Agreement

for the Formation of a Consortium

pursuant to REACH Requirements

02.03.2009

(Hereinafter referred to as the "Agreement")

Agreement

Once it is completed and signed, the contract need to be sent in original to:

EUROGYPSUM AISBL

Rue de la Presse, 4

B-1000 BRUSSELS

Belgium

And in an electronic format to:

reach@eurogypsum.org

Between

Name of Manufacturer whose address is ----------, a Company registered under the number ------- with a capital of --------- Euros (or other currency) enrolled with the Office of the Registrar Companies of ------- herein represented by ----------, duly vested with powers to execute this agreement.

On behalf of the following legal entities if the case may be:

1.....

2.....

3.....

As "founding members"

Manufacturer: Name of Company whose address is ----------, a Company registered under the number ------- with a capital of --------- Euros (or other currency) enrolled with the Office the Registrar Companies of ------- herein represented by ----------, duly vested with powers to execute this agreement.

On behalf of the following legal entities if the case may be:

1.....

2.....

3.....

---

or

Only-Representative: Name of Company whose address is ----------, a Company registered under the number ------- with a capital of --------- Euros (or other currency) enrolled with the Office the Registrar Companies of ------- herein represented by ----------, duly vested with powers to execute this agreement..

_____

or

Importer: Name of Company whose address is ----------, a Company registered under the number ------- with a capital of --------- Euros (or other currency) enrolled with trhe Office the Registrar Companies of ------- herein represented by ----------, duly vested with powers to execute this agreement.

as "Regular Members"

_____

or

Downstream User: Name of Company whose address is ----------, a Company registered under the number ------- with a capital of --------- Euros (or other currency) enrolled with the Office the Registrar Companies of ------- herein represented by ----------, duly vested with powers to execute this agreement.

_____

or

Data Holder: Name of Company whose address is ----------, a Company registered under the number ------- with a capital of --------- Euros (or other currency) enrolled with the Office the Registrar Companies of ------- herein represented by ----------, duly vested with powers to execute this agreement.

as "Associate Members"

_____

- jointly: “the Parties” -

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I. Preamble

Whereas Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (hereinafter "the REACH Regulation" or "REACH") is based on the principle that industry should manufacture, import or use substances or place them on the market in a way that, under reasonably foreseeable conditions, human health and the environment are not adversely affected. In order to ensure this, manufacturers and importers need to collect or generate data on the substances and assess how risks to human health and the environment can be controlled by applying suitable risk management measures. The responsibility for the management of these risks lies with the natural or legal persons that manufacture, import, place on the market or use these substances in the context of their professional activities.

Whereas the Parties to this Agreement are manufacturers, importers, only representatives, data owners, and/or downstream users (any terms defined in Article 3 of REACH Regulation shall have the same meaning in this Agreement), of the substances listed and identified in Appendix 1 – hereinafter referred to as the "substances" – with a registered company (i.e. a legal entity) in the European Union.

Whereas under Reach, manufacturers and importers of this agreement are subject to an obligation to register the substance within the deadlines listed in REACH Regulation.

Whereas pursuant to Article 29 of REACH, the manufacturers, importers, only representatives and data owners established both within European Union are members of the Substance Information Exchange Forum (hereinafter referred to as "SIEF") with respect to the substances.

Whereas the substances have phase-in status according to Article 3 (20) of REACH, REACH expressly encourages the joint submission of data by multiple registrants (Article 11) for registration purposes.

Whereas the parties have a common interest in fulfilling the requirements laid down by REACH, the Parties to this Agreement (hereinafter referred to as the "Parties) hereby wish to form a consortium open to other eligible entity in order to (i) collect, gather all Information required for registration (ii) share human and financial resources involved by REACH and (iii) facilitate the joint submission of data.

