to Article 11(1) of REACH, submits the information specified in Article 10(a)(iv), (vi), (vii) and (ix), any relevant indication under Article 10(a)(viii) and optionally information under Article 10(a)(v) and (b) and any relevant indication under Article 10(a)(viii) on behalf of and with the agreement of the other assenting registrants of the Substance.
- (7) *Lead Company*: the Regular Member nominated by the Steering Committee for the role of Lead Registrant for one or more Substances.
- (8) *Core Data*: the data to be submitted jointly by the Regular Members and/or the legal entities they represent in all cases pursuant to Article 11(1) of REACH as listed in Article 10 of REACH, including:
- Classification and labelling of the Substances pursuant to Annex IV section 4 of REACH.
 - Study summaries of the information derived from the application of Annexes VII to XI of REACH.
 - Robust study summaries derived from the application of Annexes VII to XI, if so required under Annex I of REACH.
 - Testing proposals where required by the application of Annexes IX and X of REACH
 - A chemical safety report when required under Article 14, in the format specified in Annex I of REACH.
- (9) *Studies*: reports in written or electronic form on investigations, tests, or other examinations (excluding or including vertebrate animals), which relate to intrinsic properties of the Substances or to the exposure assessment and risk characterisation in the chemical safety report and as such are of relevance for registration pursuant to Article 10 of REACH; these also include summaries and robust study summaries of the reports. A study can also represent a peer review of other studies.

- (10) *Information*: studies according to (9) and other test data and information made available to the Members by a Member or any third party or generated by the Members jointly, pursuant to or in the course of this Agreement.
- (11) *Coordinator*: a natural or legal person responsible for daily management of the Consortium, appointed by the Steering Committee and hereby acting within the decisions of the Steering Committee. A confidentiality agreement will ensure that the Coordinator does not misuse any data it receives.
- (12) *Trustee*. A third party independent from the Members who is appointed by the Steering Committee in order to receive and handle sensitive Information, to keep it confidential vis-à-vis the Members and any third parties, and to organise the voting system in accordance with the mechanisms provided for in this Agreement and on the basis of the information received from the Members. The Trustee will also handle invoicing for the Members when this relates to amounts that are linked to sensitive information. A confidentiality agreement will ensure that the Trustee does not misuse any sensitive data it receives. The Trustee must ensure that specific internal procedures effectively protect any Information disclosed to him.
- (13) *External Expert*: a natural or legal person appointed by the Steering Committee to provide expert input and services to facilitate the joint submission of data. The complete description of the services to be provided by External Experts will be detailed in the contract between the External Expert and the Consortium.
- (14) *Industry Technical Panel*: a panel consisting of experts appointed by the Steering Committee to review and assist the work carried out by the External Experts. The experts of the Industry Technical Panel will also advise the Steering Committee on scientific and technical aspects as required. The work done by the experts of the Industry Technical Panel is performed for no remuneration. If requested to do so by the Steering Committee, the experts of the Industry Technical Panel may however provide services as External Experts.
- (15) *Letter of access*: a letter as set out under Appendix 9 granting the rights to refer to a Full Study Report submitted to the Agency in accordance with Article 10 (a) of the REACH Regulation.

- (16) *Consortium*: a contractual cooperative structure between companies that pool resources and share costs for achieving a common and limited goal.
- (17) *Lime* – a substance that is listed in Appendix 1 hereto.
- (18) *Data holder*: a person who is in legitimate possession of a hard copy of relevant data (i.e., the full study report) with the right to use it for the registration of the Substances under REACH.

2. Purpose and Goal of the Consortium

- (1) The purpose of this agreement is to define the terms, conditions, rights and obligations of the Parties (including but not limited to voting rights, data sharing and financial obligations) with a view to preparing a joint dossier for the registration of Substances under REACH, which are manufactured, imported, used or for which the Parties hold Information or agree to jointly develop Information.
- (2) The Members shall co-operate in good faith in order to facilitate their compliance with the requirements pursuant to REACH for substance registration. In particular, the members agree to perform the following duties under this Agreement:
- a) Development of Core Data as specified in Section III.
 - b) Preparation of the chemical safety report and the guidance on safe use of the Substances as specified in Section IV.
 - c) Submission of the Core Data, the chemical safety report and the guidance on safe use of the Substances by the Lead Registrant for the purpose of registration¹.
 - d) Cooperation between Members in order to identify and share existing data, identify and fill data gaps for the purpose of joint submission.
- (3) The Substances shall be registered by the earliest deadline applicable for that Substance.

¹ An indication as to which of the information submitted jointly has been reviewed by an assessor having appropriate experience shall be provided in compliance with Article 10(a)(viii) of REACH.

- (4) The cooperation also applies to the registration dossier and substance evaluation phases pursuant to Title VI, Chapters 1 and 2 of REACH, and to possible future updates of the Core Data, chemical safety report and guidance on safe use pursuant to Article 22 of REACH.
- (5) In view of the strict deadlines set by the REACH Regulation for the submission of the Core Data required for each substance, strict adherence to any working deadline or procedure set up by the Steering Committee under this Agreement is an indispensable condition of the Membership.
- (6) The Consortium wishes to pursue the aforementioned purposes in order to avoid dual work, to reduce expenses and to file a harmonised set of data for registration.
- (7) Each individual Member of the Consortium is responsible for observing its rights and obligations according to REACH, in as much as these rights and obligations are not observed by the Consortium in accordance with this Agreement. This applies, in particular, to information which is to be submitted individually to the Agency within the registration dossier in due time by each Regular Member as well as to communication in the supply chain in the form of safety data sheets.
- (8) The Members acknowledge that any activities carried out under this Agreement have to be carried out in full compliance with EU competition law as well as the national competition laws of EU Member States. The Members acknowledge that it is their individual responsibility to observe Articles 81, 82 of the EC Treaty, Article 25(2) of REACH and the Code of Conduct attached in Appendix 5.

3. Confidentiality

- (1) In accordance with this Agreement, the Members undertake to treat all Information made available to them in the context of this Agreement as confidential and not to disclose it to third parties (i.e. any natural or legal person who is not a signatory to this agreement) unless required by law to do so for example the requirement to supply other members of a SIEF with relevant studies for consideration. Each Member undertakes to ensure that its representatives and affiliates comply with the same duty of confidentiality. Members are not under a duty of confidentiality in respect of their own data or any Information: a) which

is, at the time of disclosure, public information generally known on a non-confidential basis; or b) which after disclosure becomes public information generally known on a non-confidential basis through no fault of the Members; or c) which the Members can demonstrate through tangible evidence was in its possession before receipt from the Member disclosing it; or d) which the Members can demonstrate through tangible evidence is developed independently by it without reference to or reliance upon the subject of the information received from the member; or e) which is disclosed to the Members without restriction on disclosure by a third party who has the lawful right to disclose such information.

- (2) In accordance with competition laws, the Members agree not to provide other Members access to any commercially sensitive information which would enable a competitor to alter its commercial strategy, for example but not limited to pricing, output, marketing and distribution policy information. To the extent that the sharing of such information is necessary for the purposes of the Consortium, for example in relation to cost allocation and declaration control, the Members agree to mandate the trustee to receive and process this information.
- (3) The Members agree to provide access to Information specified in (1) to the members of the Steering Committee, the Coordinator, the Industry Experts Panel and the External Experts nominated by the Steering Committee only to the extent that is absolutely necessary for the purposes of the Consortium and subject to the condition that such parties must agree to keep such information confidential and provided that sharing the information does not breach applicable competition law.
- (4) The Members agree to use the Information specified under (1) solely for the purposes of the Consortium specified under Section II.2.
- (5) Granting access to information specified in (1) to persons other than those mentioned under (3) will be subject to a decision of the Steering Committee. Members of the Steering Committee agree to decide on the granting of access according to fair and non-discriminatory principles. For example, access may be denied if there is reason to believe that the information is not required for the purposes of REACH or that the information will be misused.

- (6) In the event of non-compliance with the duties according to the preceding paragraphs, the Members are entitled to exclude the breaching party from this Agreement by a two-thirds (2/3) majority voting. The breaching Member does not have a right to vote. The breaching Member agrees to compensate the Member who has suffered from the breach of confidentiality duties.

4. Rights to Studies

- (1) Existing Studies: The ownership rights to existing Studies made available for the purpose of joint submission in accordance with Section III.1 and Section IV.2(1) are retained by the Regular or Associate Member who owns and provides access to the respective studies and proof of their cost, or, if owned by a non-Member, the ownership rights are retained by that third party owner.

Subject to any licensing terms agreed to by the owner of any Studies, only the holder of the ownership rights may grant a right to refer to or use the study to another natural or legal person.