Whereas the Parties have a common view of the definition of the Substance,

In consideration of the above, the Parties agree as follows:

ARTICLE 1. Definitions and Interpretations

The definitions in Article 3 of REACH (such as reproduced in Appendix 10) apply in addition to:

(1) ***"Affiliate"*** means any person who directly or indirectly, controls, is controlled by, or is under the common control of any of the Parties. The term "Control" is used in the sense of the possession by a person or a group of persons acting in concert, directly or indirectly, of the right to direct or cause the direction of the management and policies of another person, whether through the board of directors or ownership of voting rights by such other person, by the articles of association, contract or otherwise. A person or a group of persons acting in concert shall be deemed to be in control of a body corporate if such person or group of persons is in position to appoint or appoints the majority of the directors of such corporate.

(2) *"**Assembly**"* means the body of the consortium in which all the Members will be represented as more fully described in Article 4.

(3) *"**Associate Members**"* means downstream users within the meaning of Article 3 (13) of REACH or data holders whose participation in the consortium has been accepted by the Regular members. An Associate member is either a company (Group/holding) acting on behalf of one or several legal entities such as described in the definition of Affiliates, or an organisation (e.g. Trade federation) acting on behalf of its members provided that they can lawfully represent them. The Coordinator will hold a list of all Associate Members.

(4) ***"Consortium"*** is a contractual cooperative structure formed by Founding Members, Regular members and Associate members.

(5) ***"Coordination Team"*** means the team described in Article 4.6 and appointed by the Steering Committee.

(6) *"**Coordinator**"* means a natural or legal person whose appointment has been ratified by the Steering committee in order to manage the administration between the consortium members and other relevant parties (e.g. External experts).

(7) *"**Core Data**"* means the data to be submitted jointly by the Regular members of the Consortium and/or the legal entities they represent in all cases pursuant to Article 11 (1) of REACH which is listed in Article 10 of REACH and which includes:

- 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.

(8) ***"ECHA"*** means European Chemical Agency which manages the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union.

(9) ***"EU"*** means European Union which includes all the current 27 (twenty-seven) member states, Iceland, Lichtenstein, Norway (as European Economic Area countries) and any other future member state of EU.

(10) *"**External Expert**"* means a natural or legal person whose appointment has been ratified 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.

(11) *"**Founding Member**"* means a Regular Member that joined the Consortium before February 25th, 2009 and / or which has borne financial and active contribution on behalf of the consortium before its incorporation is considered to be a Founding Member of the Consortium. The Coordinator will hold a list of all Founding Members.

(12) *"**Industry Technical Panel**"* means internal experts appointed by the parties among the employees of each Members to review and assist the work carried out by the External Experts. The experts of the Industry Technical Panel also advise the Steering Committee on scientific and technical aspects. , The experts of the Industry Technical Panel will provide services as External Experts.

(13) *"**Information**"* means Studies according to (19) and other test data and information made available to the consortium by a consortium member or generated / determined by the consortium within the framework of this Agreement.

(14) *"**Lead Registrant**"* means a manufacturer, importer or only representative who, 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 such as elected by the Steering Committee.

(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.

*(15) "**Members**"* means all Founding and Regular Members of the Consortium excluding the Associate Members.
(16) "Organs " means all the different bodies which set up the Consortium.
*(17) "**Parties**"* means all the signatories to this Agreement
*(18) "**Regular Members**"* means Manufacturers, importers or only representatives, who are subject to a registration requirement according to REACH and who belong to the Consortium as Members who joined the Consortium after the SIEF Meeting of February 25th, 2009 until 30 April 2009. A Regular Member is a legal entity subject to registration. The Coordinator will hold a list of all Regular Members.

*(19) "**Steering Committee**"* means the committee of the consortium authorised to make decisions. The Steering Committee will consist of several Members such as described in article 4.2.1.
*(20) "**Studies**"* means 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. Studies mean also all information, data or statistics or conclusions in deduction from such studies.
*(21) "**Substance**"* means a chemical element and its compounds such as listed in Appendix 1. The term substance includes both substances obtained by a chemical manufacturing process and substances in their natural state. The term substance also includes its additives and impurities where these are part of its manufacturing process but excludes any solvent which can be separated without affecting the stability of the substance or changing its composition. More generally, substance is the one which comply with the definition of Article 3 (1) of REACH.

"**Third Party Representatives**" means a natural or legal person appointed by a manufacturer, importer or only representative pursuant to article 4 of REACH Regulation. Any manufacturer, importer may appoint a third party representative for all proceedings under article 11, 19 title III and article 53 involving discussion with other manufacturer and importer or, where relevant, downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturer, importer or, where relevant, downstream user.

*(22) **"Tonnage band"*** will be calculated on the basis of the tonnage band of calcium sulfate produced/imported by each regular member in terms of calculated calcium sulfate anhydrous equivalents.

From hemihydrate x 0.94
From dihydrate x 0.79

All the costs based on the Tonnage band will be calculated per band of 500.000 tons according to :

- 0 to 500.000 tons = 1 vote
- 500.000 to 1.000.000 tons = 2 votes
- 1.000.000 to 1.500.000 tons = 3 votes
- 1.500.000 to 2.000.000 tons = 4 votes
- Etc until the highest tonnage produced by a Member

It means that the cost allocation will be calculated according to the number of votes each Member will have.

*(23) "**Trustee**"* means an independent third party who in view of the exchange of sensitive individual data, whose appointment has been ratified by the Steering Committee and who is a legal or natural person who will act in neutral capacity. A confidentiality agreement will ensure that the Trustee does not misuse any sensitive data (e;g; volumes, etc..) it receives.

ARTICLE 2. Purpose and scope of the Consortium

(1) The Members shall co-operate in order to facilitate their compliance with the requirements pursuant to REACH for substance registration. In particular, the following duties are performed by the Members:

a) Development of core data as specified in Article 5.
b) Preparation of the chemical safety report and the guidance on safe use of the substances as specified in Article 6
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 registration[1].
d) Co-operate in order to identify and share existing data, identify and fill data gaps for the purpose of joint submission.

(2) The rights and obligations (e.g. voting rights, data sharing and financial obligations) of the Parties pursuant to this Agreement are applicable to each member only for those particular substances manufactured, imported, used or for which he holds information.

(3) 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.

(4) The consortium wishes to pursue the aforementioned purposes in order to avoid dual work, to reduce expenses and to file an harmonised set of data for registration.

[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;

(5) Nothing in this consortium Agreement shall be construed or interpreted or shall imply any fringement of Articles 81, 82 of the EC Treaty. The Parties are aware of the fact that activities of the consortium aimed at the joint fulfilment of registration requirements could represent a case of application of Articles 81, 82 of the EC Treaty. The Parties explicitly agree to observe Articles 81, 82 of the EC Treaty, Article 25 (2) of REACH and the Code of Conduct attached in Appendix 5.

ARTICLE 3: Memberships

A. 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 subject to registration requirements concerning the substance in Appendix 1 and agree to pay the relevant fees pursuant Article 7.1 (4) below. Members of the Steering Committee agree to decide according to fair and non-discriminatory principles and any decision refusing admission shall clearly state the reasons why membership was not granted.

(2) Any only representative applying to become a Member of the Consortium will be required to disclose to the Trustee the identity and the number 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 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 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 allocate the share of the cost in accordance with the cost key specified under Appendix 8. Information regarding the Third Party Representatives' principals must be held confidential by 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) For the purpose of this agreement each only representative or third party representative shall count for each non EU or EU manufacturer it is representing as separate member

(5) 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.