Subject to compliance with the confidentiality provisions of this Agreement, Regular Members may refer to such Studies in order to satisfy the requirements applying to them under REACH provided they have received a letter of access for such Studies from the owner of the Study or any other natural or legal person lawfully licensed by the study owner to deliver a letter of access. A template of such a letter of access is set out in Appendix 9. At the discretion of the Member owning the Study, the letter of access can be delivered for free or subject to financial compensation in accordance with the cost key agreed upon in Section V.1(4).

- (2) New Studies: The Regular Members shall have joint ownership of Studies generated by the Consortium pursuant to Section III.2 and Section IV.2(2) with respect to their rights and obligations under REACH, provided that those Regular Members have paid in full their share of the cost of the Studies in accordance with the cost key agreed upon in Section V.1(4). The Regular Members shall have the right to use the Studies for their own purposes and that of their Affiliates outside the scope of REACH (for example, in support of a dossier under Directive 98/8 on biocides or Directive 91/414 on plant protection products, as amended) or outside the territory of the European Union (for example, for purposes of compliance with regulatory regimes such as the Toxic Substances Control Act – TSCA - in

the United States), provided that this is limited to the fulfilment of regulatory obligations imposed by competent authorities and that this does not undermine data protection rights on those Studies to the detriment of other Regular Members.

Granting a right of access to the studies generated by the Members pursuant to Section III.2 to third parties for use within or outside the scope of REACH is subject to a decision of the Steering Committee in each case. Members of the Steering Committee agree to decide according to fair and non-discriminatory principles. For example, access may be denied if there is reason to believe that the studies will be misused.

5. Organisation

- (1) The Consortium, including its rights and obligations arising from this Agreement shall not constitute a legal entity between the Members. In external legal relations (including but not limited to entering into contracts with third parties such as the Co-ordinator, the Industry Experts Panel and External Experts nominated by the Steering Committee), the Consortium shall not act under its own name but as a community of all individually designated Members. Collectively, the Members are subject to the rights and duties of the Consortium defined in this Agreement.
- (2) The Coordinator shall, upon prior decision 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. Only the Members who are required to submit the Study according to their tonnage band shall be listed as parties to the agreement and shall be liable for the expenses incurred.
- (3) The Coordinator acts entirely in its capacity as representative of the Members and bears no individual responsibility or liability for its actions taken in this capacity, with the exception of gross negligence or wilful misconduct. The Coordinator is accountable to the Steering Committee

5.1 Members' representation in the Steering Committee

- (1) Each Regular Member shall appoint in writing a natural person to act as its delegate at meetings of the Steering Committee by using the template in Appendix 2 of this Agreement. Such a delegate will be entitled to attend and vote at Steering Committee

Meetings on behalf of the Regular Member and may in like manner appoint a deputy who shall be entitled to attend meetings with or without the principal delegate but who may not vote thereat except in the absence of the principal delegate.

- (2) One or more Associate Members may be notified of any meeting of the Consortium if the interest of the Consortium so requires, but any attending Associate Member shall act in an advisory capacity only and will not have any voting rights. The decision as to whether the interest of the Consortium requires the attendance of the Associate Member will be taken by the Steering Committee according to fair and non-discriminatory principles.
- (3) A list of the nominated delegates and deputies of the Regular Members of this Agreement as well as the Associate Members will be maintained by the Coordinator.
- (4) The Coordinator shall compile and keep up to date the list of the delegates and deputies of Regular Members and the list of Associate Members. Appointments, revocations or replacements of delegates by the Regular Members shall be notified in writing to the Coordinator.

5.2 Presidency of the Steering Committee, Lead Registrant(s) and Coordinator

- (1) The Steering Committee shall elect from among its members' a President and a Vice-President, each to serve for a term of office to be decided by the Steering Committee. In case the President is absent or unavailable, the meetings of the Steering Committee shall be presided over by the Vice-President. In case the President and the Vice-President are absent or unavailable, the Steering Committee shall elect from among its members attending the meeting a person to chair the meeting.
- (2) The Steering Committee shall elect a Lead Company to be nominated for the role of lead registrant within the SIEF for each Substance listed in Appendix 1. The same legal entity can be nominated and/or elected as Lead Company for more than one Substance listed in Appendix 1.
- (3) If there is a SIEF-related conflict with the appointment of the Lead Company as Lead Registrant, the Members will endeavour to secure agreement of non-Consortium SIEF participants to the appointment of a Lead Company from this Consortium. In the event that no such agreement can be reached or if the Steering Committee is dissatisfied with the

selection of a non-Consortium Lead Company, the Steering Committee will attempt to act under the REACH Regulation to secure the right for the Lead Company to submit the Core Data separately on behalf of the Members.

- (4) Written invitations to the Steering Committee meetings, detailing the agenda, shall be sent out to the duly appointed delegates of all Regular Members with three weeks' notice by the Coordinator.

5.3 Decision making – voting rights within the Steering Committee

- (1) Only Regular Members are entitled to vote on proposals discussed by the Steering Committee. Each Regular member will be assigned a number of votes according to its tonnage category calculated on the sum of the tonnage² manufactured or imported into the EU for each substance listed in Appendix 1 and on the basis of the voting categories defined in Appendix 3 hereto.

Resolutions shall be decided via written procedure by secret ballot. The trustee will organise the voting procedure and communicate the final decision. The votes cast by individual Regular Members shall be kept confidential and not communicated to the Steering Committee or any of the Members by the Trustee. Any Member could, at his own cost, request an external Trustee to check the secret ballot, the Trustee appointed by the Consortium being bound to allow, within the following 10 business days, the Trustee designated by the requesting Member the original documents of the vote concerned, provided the external Trustee is submitted to confidentiality provisions equivalent to those applying to the Trustee appointed by the Consortium.

- (2) Standard way of deliberation: Unless specified otherwise in this Agreement, the Steering Committee may deliberate and validly act only if the Regular Members present or represented hold at least one half of the votes of the current Regular Members. Any Regular Member's delegate (or deputy) who is unable to attend a particular Steering Committee meeting may appoint one of his colleagues in the Steering Committee to represent him at that particular meeting, provided that such appointment has been notified

² All tonnages shall be expressed in metric tonnes and the year of reference for the determination of the tonnage is the year before the year of admission of the Regular member (e.g. the reference year for a Regular member joining the consortium in 2009 is the year 2008).

in writing to the President or to the Coordinator in advance of the meeting. All decisions shall be taken by simple majority of the votes cast; in case of a tie vote (i.e. 50% of the votes for and against), the President has no additional casting vote and another discussion should take place before another vote can take place.

- (3) Special way of deliberation: As an exception to the standard way of deliberation detailed above under (2), the Steering Committee may deliberate and take resolutions only if the Regular Members present or represented hold at least two-thirds of the votes of the current Regular Members. In the special way of deliberation, all decisions shall be taken by a two-thirds majority of the votes cast. The special way of deliberation will apply only in relation to decisions as to:
- any modifications to this Agreement and the Appendixes 1, 3, 7, and 8
 - exclusion of a Member; or
 - decisions regarding admitting new Members.
- (4) The Steering Committee reserves the right to make all decisions, unless otherwise specified in this Agreement.

If the quorum for discussing and voting on a matter is not reached at a meeting of the Steering Committee, that matter shall be automatically postponed for discussion and vote to the next meeting of the Steering Committee irrespective of whether or not the quorum is reached.

- (5) A delegate in the Steering Committee shall be excluded from voting on decisions that concern personally him or the Member he represents (e.g., exclusion from the consortium, breach of confidentiality duties, payment defaults, assessment of the quality or value of his data, appointment or withdrawal as Lead Registrant), or matters by which the Member is not affected (e.g., voting on tests not required for registration of the Member in question, voting on issues concerning a specific Substance not manufactured or imported by the Regular Member).
- (6) Upon the request of the Coordinator or of at least 25% of the Regular Members, the President or Vice-President of the Steering Committee may determine that an urgent matter must be dealt with other than by way of holding a Steering Committee meeting, for example, by calling for votes by email or other written procedure. In such case, the Trustee with the assistance of the Coordinator shall, using the contact details of the Regular Members notified to the Coordinator

from time to time, communicate the details of the matter (and the appropriate voting procedure) to each Regular Member entitled to vote on that matter and request votes to be submitted to the Trustee in writing by no later than two clear Business Days (in the Member's country) following the date of the notice. In determining the final decision from the responses to the request for votes in this paragraph, the Trustee shall determine whether the responses received constitute quorum as required by this Agreement and:

- (a) if the responses satisfy the requirements for quorum, determine the decision in accordance with those responses; or
- b) if the responses do not satisfy the requirements for quorum, the Trustee shall determine the decision in accordance with both the responses received within the two clear Business Days and those received within an additional 24 hours past the end of the two clear Business Days allowed for voting and such responses taken together shall be deemed to satisfy quorum for the purpose of reaching a decision on the matter. For the avoidance of doubt, the Trustee is under no obligation to notify the Regular Members that quorum has not been reached on the basis of the responses received within the two clear Business Days following the date of the notice.