(6) A newly admitted Regular or Associate Member shall sign a declaration thereby recognising the terms and conditions as set out in this Agreement. Pursuant to the cost key specified under Appendix 7, the new member shall pay a portion of the expenses incurred by the Consortium to date pursuant to Article 7.1 (2)a) and b) in the form of a prorated refund to the other Consortium Members. Moreover, in order to compensate for the activities of the Consortium Members to date, inter alia for expenses incurred by the Consortium in accordance with Article 7.1 (2) c) and d) thus far, the new member shall pay an additional "advantage compensation" to the existing Consortium Members. Members of the Steering Committee agree to decide the "advantage compensation charged" according to fair and non-discriminatory principles and based on objective criteria. The Steering Committee shall define the amount of this additional payment as a pro rated share of the actual recorded expenses of the Consortium Members at the time of admittance. Time advantage compensation for all subsequent new Members must be calculated on the same basis, except where the principles of fair and non-discriminatory treatment require a readjustment of past cost sharing practices (c) and (d).

(7) Upon payment of the amounts indicated in (5), the new Member has the same rights and obligations than a Regular member.

B.. 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 Substance, this means that termination will not be permissible after 1 June 2010 until the 1 December 2010 deadline for registration has passed.
(3)
(4) Exclusion from the Consortium requires a decision taken by a special way of deliberation by the other Assembly Members. Exclusion takes place only in the event of serious reasons such as material breach of this Agreement that has not been repaired within 30 calendar days after formal notice has been sent by the Steering Committeeby registered mail to the Member concerned. The defaulting Member shall have the right to present its defense to the General Assembly before a final decision is taken. The decision of the General Assembly shall be immediately notified to the Member by registered mail and the exclusion shall be effective upon the date of receipt of this letter. 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 Articles 9 and 5.1 and Article 3.D (Confidentiality, Right to Studies and Liability) which continue for a period of 12 years following first registration of the Substance by a Member provided the payment to date of the withdrawing Member's share of any Consortium expenses owed pursuant to Article 7 has been made. The rights of remaining members to use the studies as specified in Article 5.1 that have been made available by the Member, who has withdrawn, shall continue to exist.

C. Transfer of Membership

(1) A Regular Member shall be entitled to transfer membership including all rights and obligations to another legal entity subject to registration requirements with respect to the Substance. Such transfer shall be notified in writing to the Coordinator.
(2) The transfer of discrete rights and obligations arising from membership is excluded.

D. Liability of Members

- Liability of each Member of the Consortium

Each individual member shall remain 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.

- Liability between the Members of the Consortium

Each Party is required to exercise due care and diligence with regard to each other Parties in observing the rights and obligations arising from this Agreement. No Party shall be liable for any direct, indirect or consequential loss or damage incurred by another Party 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 Article 5 and in accordance with Article 6.2 (2) and for any infringement of third party intellectual property rights in providing the relevant Study to the Consortium.

The liability of the Members related to the costs and liabilities of the Consortium shall be several and not joint.

Within the scope of this Agreement, each Member shall commit not to take any legal action against any other member of the Consortium except if a member commits a serious material breach or a wilful misconduct.

In any case, the liability between the Members shall exclude indirect or consequential loss or damage such as but not limited to loss of profit or loss of revenue.

- Liability of Members of the Consortium towards third parties

In accordance with the general rules, each member shall be liable with regards to third Parties within the scope of his responsibility.

ARTICLE 4. Organisation of the Consortium

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 Coordinator, 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 Parties. Collectively, the Parties are subject of the rights and duties of the Consortium defined in this Agreement.

The structure of the Consortium is provided in Appendix 5.

4.1. General Assembly

4.1.1. Composition of the Assembly

The Assembly shall comprise Founding Members and Regular Members. Associate Members shall attend all the meetings of Assembly only as observers.

Each Member shall designate one natural person to act as the representative of that Member in the Assembly. This representative shall have authority to commit that Member in decisions to be taken by the Assembly and must be able to produce duly executed original proof of such appointment.

4.1.2. Role of the Assembly

The Assembly shall take measures and decisions related to:

- election of two Regular Members of the Steering Committee (being said Founding Members cannot take part in the election of the Regular Members);
- withdraw or expulsion of a Member of the Assembly;

- approval of the annual budget based on the proposal made by the Steering Committee with the exception of the fixed fees covering the Coordinator costs and Trustee costs per Members (appendix 7) which will be charged upon the signature of the Consortium Agreement.