The Trustee will communicate the final decision on the matter to the Regular Members within two clear Business Days of the deadline for the submission of votes.

5.4 Structure

- (1) The Steering Committee shall appoint a Coordinator to assist the Steering Committee for the duration of the Agreement. Such an appointment may be revoked at any time by a decision of the Steering Committee according to the standard way of deliberation.
- (2) The Steering Committee may appoint sub-committees and working groups, such as Panels for Health, Environment and Industry Technical experts, consisting of such persons as the Steering Committee may think fit, on such terms as the Steering Committee may think fit.
- (3) The Steering Committee may use the services of External Experts or other competent third parties under the terms and conditions to be agreed by the Steering Committee according to the standard way of deliberation
- (4) The structure of the Consortium is set out in Appendix 6.

(5) The Lead companies' and Coordinator's details will be made available in Appendix 4.

(6) The Coordinator will maintain and provide access to the Lead Companies' details to the Members following their appointment.

6. Working and Finance Plan

The Coordinator, assisted by the Industry Technical Panel, shall prepare a working and finance plan concerning the planned activities until submission of the registration dossier, in particular concerning development of information stated in Sections III and IV. A preliminary working and finance plan will be presented at the first meeting of the Steering Committee and updated every six months. The initial working and finance plan as well as its subsequent updates shall be agreed and adopted by the Steering Committee.

Section III: Development of Core Data

1. Provision of Existing Studies on Core Data

(1) As soon as reasonably practicable (e.g., within one month of the commencement date of this Agreement, or with month week after joining the Consortium subsequent to the commencement date if this Agreement), the Members shall inform the Coordinator of any relevant existing study legally owned by them and other available studies of which they are aware or Core Data concerning the relevant Substance(s).

(2) On the basis of competent analysis and in accordance with principles provided in the ECHA Guidance on Data Sharing and Guidance on Evaluation of Available Information, respecting the usability of the Studies made available for registration in accordance with (1), the Coordinator shall prepare a proposal for their financial value on the basis of the valuation rules indicated in Appendix 7. This proposal shall be agreed and adopted by the Steering Committee.

2. Determination of New Test Data

(1) To the extent required under Annexes VII to XI of REACH and upon proposals from the Industry Technical Panel and External Experts, the Steering Committee shall agree for each Substance the end points that are still subject to testing and shall thereby take into account

the regulations specified in Annex XI of REACH on the rules for adapting the testing regime. The possibility of read-across of Studies and waivers (e.g. adaptation to testing requirements) shall be carefully considered by the Industry Technical Panel and External Experts to decide to what extent testing of one Substance will fill data gaps for other Substances covered by the Consortium. The Industry Technical Panel should identify testing needs, formulate proposals for additional tests pursuant to Article 10(a)(ix) of REACH to the extent provided for in Annexes IX and X of REACH, and recommend who should undertake the testing. The Steering Committee then shall endorse the test proposal and the contract laboratories.

Section IV: Preparation of a Chemical Safety Report

1. Uses

Uses of the Substances to be assessed in the chemical safety report will be proposed by the Members, evaluated by the Coordinator and Industry Technical Panel and approved by the Steering Committee. For the uses agreed to be covered under the joint Chemical Safety Report, the Steering Committee may require the assistance of the Trustee if there is a need to collect confidential information. Should the Steering Committee decide not to cover a specific use under the joint submission, each Regular member may decide to produce its own Chemical Safety Report covering its own specific use.

2. Development and Provision of Information Concerning Chemical Safety Assessment

- (1) To the extent available, the Parties shall provide the Trustee with the required Studies, in particular with respect to information on exposure to the Substances, for the purposes of the chemical safety report on uses to be assessed jointly.
- (2) The Steering Committee shall oversee the Industry Technical Panel's work to arrange for provisions of missing Studies pursuant to (1).

3. Preparation of the Chemical Safety Report and Guidance on Safe Use

The Coordinator and Industry Technical Panel are responsible for the preparation of the chemical safety report and the guidance on safe use of the substances. The Steering Committee will review the Chemical Safety Report and the Guidance on Safe Use of the Substances and, provided that the Steering Committee is satisfied with their content, will adopt them.

Section V: Financial Rights and Obligations

1. Consortium Expenses

- (1) The Regular Members shall bear the Consortium expenses according to the allocation determined by the Cost Key in Appendix 8 taking the expenses detailed under paragraph (2) into consideration.
- (2) The Consortium expenses are those connected with the management, coordination and commissioning of Core Data. These expenses include:
 - a) *Historical expenses*; Any compensation paid to a Member or a third party for a work carried out outside the scope of this agreement, provided that the Steering Committee has agreed on (i) the relevance of this work for the attainment of the objectives of the consortium and (ii) the compensation to be paid to get the right to use this work.
 - b) *Generic administrative expenses to run the consortium*. These are the running expenses incurred by the consortium. These include, in particular, remuneration for coordination. (technical experts in-house, secretariat, trustee, finance person,...) and expenses for organising meetings. This does not include the work of external experts (consultants).
 - c) *Research expenses*. These are the costs of the external experts
 - d) *Compensation for existing studies*. Expenses to be paid to the Regular or Associate Members or Third Party in accordance with the valuation rules pursuant to Section III.1(2) as reimbursement for existing Studies made available to the Consortium by them.
- (3) Expenses incurred by Members in the performance of their individual duties cannot be recovered unless specifically approved by the Steering Committee.
- (4) The Consortium expenses stated under (2) shall be allocated to the Regular Members in accordance with the cost key specified under Appendix 8.
- (5) All payments due here above 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 payee would have received and so retained had no such deduction or withholding been made or required to be made (gross-up amount). If upon application of the beneficiary any withholding tax can be reduced, or refunded, or an exemption from withholding tax is granted, payer shall file on behalf of payee for such reduction, refund or exemption. Payee shall render any assistance to payer to obtain such withholding tax reduction, refund or exemption. Payer shall be entitled to any refund of withholding taxes.

- (6) Indirect Taxes, including but not limited to Value Added Tax (VAT), Goods and Service Tax (GST), Service Tax and Business Tax, as applicable pursuant to the relevant tax law, shall be borne by payer. However, payer is entitled to withhold any payment of indirect taxes unless payee has provided payer with a sufficient invoice for purposes of indirect taxation.
- (7) All invoices sent by the Trustee are payable within 30 days. After this delay, a reminder will be sent by registered mail and the amount of the invoice will be automatically increased by 5%. Should an invoice not be settled within 3 months by a Member, the Member will be automatically subject to expulsion from the consortium. The final decision will be taken by the Steering Committee in accordance with the procedure detailed in section VI.2 (3).

2. Computation of Expense Allocation, Settlement Date, Advance Payments

- (1) The Coordinator shall compute the allocation of all expenses incurred by the Consortium up to the end of each calendar year by 1st March of the respective following year, thereby taking into account charges having an effect on the past. The Steering Committee shall review these accounts and provided the Steering Committee is satisfied with their accuracy and completeness, the Steering Committee shall adopt them.
- (2) Advance payments that are likely to be incurred by the Members in respect of which the Member wants to be reimbursed by the Consortium can be agreed through a resolution of the Steering Committee Deliberating according to the standard way of deliberation.
- (3) The Trustee shall review the relevant tonnage category for each Member every three years and adapt the relevant fees and cost allocations for the next year. However, any prior

decision made by the Members pursuant to the tonnage category that was allocated to them at the time of the decision shall not be affected.

Section VI: Memberships

1. Production tonnage notification obligations

- (1) All Regular Members shall provide faithfully the Trustee with its tonnage category and any other adequate data for checking the tonnage category. For that purpose, all tonnages shall be expressed in metric tonnes and the year of reference for the determination of the tonnage is the year before the year of admission of the Regular member (e.g. the reference year for a Regular member joining the consortium in 2009 is the year 2008).

2. Admission of New Regular or Associate Members

- (1) The Consortium may admit new Regular Members by decision of the Steering Committee deliberating following the special way of deliberation. Applicants shall not be denied membership provided that they are manufacturers, importers, only representatives subject to registration requirements concerning the substances in Appendix 1 or a Third Party Representative of any such party. The applicant shall (i) sign a declaration thereby recognising the terms and conditions as set out in this Agreement as well as all the decisions validly taken by the Steering Committee before the date of the admission of the newly admitted Member, (ii) commit to provide faithfully the Trustee with its tonnage category and any other adequate data for checking the tonnage category, and (iii) agree to pay the relevant fees pursuant Section VI.1(5) below. Members of the Steering Committee agree to decide on the admission of new Members according to fair and non-discriminatory principles and any decision refusing admission shall clearly state the reasons why membership was not granted. The applicant whose application was refused shall have the right to make submissions in writing to the Steering Committee and the Steering Committee shall review such submissions and reply in writing within 3 months of receiving them.
- (2) Any only representative applying to become a Member of the Consortium will be required to disclose to the Coordinator and to the Trustee the number and identity of their principals and evidence of their authority to act as the representative of each principal. Information regarding the only representatives' principals must be held confidential by the Coordinator

and the Trustee and must not, without the prior written consent of the only representative, be disclosed to any Member or other third party.

- (3) Any third party representative applying to become a Member of the Consortium will be required to disclose to the Coordinator and to the Trustee the number and identity of their principals and evidence of their authority to act as the representative of each principal, for the purpose of delivering letters of access and allocating the share of the costs in accordance with the cost key specified under Appendix 8. Information regarding the third party representatives' principals must be held confidential by the Coordinator and the Trustee and must not, without the prior written consent of the third party representative, be disclosed to any Member or other third party.
- (4) By decision of the Steering Committee deliberating following the special way of deliberation, the Consortium may admit new Associate Members provided that these Members can contribute Information to pursue the joint purposes of this Consortium.
- (5) Pursuant to the cost key specified under Appendix 8, A newly admitted Regular or Associate shall pay a portion of the expenses incurred by the Consortium to date pursuant to Section V.1(2) b) and c) in the form of a prorated refund to the other Members.
- (6) Upon payment of the amounts indicated in (5), the new Member has the unlimited rights and obligations of a Regular Member or Associate Member as applicable.
- (7) The Steering Committee shall take decisions relating to the granting of a Letter of Access to non-Members, including but not limited to decisions as to whether or not access is to be granted, the amount of compensation, the terms and conditions under which access is granted, as well as the specific legal entities to which access is granted.

3. Withdrawal of a Member

- (1) A Member withdraws from the Consortium by termination or through exclusion from the Consortium.
- (2) Termination is permissible subject to 6 months notice in writing being given. Considering the registration deadline (1 December 2010) for the Substances, this means that termination will not be permissible after 1 June 2010 until the 1 December 2010 deadline for registration has passed.

- (3) Exclusion from the Consortium requires a decision by the other Steering Committee members deliberating according to the special way of deliberation. Exclusion takes place only in the event of serious reasons such as material breach of this agreement, such as the lack of collaboration with the Trustee, wrongful declarations, breach of confidentiality provisions, or default of payments. The Member whose exclusion is to be decided by the Steering Committee shall not have the right to vote.
- (4) In the event of withdrawal, the rights and obligations pertaining to this Agreement cease to exist other than with respect to the rights and obligations specified in Sections II.3, II.4, and Section VI.5 (Confidentiality, Right to Studies and Liability) which continue for a period of 12 years following first registration of the Substance by a Member. In relation to any surviving rights in Sections II.3, II.4 and Section VI.5, such rights will only continue to exist if all of the withdrawing Member's share of any Consortium expenses owed pursuant to Section V have been paid in full. The rights of remaining Members to use the Studies as specified in Section II.4 that have been made available by the Member who has withdrawn, shall continue to exist.

4. Transfer of Membership

- (1) A Member shall be entitled to transfer his membership including all its rights and obligations under this Agreement to a third party, provided that the party to which the Membership is transferred must meet all the requirements and conditions of membership set out in Section VI (2). Any such transfer is subject to prior 2/3 majority vote of the Members acting in the Steering Committee, which shall not be unreasonably withheld. The third party which benefit from this transfer of membership shall explicitly accept this transfer. The transfer by a Member of individual rights or obligations arising from his membership to a third party shall not be permitted. It is understood that after the transfer of its membership the former Member shall cease to have any rights arising from this Agreement.
- (2) The Member who intends to transfer his membership shall notify the Trustee by registered letter at least 30 days before the transfer of membership. The Members acting in the Steering Committee shall decide pursuant to paragraph 1 above, within 30 days of notification; the absence of a decision means acceptance.
- (3) The consent of the Steering Committee shall not be required in case of a transfer of membership by a Regular Member to an Affiliate or in the case of restructuring within a

Regular Member's group of companies or in case of a merger, an acquisition, a division or sale of a branch of activities, or any other type of concentrative operation, to the extent that the merged entity or branch of activities was a Member of the Consortium. In such a case, the cost shares already paid by the Member of the Consortium under this Agreement shall be taken into account when calculating the cost shares due by the new Member.

5. Liability of the Members

- (1) Each Member is required to exercise due care and diligence with regard to each other Member in observing the rights and obligations arising from this Agreement. No Party, [including any Lead Registrant], shall be liable for any direct, indirect or consequential loss or damage (including but not limited to loss of actual or anticipated profits, loss of revenue, loss of use and any loss arising from business interruption) incurred by another member in connection with the activities contemplated in this Agreement, unless such loss or damage was caused by gross negligence or wilful misconduct. Members of the Consortium assume liability for the correctness of any Studies provided in accordance with Section III.1(1) and in accordance with Section IV.2(1) and for any infringement of third party intellectual property rights in providing the relevant Study to the Consortium.
- (2) 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.
- (3) Other than as stated above, each Member shall be liable to third parties within the scope of that Member's responsibility. The Members of the Consortium shall support a Member against whom a claim for liability is made by a third party in the defence against this claim to the extent possible and reasonable, provided a full, written explanation of the circumstances and details of the basis for the claim is provided to them.

Section VII: Duration and Dissolution of the Consortium

1. Duration

By mutual agreement, the date of entry into force of this Agreement is 15 March 2009. The Agreement will be signed by duly authorised representatives of all Members. The Consortium shall exist for an indefinite period of time.

2. Dissolution of the Consortium

The Consortium may be dissolved by decision of the Steering Committee by a two thirds majority of the votes cast. A respective resolution shall be taken if the purpose as defined under Section II.2 has been fulfilled to its full extent.

3. Winding up of the Consortium

- (1) In the event of dissolution the Consortium is to be wound up, all asset-involving rights and obligations of Members jointly and separately and in relation to third parties resulting from this Agreement shall be settled. Any continuing rights of individual Members to the Studies determined pursuant Section III or IV shall be transferred to a third party who shall keep these rights for the respective Members in a fiduciary capacity.
- (2) Upon liquidation pursuant to (1), all rights and obligations of the Members arising from this Agreement that do not involve assets shall lapse. This does not apply to the obligations specified in Sections II.3, II.4 and VI.5 for a period of 12 years following first registration of the Substance(s) by a Member.

VIII: Concluding Provisions

1. Exclusivity and Amendments to the Agreement

- (1) The legal relationships of Parties with respect to this Consortium shall be governed exclusively by this Agreement; other arrangements do not exist or are ineffective.
- (2) Amendments to this Agreement can only be made following a vote of the Steering Committee through the special deliberation procedure and are only effective in written form.

2. Governing law

This Agreement is governed by the laws of Belgium and the Parties submit to the exclusive jurisdiction of the courts of Belgium.

3. Jurisdictional venue, Arbitration

- (1) Any dispute between Members (“Disputing Members”) concerning the negotiation, formation, interpretation and/or implementation of this Agreement, shall be resolved by arbitration under the rules of conciliation and arbitration of the International Chamber of Commerce. The decision of this Chamber shall be final and binding on the Disputing Parties. The arbitral tribunal consists of three arbitrators: each Member designates one arbitrator; these two arbitrators then designate the third arbitrator who acts as chairperson; the chairperson shall have a university degree in law. The cost of arbitration shall be paid by the Disputing Members involved on equal terms; any out-of-court costs shall be borne by the party responsible for incurring said costs. The arbitral tribunal shall decide on the regulation of the cost of arbitration including out-of-court costs incurred by the Disputing Members in accordance with the outcome of the arbitration. The language of the proceedings shall be English. The seat of arbitration shall be Brussels, Belgium. The arbitration shall be based on the substantive law of Belgium.
- (2) Nothing in this Agreement prevents a Member from seeking interlocutory or interim relief from a court of law.

3. Severability

- (1) If a provision of this Agreement is found to be unclear, an interpretation that comes closest to the intent of the Parties as expressed in this Agreement shall apply. If a [loophole] is found in the Agreement, the same applies to the supplementary interpretation.
- (2) If a provision is invalid, this does not affect the validity of the other provisions. In place of the invalid provision an admissible provision which will come as close as possible to the intent of the Parties is deemed agreed upon; the Parties agree to make a respective written amendment to the Agreement without any delay.

4. Counterparts

This Agreement will be executed in a number of counterparts which will together constitute one document, held by the Coordinator as custodian of the Agreement. The Coordinator will circulate one complete copy of the Agreement to all Members.