4.1.3. Meetings of the Assembly

a – Organisation of the metings

Meetings shall be held upon written notice given by the Steering Committee four weeks before the date of the meeting.
Meetings shall be held at least once a year.

b – Quorum

A meeting of the Assembly can be held if a quorum of 50% plus one of the representatives of the Members are present or represented at the meeting.

If the quorum is not achieved within 30 minutes following the beginning of the meeting, the meeting shall be dissolved. In this case, the Coordinator shall convene a new meeting at least 2 weeks later.

At this new meeting, if the required quorum is still not achieved within 30 minutes following the beginning of the meeting, the present Members shall be entitled to deliberate and take decisions as if a quorum were present.

Members may be represented at each meeting by another Member provided the latter is able to show at the start of each such meeting an original proxy duly signed by the former.

4.1.4. Voting Rights in the Assembly

The decisions of the Assembly shall be taken according to the rules described in the present paragraph.

Each Member shall have a voting right per each 500.000 tonnage production band:

- 0 to 500.000 tons = 1 vote
- 500.000 to 1.000.000 tons = 2 votes
- 1.000.000 to 1.500.000 tons = 3 votes
- 1.500.000 to 2.000.000 tons = 4 votes
- Etc until the highest tonnage produced by a Member

The Trustee shall keep confidential the tonnage of Production per Member, the number of votes, the vote cast per Member of the Assembly.

Resolutions shall be decided via written procedure by secret ballot. The Trustee will organise the voting procedure and communicate the final decision. The number of votes cast by individual Regular Members shall be issued and kept confidential and not communicated to the Steering Committee or any of the Members by the Trustee. Any Member could request an external Trustee to check the secret ballot, being the Coordinator bound to allow, within the following 10 business days, the Trustee

designated by the requesting Member the originals documents of the concerned voting, provided the Trustee have signed a confidentiality undertaking on equal basis to the these applicable to the Coordinator and its fees have been already paid by the requesting Member. For the avoidance of doubt, Associate Members shall have no voting rights in the Assembly.

4.2 Steering Committee

4.2.1 Composition of the Steering Committee

(1)The Steering Committee shall be composed of 8 seats allocated such as follows :

- 5 (five) seats for the Founding Members

- 2 (two) seats for the Regular members elected by the Regular Members of the Assembly. In order to allocate the seats of the Regular Members, Regular Member of the Assembly shall elect two (2) legal entities to act as its representative(s) in the Steering Committee.

- 1 (one) seat for the President elected or ratified by the members of the Steering Committee.

The Members who have a seat in the Steering Committee will be entitled to attend and vote at Steering Committee meetings and may in like manner appoint a deputy who shall be entitled to attend meetings with or without the principal representative but who may not vote thereat except in the absence of the principal representative.

(2) One representative of all Associate Members shall be elected by the other Associate Members by simple majority. One or more of these Representatives of Associate Members may be notified of any meeting of the Consortium if the interest of the Consortium so requires, but any attending Associate Member's Representatives 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's Representatives will be taken by the Steering Committee.

A list of nominated representatives and deputies of the Funding/Regular members of this Agreement as well as the Associate Members will be maintained by the Coordinator.

(3)The Coordinator shall compile and keep up to date the listing of the representatives and deputies of Regular members and the list of Associate members. Appointments, revocations or replacements of representatives by the Members shall be notified in writing to the Coordinator.

4.2.2. Role of the Steering Committee

The Steering Committee shall take measures and decisions related to:

- functioning of the Consortium
- supervision of the achievement of the Consortium's scope
- supervision of the activities of the organs of the Consortium
- admission of a Member
- proposal of the annual budget to the Assembly

- authorization of expenses and more generally supervision of the budget and expenses after approval of the Assembly
- preparation of the registration dossier
- approval of Substance to be registered
- approval of Work plan of the different organs
- approval of further research proposals and data waivers
- approval of panel composition
- approval of involvement of specialised experts where needed
- discussion on advocacy activities where required

4.2.3. Meetings of the Steering Committee

The meetings of the Steering Committee shall be held on an adhoc basis to review the progress according to the agenda and the budget.