IX: Transitional Provisions

1. Special rules for the kick-off meeting of the Steering Committee on 26 March 2009

By way of derogation from the provisions in this Agreement relating to the voting rules and invitation to the Steering Committee meeting, the Regular Members decide the following:

- (i) the kick-off meeting of the Steering Committee will take place on 26 March 2009 in Brussels (Belgium).
- (ii) The scope of the kick-off meeting shall be limited to decisions allowing the Consortium to become operational, which are detailed below:
 1. *Welcome & antitrust statement*
 2. *Election of the President, Vice-President and Lead Company*
 3. *Setting-up of the Industry Technical Panel and appointments of experts*
 4. *Election of the Chair of the Industry Technical Panel*
 5. *Appointment of the Coordinator (confirmation or invalidation)*
 6. *Appointment of and mandate to the Trustee*
 7. *Work Programme of the Industry Technical Panel*
 8. *Mandate to the Industry Technical Panel*
 9. *Appointment of External Experts*
 10. *Finance*
 - *Budget*
 - *Invoicing plan*
 11. *Date & place of the next meeting*
- (iii) All the decisions to be taken at this meeting shall be taken by simple majority of the Regular Members present or represented on the basis of a single vote (i.e. 1 vote) for each Regular Member present or represented, irrespective of the respective tonnage categories.

2. Appointment of the Coordinator

- (1) The Members decide to appoint IMA-Europe aisbl as the Coordinator of this Consortium. This decision shall be confirmed or invalidated by the Steering Committee at its first meeting.

Member (Company's name)	Place	Date
.....
<p>I hereby declare that I am entitled to lawfully engage the company and I have been informed of the consequences of an invalid mandate.</p> <p>Please handwrite "Read and approved" and sign</p> <p>(Signature)</p> <p>Name:</p> <p>Position in the company:</p>		

LIST OF APPENDIXES

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Appendix 1: Substance Specifications

Chemical name	EINECS	CAS	Formula
Calcium oxide	215-138-9	1305-78-8	CaO
Calcium dihydroxide	215-137-3	1305-62-0	CaH2O2
Calcium, magnesium oxide	253-425-0	37247-91-9	CaMgO2
Calcium magnesium tetrahydroxide	254-454-1	39445-23-3	CaH4MgO4
Dolomite calcined	281-192-5	83897-84-1	CCaMgO4
Calcium magnesium (di)hydroxide oxide	261-235-4	58398-71-3	CaH2MgO3
Lime (chemical) hydraulic	285-561-1	85117-09-5	-

Appendix 2: List of Regular members, their delegates and deputies, and of Associate members

I. REGULAR MEMBERS

Company name : Address : Duly appointed Delegate: Surname and first name : Address : Tel. : E-mail : Duly appointed Deputies: Surname and first name : Address : Tel. : E-mail :

Company name : Address : - Duly appointed Delegate: Surname and first name : Address : Tel. : E-mail : Duly appointed Deputies Surname and first name : Address : Tel. : E-mail :

II. ASSOCIATE MEMBERS

Organisation/Company name : Address :
--

Duly appointed Delegate:

Surname and first name :

Address :

Tel. :

E-mail :

Appendix 3 – Allocation of votes based on tonnage categories

Each Regular member will be assigned a number of votes according to its tonnage category calculated on the sum of the tonnage³ manufactured or imported into the EU for each substance listed in Appendix 1, as follows.

a. below 1,000 T:	1 vote
b. between 1,000 T and 10,000 T:	2 votes
c. between 10,000 T and 50,000 T:	6 votes
d. between 50,000 T and 200,000 T:	25 votes
e. between 200,000 T and 500,000 T:	70 votes
f. between 500,000 T and 1,500,000 T:	200 votes
g. above 1,500,000 T:	250 votes

Example

Company A manufactures 180,000 T of calcium oxide and transforms 20,000 T of this production into 26,430 T of calcium dihydroxide.

-Tonnage for calcium oxide manufactured or imported: 180,000 T

-Tonnage for calcium dihydroxide manufactured or imported: 26,430 T

-Sum of the tonnage for each substance manufactured or imported = 180,000 T + 26,430 T = 206,430 T

This tonnage corresponds to a tonnage category between 200,000 T and 500,000 T.

Company A is assigned 70 votes

³ All tonnages shall be expressed in metric tonnes and the year of reference for the determination of the tonnage is the year before the year of admission of the Regular member (e.g. the reference year for a Regular member joining the consortium in 2009 is the year 2008).

Appendix 4: Lead Company(s) and Coordinator

I. Lead Company(s)

Lead Company for calcium oxide

Legal entity name :

Address :

Contact person :

Address : Rue

Tel.

E-mail :

Lead Company for calcium dihydroxide

Legal entity name :

Address :

Contact person :

Address :

Tel.

E-mail :

Lead Company for calcium magnesium oxide

Legal entity name :

Address :

Contact person :

Address :

Tel.

E-mail :

Lead Company for calcium magnesium tetrahydroxide

Legal entity name :

Address :

Contact person :

Address :

Tel.

E-mail :

Lead Company for dolomite calcined

Legal entity name :

Address :

Contact person :

Address :

Tel.

E-mail :

Lead Company for calcium magnesium (di)hydroxide oxide

Legal entity name :

Address :

Contact person :

Address :

Tel.

E-mail :

Lead Company for lime (chemical) hydraulic

Legal entity name :

Address :

Contact person :

Address :

Tel.

E-mail :

II. COORDINATOR

Name : IMA-Europe aisbl

Address : Rue des Deux Eglises 26, B-1000 Brussels (Belgium)

Contact person : Dr Roger Doome

Address : Rue des Deux Eglises 26, B-1000 Brussels (Belgium)

Tel. +32 2 210 44 20

E-mail : r.doome@ima-europe.eu

Appendix 5: Code of Conduct

REACH competition law compliance guidance
(compiled by Cefic⁴)

⁴ www.cefic.eu

Cefic REACH competition law compliance guidance

Could competition law apply to REACH activities? YES.

It is expressly stated in the REACH Regulation (hereinafter "REACH") that "*this Regulation should be without prejudice to the full application of the Community competition rules.*" (Recital 48). Therefore, rules of competition law adopted at Community level (hereinafter "EC competition law"), but also at the national level, do apply to REACH and all related activities.

REACH is not a competition law free zone

This guidance on EC competition law is intended to help anyone involved in REACH activities, including consortia formation, to assess the compatibility of their activities with EC competition law. Companies involved in REACH should always ensure that their activities comply with EC competition law irrespective of the form of co-operation they choose.

Important Note: *Readers of this guidance should not presume that they know all there is to know about EC competition law just by reading this document. This guidance is designed to allow companies involved in REACH to make a preliminary assessment of their conduct under EC competition law. It does not intend to substitute the applicable EC competition law provisions, as these have been interpreted by the European Courts, the European Commission and the national competition authorities. It only gives general guidance and thus does not and cannot cover all the different competition scenarios that may arise from REACH. Seek legal advice if needed.*

For Cefic and its members: for further clarification and questions, contact
Nicole L Maréchal, Cefic Senior Legal
Counsellor & Governance Officer
Tel. + 32 2 676 72 18 - E-mail: nma@cefic.be



Brief introduction to EC competition law

EC competition law is not intended to prohibit legitimate activities of companies. Its objective is to protect competition in the market as a means of enhancing consumer welfare. Therefore, agreements between companies or decisions by associations or 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 are prohibited - Article 81 (1) of the EC Treaty.

Three basic points should be borne in mind:

1. regardless of the good intentions of companies and groups of companies, if the effect of activities is found to affect competition and markets unduly, this activity will be illegal;
2. Article 81 (1) can be violated by agreements (regardless of their form, whether express or implied, for example: a decision by a consortium, actions minuted as a follow-up of a meeting, exchanges of e-mails.....) as well as by concerted practices;
3. to violate Article 81 (1) it is not required that there is an actual effect on the market; the object to impede competition is sufficient to infringe the law.



EC competition law also prohibits the abuse of a dominant position (Article 82 of the EC Treaty). This may be conduct of one single company, or of a group of companies.

A competition investigation may be initiated either by a competition authority itself; or following a complaint by a third party, or following a leniency application to a competition authority of a party to the unlawful agreement that would like to cease its unlawful activity.

Companies engaged in conduct in breach of Article 81 or Article 82 may not only find that their agreements will be void and unenforceable, but are exposed to significant fines and, under certain Member States legislation, criminal sanctions. Furthermore, an infringement of EC competition law may expose the infringer to significant civil damage claims.

For more information on EC competition law, Articles 81 & 82 of the EC Treaty (see backcover), and the web site of the Commission Directorate General Competition or the web sites of the national competition authorities of the EU Member States (http://ec.europa.eu/comm/competition/index_en.html).

Management of activities DO & DON'T

 DO	 DON'T
REACH ACTIVITIES AND EC COMPETITION LAW	
DO pay attention to EC competition law as this may apply to REACH related activities	DO NOT presume that because you are strictly applying REACH, EC competition law will not apply
COMPETITION COMPLIANCE	
DO comply with EC competition law when acting under REACH DO always refer to EC competition law compliance, adopt a system, and strictly adhere to it DO avoid any misunderstanding by competition authorities about what you are doing	DO NOT misuse REACH activities to engage in anticompetitive conduct such as cartel activities DO NOT ignore, and thus DO know the most important EC competition law rules, as ignorance is not an excuse with competition authorities
ORGANISATION OF ACTIVITIES	
DO have an effective organisation (e.g. by signing appropriate agreements including rules for defining items such as membership, data sharing, cost sharing, adoption of an EC competition law compliance set of rules)	DO NOT work in a disorganised way. If you have rules or sign an agreement apply these in full and ensure they are followed
TYPE OF ACTIVITIES	
DO always apply EC competition law compliance to any type of REACH related activities : not only formal meetings, but also activities such as conference calls, use of IT systems, exchange of correspondence, e-mails, informal meetings	DO NOT engage in prohibited activities during social gatherings incidental to your lawful activities or otherwise; EC competition law rules will equally apply to these
WORKING UNDER REACH	
DO limit your activities to what is strictly required under REACH	DO NOT go beyond activities which are strictly required under REACH
OVERSIGHT AND SUPERVISION	
DO refer to this guidance when conducting activities and distribute it regularly to REACH participants, in particular to newcomers DO have an agenda and minutes which accurately reflect the discussions and matters; limit your discussions to the agenda topics and consult with legal counsel when necessary DO use an independent third party or trustee if necessary (e.g. to exchange individual tonnages from companies when determining the cost sharing of each participant)	DO NOT apply EC competition law compliance guidance infrequently but instead, apply it in your day-to-day activities in order for it to become routine good practice DO NOT deviate from agenda DO NOT draft agenda and/or minutes which do not reflect discussions or activities DO NOT organise the exchange of sensitive information via a company representative who will simply sign a secrecy agreement
RECORD KEEPING	
DO keep a written record of your REACH activities DO ensure retention of the agenda, minutes and other important documents	DO NOT believe that written communications are discouraged. On the contrary, if you are involved in an inquiry conducted by a competition authority your defence may rely heavily on accurate records prepared in the ordinary course of REACH activities which have far more credibility than after-the-fact oral explanations
NECESSARY VIGILANCE	
DO protest against any inappropriate activity or discussion (whether it occurs during meetings, conference calls, social events, or when working via electronic means – for example using a dedicated intranet). Ask for these to be stopped; dissociate yourself from these and have your position clearly expressed in writing, ideally in the minutes or in any case as soon as possible after the respective meeting or activity If a third party or trustee is used to facilitate the meeting, he/she should stay in the room, stop the inappropriate activity and record the incident	DO NOT pursue activities in breach of EC competition law
LEGAL ADVICE	
DO recognise and acknowledge that an issue or question may be complex and needs to be handled in a proper way	DO NOT presume that you know all about competition law rules just by reading this document. It is neither exhaustive nor a substitute for legal advice
DO ask for guidance at an early stage	DO NOT wait to seek appropriate legal advice and DO NOT ignore important questions as these will not be resolved by themselves
DO always remember that if you are uncertain DO NOT act. Ask and wait for the answer, before acting	

REACH DO & DON'T

Working in SIEF

Substance Information Exchange Forums (hereinafter "SIEFs") are provided for in REACH. The aims of the SIEFs are to: (a) facilitate data sharing for the purpose of registration, between potential registrants, thereby avoiding duplication of studies; and (b) agree classification and labelling (for more details, see Article 29 of REACH and related Guidance on Data Sharing available on the ECHA web site http://ec.europa.eu/echa/reach_en.html).

- ✓ **DO** ensure, that the issue of sameness and identity check are handled by applying objective and transparent criteria when discussing the SIEF's formation.
- ✓ **DO** ensure that, before any discussion on the issue of sameness starts with other undertakings, each undertaking individually identifies its own substance(s) and documents its reasons for this approach.
- ✓ **DO** ensure that any deviation from this approach, following discussions with other undertakings, is clearly and objectively justified and documented.
- ✓ **DO** ensure that the final decision on sameness is clearly and objectively justified and those reasons documented.
- ✗ **DON'T** misuse this process to unduly exclude certain competitors.

Consortium membership/participation

Formation of a consortium is one way for companies to organise their co-operation under SIEFs. There are several possible forms of co-operation that companies can choose, consortia being just one of these that is often referred to. A consortium does not need to be a 1:1 image of a SIEF and may only involve some of the participants of a particular SIEF. It may also cover some of the activities to be conducted under REACH, or alternatively, it may cover more than one SIEF.

However, it is generally advisable to open membership of consortia to undertakings that are registrants or potential registrants of the substance(s) to which the consortium relates:

- (i) manufacturers and importers;
- (ii) producers and importers of articles from which the relevant substance(s) are intended to be released;
- (iii) only representatives of (i) and (ii).

In addition, the members of a consortium may consider inviting the following groups to participate in the consortium (this does not necessarily mean that such groups should ultimately be invited):

- (iv) downstream users;
- (v) data holders;
- (vi) other third parties that may have an interest in being involved in a given consortium.

When preparing membership/participation conditions, it is important to have written rules (including a well documented "decision-making" process) which are:

- clear and transparent, avoid ambiguity; and
- based on objective criteria, applied in a non-discriminatory way, with a straightforward admission mechanism.

In addition, distinctions between different types of membership/participation may be made when relevant (e.g. full member, associate member, observer or expert).

- ✓ **DO** ensure that any distinctions between or within categories of members/participants as regards their rights are based on objective criteria. Nonetheless, there are limits to such distinctions, for example :
 - ✗ **DON'T** base distinctions only on size/level of turnover. Note, however, that distinctions may be based on objective criteria, for example, between categories of consortium members that have greater obligations under REACH because they fall into higher tonnage bands;
 - ✗ **DON'T** base distinctions purely on membership of a particular trade association, sector group or other body, as these are separate entities.
- ✓ **DO** ensure as a general rule that, where the membership of a consortium is limited, the rules of the consortium do not result in the total exclusion of access by non-members to data produced in the context of REACH. Such exclusion may, however, be justified in certain circumstances to be interpreted in the light of REACH and related obligations on data sharing and EC competition law.
- ✓ **DO** ensure that the final decision on membership is clearly and objectively justified and the reasons for this decision are documented, in particular in cases where membership is refused.
- ✓ **DO** ensure, as a general rule, that membership rules are sufficiently flexible to allow new members to join at a later date.
- ✓ **DO** base resolution of membership disputes, where possible, on arbitration by an impartial body which applies objective criteria.

Costs

- ✓ **DO** ensure that costs are carefully calculated using a coherent and objectively justified methodology that is well documented.
- ✓ **DO** ensure that costs are only recovered for necessary data.
- ✓ **DO** ensure that costs are divided according to a transparent methodology that is well documented and that is applied in a non-discriminatory way, taking into account all relevant objective factors such as the level of access and right of use.
- ✓ **DO** ensure that any sensitive information supplied for the purposes of cost calculations - such as production volumes - are not directly or indirectly exchanged between participants but are channelled through an independent third party or trustee (See also below).

Data sharing

- ✓ **DO** ensure that differences in levels of access or ownership rights are objectively justified.
- ✓ **DO** ensure that differences in levels of access or ownership rights are reflected in divisions of costs and undertakings are not required to pay for access to information that they do not require for registration.
- ✓ **DO** respond promptly to data requests made legitimately under the REACH data sharing rules (which may not necessarily imply “immediate communication” of the relevant data, since – among others – a process of negotiation may occur).
- ✓ **DO** ensure that, when choosing between alternative sources of data, choice is based on objective criteria related to the quality of the data, taking into account in particular its reliability, relevance and adequacy. The processes followed in order to define and apply these criteria must be carefully documented.

Discussions on business related issues

X DON'T discuss business related issues that ought to be decided individually by each company.
This applies for example to:

- changes in sales, supply, purchasing and marketing strategy resulting from REACH, including company business plans;
- possible de-selection of substance or use. This is to be defined on an individual basis only and there should not be any “collective de-selection”.

Exchange of information

Even if most of the information to be exchanged under REACH is unlikely to be problematic under EC competition law (because this information is mostly of a scientific or technical nature and does not enable competitors to align their market behaviour), certain information exchanged (such as volume information) can raise EC competition law issues. As a consequence:

- ✓ **DO** limit your exchanges of information to what is strictly necessary under REACH.
- X DON'T** exchange non-public sensitive information such as (non exhaustive list):
 - Individual company prices, price changes, terms of sale, industry pricing policies, price levels, price differentials, price mark-ups, credit terms etc;
 - Costs of production or distribution etc;
 - Individual company figures on sources of supply, costs, production, inventories, sales, etc;
 - Information as to future plans of individual companies concerning technology, investments, design, production, capacity, distribution or marketing of particular products including proposed territories or customers;
 - Matters relating to individual suppliers or customers, particularly in respect of any action that might have the effect of excluding them from the markets.
- X DON'T** exchange technical information if this exchange is not necessary under REACH, especially if this exchange of technical information may provide competitors with the ability to align their market behaviour.
- ✓ **DO** reduce the frequency of exchanges.
- ✓ **DO** exchange tonnage bands instead of individual more specific volume information. If not feasible, and specific volume information or other sensitive data needs to be communicated, use precautionary measures, e.g. organise such exchange via an independent third party or trustee (See p.6).