The Members of the Steering Committee will be entitled to attend the meeting in person or by other means including but not limited to conference call, teleconference or otherwise. 4.2.4. Presidency of the Steering Committee,

(1) The Steering committee shall elect or ratify, for the duration of the agreement a President. The President shall be an expert recognized for its competences on the Substance.
(2) The President is neutral, he has no voting right and he is not taken into account in the calculation of the representatives for each tonnage band and / or type of gypsum. His term of office covers the duration of the consortium agreement.
(3) The President will provide its services as an External Expert.
(4) The Steering Committee may not meet in absence of the Lead registrant(s) and the President and the Treasurer.

The President and the Treasurer of the Consortium shall have the power to supervise the functioning and the work of the Steering Committee. These powers shall be detailed in the Steering Committee rules of procedure (Appendix 8). 4.2.5. Treasurer of the Steering Committee

(1) The Steering Committee shall elect, for the duration of the agreement and from among its members a Treasurer.

(2) The Treasurer shall follow the Budget and all the expenses.

4.2.6. Voting rights in the Steering Committee

(1) Each member of the Steering Committee is entitled to one vote on any decision taken at a steering Committee meeting. Resolutions shall be decided by via written procedure (mail, e-mails).

(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 one half of the votes. Any Regular members' representative (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 to the President or to the Coordinator in advance of the meeting. All decisions shall be taken by absolute majority of the votes cast; in case

of a tie vote, 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 two-thirds of the representatives are present or represented. 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 in respect of Articles 3.A. (1) and (4), to any modifications of the appendixes 1,5,6,7,8,9. (4)The Steering Committee reserves the right to make all decisions, unless otherwise specified in this Agreement or in the Steering Committee Rules of Procedure which are included in Appendix 8.

(5) A representative in the Steering Committee shall be excluded from voting in the event of conflicts of interest or for 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 Members).

(6) Veto Right: As an exception to the standard way of deliberation and to the special way of deliberation, each member of the Steering Committee will have a veto right and may use this veto right when a decision to be taken by the Steering Committee will refer to:

- Approval of the substance to be registered (as mentioned in article 4.2.2)

- Costs repartition and proposal of the annual budget to the Assembly (as mentioned in article 4.2.2)

If a member of the Steering Committee uses its veto right, all the members of the Steering Committee will have to negotiate and find a solution.

If no agreement can be reached, the Members of the Steering Committee shall have to vote again for the same decision. If six of the seven members agree, the decision shall be adopted.

The member of the Steering Committee which does not agree with the adopted decision will have two possibilities:

-Either this member accepts the decision;

- Or this member has the possibility to withdraw from the Consortium.

4.2.7. Liability of the Steering Committee

The Steering Committee shall not be liable for all liabilities in relation with its role, position and duties under this Agreement other than liabilities attributable to wilful misconduct or gross negligence.

The President of the Steering Committee bears no individual responsibility or liability for any act or omission in this capacity, unless caused by their gross negligence or wilful misconduct. In case of claim or action against the President of the Steering Committee in connection with its duties under this Agreement, the others members will indemnify the President against any expenses, fees, damages or any other kind of losses.

4.3. Lead Registrant

4.3.1 Nomination of the Lead Registrant

The Steering Committee shall elect from among its members (in this case down to a legal entity) and for the duration of the Agreement one Lead Registrant.

4.3.2 Role of the Lead Registrant

The Lead Registrant shall manage and supervises all measures, decisions and actions related to

- constitution and submission of Registration Dossier;
- contact with the Agency on behalf of the Consortium.