Use of an independent third party or trustee

If under particular circumstances, participants to a SIEF or consortium need to use sensitive individual figures (e.g. for the exchange of information or cost allocation) it is recommended to do so via an independent third party or trustee.

Who could be an independent third party?

A legal or natural person not directly or indirectly linked to a manufacturer/importer or their representatives. This independent third party may be for example an accountant, an auditor, a consultant, a law firm, a laboratory, a European/international organization, a neutral company, etc. The independent third party will not necessarily represent any participants but can be hired by them, for example to support certain activities. It is advisable that the independent third party signs a confidentiality agreement that will ensure that the independent third party undertakes not to disclose the information it receives.

The following activities can be facilitated by a independent third party for EC competition law purposes:

- ***Produce aggregated anonymous figures***

When participants need to refer to the aggregate of sensitive individual figures, the independent third party will request them to provide their individual input. The input will be collated and aggregated into a composite return that does not give the possibility of deducing individual figures (e.g. by ensuring that there will be a minimum of three participants). In addition, no joint discussion shall take place between this independent third party and the participants on the anonymous or aggregated figures. Questions should be addressed on an individual basis between each participant and the independent third party, who should not reveal any other data during such discussion.

- ***Calculation of cost allocation based on individual figures for cost sharing***

Where participants decide that all or part of their cost sharing should be based on their actual and individual figures (e.g. sales or production volumes), the independent third party will send a questionnaire to each of the individual participants to collect the relevant confidential individual information. It will then send to each participant an invoice corresponding to its particular amount only.

- ***Companies need to send sensitive individual information to the authorities, without circulating it to the other actors***

The independent third party would produce a non-confidential version of the same document for the remaining participants or the public that shall not contain sensitive information.

Meetings checklist

Actions	Completed ✓
Circulate the agenda in advance	
Stick to the agenda for the meeting discussions	
Have an accurate participation list (to be signed by each participant) and minutes	
Distribute this leaflet at the beginning of the first meeting (and to newcomers) and always refer to it and to EC competition law compliance at the beginning of each meeting	
Have detailed minutes	
Limit social contacts outside of meetings, and continue to abide by these guidelines at such social events, if any.	

EC competition law compliance tips for companies involved in the REACH process

- Widely voice in your own organisation the need for having EC competition law compliance for REACH activities as well and adopt a robust system that you apply effectively;
- Include EC competition law compliance in your REACH management process, and include REACH related aspects in your competition law compliance system;
- Make sure that the participants in the REACH process have received adequate EC competition law compliance training;
- Strictly limit the participation of marketing and business people in SIEFs and consortia.

Appendix - articles 81 & 82 of the EC treaty

Article 81

1. The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by 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 this Article shall be automatically void.
3. The provisions of paragraph 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 contributes to improving the production or distribution of goods or to promoting 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

Any abuse by one of 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 insofar as it may affect trade between Member States.

Such abuse may, in particular, consist in:

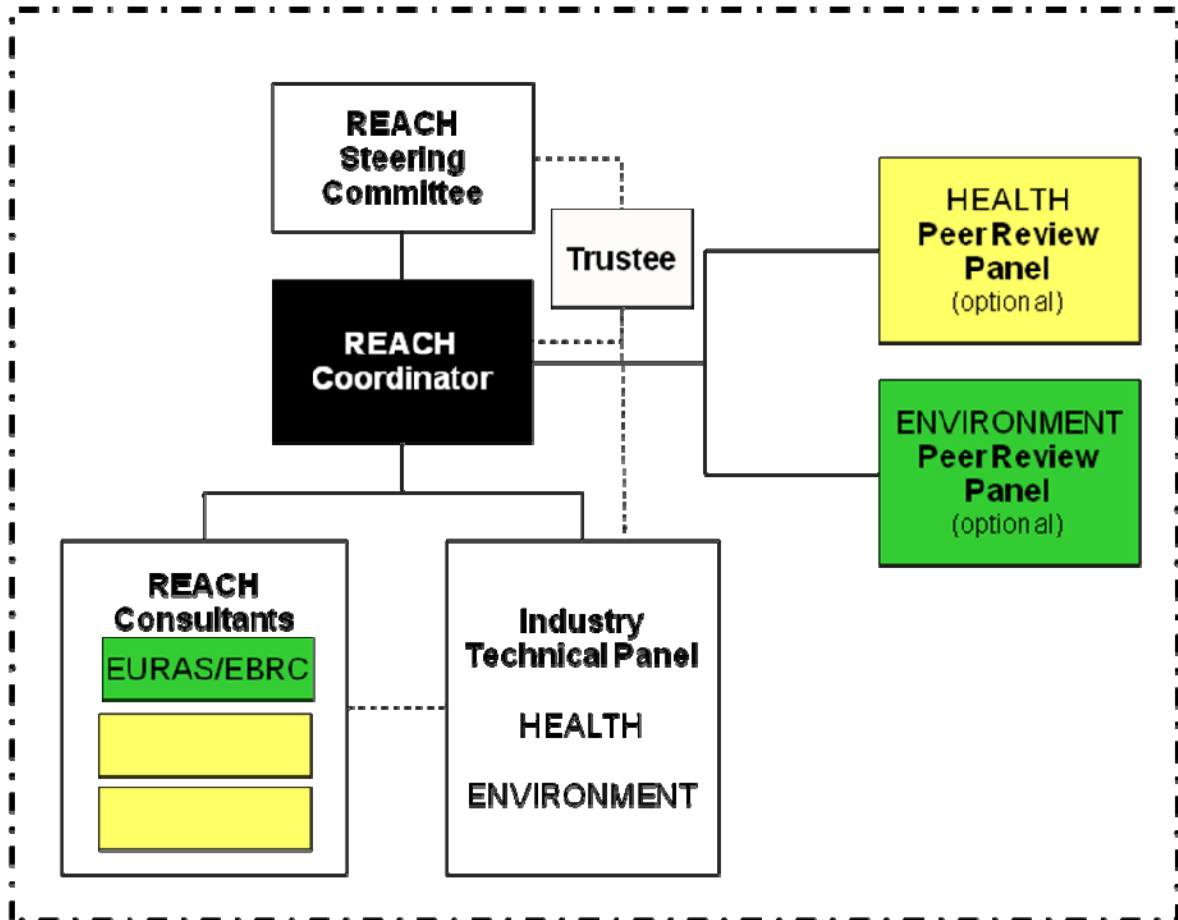
- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing 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.



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Appendix-6: Consortium Structure

I. Consortium structure



Appendix-7: Value of studies - Valuation Rules

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

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

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

The responsibility for the quality of data remains always with the registrant. In this context it should be noted that in case of joint submission several potential registrants of the same substance should jointly decide on the key studies to be included in the Lead Registrant's file. If the potential registrant does not agree with this selection, he has the possibility to opt out, e.g. if he considers the data of insufficient quality or on the contrary if he finds that selected data are of unnecessarily high standard (and too costly) at least for his application (see page 81 of RIP 3.4).

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

RIP 3.4 takes as a basis Klimish rating (adequacy, relevance and reliability). The valuation rules described below have been based on RIP 3.4 recommendations and rules previously developed in practice⁵:

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

- a) The aforementioned 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.

⁵ www.cesio2004.de

- 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. The robust summary may also be integrated into the IUCLID data set.
- 1.2. The quality of the reports is determined by the Industry Technical Panel, or experts commissioned by the Steering Committee, in accordance with the Klimisch et al.⁶ method by classifying the report into one of the following categories: (1) reliable without restriction, (2) reliable with restrictions, (3) not reliable, (4) not assignable.
- 1.3. The allocation to the four categories must be accompanied by appropriate substantiation in accordance with the requirements described in the chapter "Documentation of reliability categories in data sheets (IUCLID)" of the Klimisch et al. publication.
- 1.4. The quality of the robust summaries and IUCLID datasets is determined by the Industry Technical Panel, or experts commissioned by the Steering Committee,
- 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 Industry Technical Panel, or experts commissioned by the Steering Committee,, should develop a robust summary and an IUCLID update.
- 1.6. Also studies, for which no standard protocol exists, e.g., exposure studies, must be documented by an IUCLID data set and a robust summary, and are also to be evaluated under the Klimisch et al. method.

2. Financial Valuation

- 2.1. From a scientific viewpoint, reports in category (1) "reliable without restriction" and (2) "reliable with restrictions" qualify for financial compensation, whereas reports in categories (3) "not reliable" and (4) "not assignable" are deselected from the subsequent procedure. This does not mean that the

⁶ H.-J. Klimisch, M. Andreae, and U. Tillmann, A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data, *Regulatory Toxicology and Pharmacology* 25, 1-5 (1997)

information contained in reports from the latter two categories is classified as useless. Upon a recommendation of the Industry Technical Panel, the Steering Committee may decide in some particular circumstances to use the "weight of evidence" analysis instead, in which case if no higher ranking studies are available for a particular endpoint, then Klimisch 3 studies may be compensated and used.

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

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

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

- i) Testing Institute A
- ii) Testing Institute B
- iii) Testing Institute C

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

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

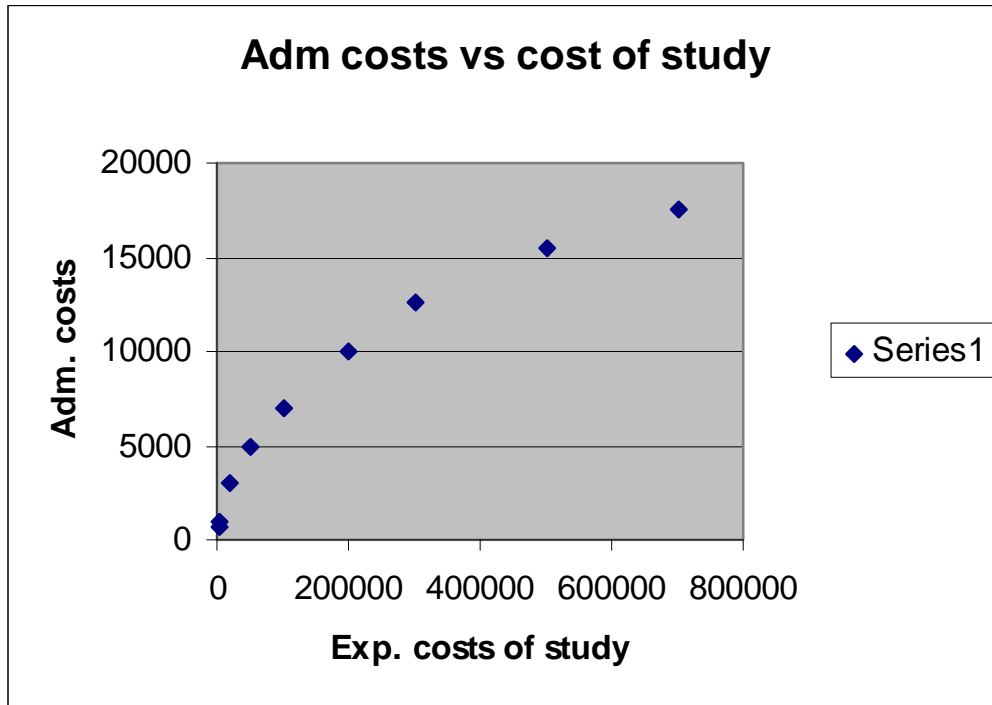
- 2.4. In cases of testing for inherent substance properties, the limitation (2) "reliable with restriction" arises mostly from the fact that the study was conducted at a date prior to the introduction of the GLP standards. The deduction is determined from the difference presented in the price lists of institutes or to be inquired there.
- 2.5. Deductions due to other deficiencies can be evaluated only on a case-by-case basis. The total deduction should not exceed 20% of the price of the standard test. The following should serve as a guidance:
 - i) Non-GLP, a reduction with 20%
 - ii) A study classified as a Klimisch 2 study due to deficiencies which could have been overcome with a reasonable effort should have its value reduced with up to 20%.
- 2.6. For surveys, which are not supported by any standard test protocols, the party supplying the report should provide a document with an overview of the process steps, including the expenses and the time required (working days, costs per working day), such as:
 - i) Development of study concept
 - ii) Exploratory studies
 - iii) Performance of the study
 - iv) Analyses
 - v) Expenses for further contractors
 - vi) Administrative costs (see 2.9).

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

- 2.7. The calculation of expenses for substance analysis, for which no market prices are available, requires the following information from the party supplying the report for each analytical procedure:
- i) Brief description of the procedure or method, including the limit of detection
 - ii) Estimated costs for the development or provision⁷ of the procedure or method
 - iii) Costs per analysis
 - iv) Number of analyses performed
 - v) The development and provision costs can also be included in the costs for each analysis.
- 2.8. Robust summaries contributed by the supplier or developed by experts commissioned by the Technical Committee should be compensated by 30% of the value of the admin costs according to 2.9.
- 2.9. A surcharge to the sum total of experimental costs (substance testing and analysis) is charged for administrative expenses (processing, monitoring and professional support by the commissioning party, travel expenses, archival of the test substance and raw data). The surcharge depends on the experimental value of the study according to Attachment 3b. In the case of significant amounts in excess of the above surcharge, the expenses are to be substantiated and documented individually.
- 2.10. The decision to conduct a study involves the risk that the study results could adversely affect or prevent future substance marketing; hence, the individual member contributing a report to the consortium was exposed to the risk that the investments made in the study are of minor or no benefit. The other members of the consortium, new parties or parties wishing to acquire a specific study are not exposed to this risk since they already know the study result. Therefore, the contributing member(s) is granted a fixed surcharge of 30% of experimental costs.
- 2.11. The current value of a given report is comprised of the experimental and administrative expenses, as well as the risk premium specified above.

⁷ Provision of analytical procedure or method includes the measures required for testing a method known from the literature for compatibility with the intended use.

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



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

Appendix-8: Cost Allocation Key

COSTS ALLOCATION

The total expenses of the consortium will be shared by the Regular members.

Each Regular member will be assigned a number of shares according to its tonnage category⁸ calculated on the sum of the tonnage⁹ manufactured or imported into the EU for each substance listed in Appendix 1, as follows.

a. below 1,000 T:	1 share
b. between 1,000 T and 10,000 T:	2 shares
c. between 10,000 T and 50,000 T:	6 shares
d. between 50,000 T and 200,000 T:	25 shares
e. between 200,000 T and 500,000 T:	70 shares
f. between 500,000 T and 1,500,000 T:	200 shares
g. above 1,500,000 T:	250 shares

Expenses will be allocated collectively to the substances listed in Appendix 1. This means that there will be no specific expense accounting for a specific substance listed in Appendix 1.

The total expenses incurred by the consortium under this agreement will be divided by the total number of shares assigned to all the Regular members.

Each regular member will be charged on a pro-rata of the number of its shares according to the following formula:

$$Fee = \frac{X * E}{Z}$$

With X, the number of share assigned to the Regular member according to its tonnage category
E, the total expenses incurred by the consortium
Z, the total number of the shares assigned to all Regular members

⁸ The tonnage categories are identical to the tonnage categories used for the allocation of the votes as detailed in Appendix 3

⁹ All tonnages shall be expressed in metric tonnes and the year of reference for the determination of the tonnage is the year before the year of admission of the Regular member (e.g. the reference year for a Regular member joining the consortium in 2009 is the year 2008).

Example

The total expenses for the consortium is €1,000,000

For all the Regular members, there are 4000 shares assigned

Company A manufactures 180,000 T of calcium oxide and transforms 20,000 T of this production into 26,430 T of calcium dihydroxide.

-Tonnage for calcium oxide manufactured or imported: 180,000 T

-Tonnage for calcium dihydroxide manufactured or imported: 26,430 T

-Sum of the tonnage for each substance manufactured or imported = 180,000 T + 26,430 T = 206,430 T

This tonnage corresponds to a tonnage category between 200,000 T and 500,000 T.

Company A is assigned 70 shares

Fee to be paid by Company A = $(70 \text{ shares} * €1,000,000) / 4,000 \text{ shares} = €17,500$

Appendix 9: Standard letter of access

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

Whereas, IMA-Europe A.I.S.B.L. acting as coordinator of the consortium on *[insert the name of the substance to be registered]* for the registration under REACH Regulation;

Whereas IMA-Europe A.I.S.B.L. has been lawfully licensed by the legal data owner(s) to deliver letters of access.

IMA-Europe A.I.S.B.L. hereby allows 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 exact name of the substance to be registered]*

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

by Applicant: *[Legal entity name and address]*

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

The Dossier covers documents as follows: *[if reference is restricted to certain parts of the Dossier insert exact name of the data, studies, summaries, waiving arguments, testing proposals and/or assessments]*

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 *[Legal entity name]* and is not transferable to any other entity or person.
3. *[Legal entity name]* is not authorised to receive any copies of the Dossier nor is *[Legal entity name]* authorised to inspect or view the Dossier or any related specific document in whole or in part.
4. This Letter of Access shall in no event be construed as granting *[Legal entity name]* any property rights whatsoever in the Dossier.

Done on

For and on behalf of IMA-Europe A.I.S.B.L.,

Dr Roger Doome
Technical Director

Last updated: 13/03/2009