4.3.3 Liability of the Lead Registrant

The Lead Registrant shall not be liable for all liabilities in relation with its role, position and duties under this Agreement other than liabilities attributable to wilful misconduct or gross negligence. In case of claim or action against the Lead Registrant in connection with its duties under this Agreement, the others members will indemnify the Lead Registrant against any expenses, fees, damages or any other kind of losses.

4.4 Coordinator

4.4.1 Nomination of the Coordinator

The Steering Committee hereby appoints or ratifies the appointment of a Coordinator to assist the Steering committee for the duration of the Agreement. Such an appointment may be revoked anytime by a decision of the Steering committee according to the standard way of deliberation.

4.4.2 Role of the Coordinator

The main role of the coordinator shall be to facilitate communications amongst all Parties involved in the Consortium as and when required and to provide administrative services to the Consortium.

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 Articles 5 and 6. A preliminary working and financial plan will be presented at the first meeting of the Steering Committee and updated every six months. The initial working and financial plan as well as its subsequent updates shall be agreed and adopted by the Steering Committee.

In addition, the Coordinator will have the following tasks:

- Consortium Agreement: collection of signed agreements, updating of agreement, collection of fees.
- Preparation of the budget
- Contracts, invoices (consultants, peer review experts, researchers)
- Consortium day to day running
- Organisation of the meetings of the Coordination Team, Industry Technical Panel, Steering Committee and General Assembly.

- Minutes of the meetings
- Ensure follow-up of action points

4.4.3. Liability of the Coordinator

The Coordinator shall not be liable for all liabilities in relation with its role, position and duties under this Agreement other than liabilities attributable to wilful misconduct or gross negligence. In case of claim or action against the Coordinator in connection with its duties under this Agreement, the others members will indemnify the Coordinator against any expenses, fees, damages or any other kind of losses.

4.5. Trustee

4.5.1. Nomination of the Trustee

The Steering Committee hereby appoints or ratifies the appointment of a Trustee to assist the Steering Committee for the duration of the Agreement. Such an appointment may be revoked anytime by a decision of the Steering Committee according to the standard way of deliberation.

4.5.2. Role of the Trustee

The main role of the Trustee shall be to ensure the management of confidential information which need to be collected for the fulfilment of the Registration Dossier.

In addition, the Trustee will have the following tasks:

- Coordination of data collection
- Central storage of confidential data (questionnaires, additional monitoring data, test results)
- Management of the voting procedure (collection of the votes for each decision to be taken, invoicing of the Members, collection of the payment).

4.5.3. Liability of the Trustee

The Trustee shall be liable for all liabilities in relation with its role, position and duties under this Agreement.

4.6 Coordination Team

The main role of the Coordination Team will be to:

- Report to the Steering Committee on the progress of work
- Liaise with the Agency, Commission and Member States when necessary.

4.7 Industry Technical Panel

4.7.1 Composition

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, provided that the power to take decisions shall be retained by the Steering Committee.

4.7.2 Role of the Industry Technical panel

The main role of the Industry Technical Panel will be :

- To collect appropriate data for the completion of the Chemical Safety Assessment
- To assist in the development of exposure scenarios
- To provide toxicological, ecotoxicological, occupational and environmental input on draft reports.

4.7.3. Tasks of the Industry Technical Panel

The identified tasks of the Industry Technical Panel will be to:

-Assist consultants with the collection of relevant existing exposure and effects data;
-Collect local calcium sulphate emission and monitoring data around producing and using plants;
-Collect information on the production, processing, use, recycling and disposal of calcium sulphate;
-Review and comment on the Chemical Safety Assessment draft reports that come out on a regular basis (eg 3 X/year);
-Identify research projects to fill data gaps;
-Manage research projects set-up for the CSR;
-Where specific issues arise on which advice is needed but for which there is insufficient expertise in the Industry Technical Panel, identify specialised experts.

4.8 External Experts

The Steering committee may use the services of External experts (hereinafter referred to as the “Consultants”) or other competent third parties under the terms and conditions to be agreed by the Steering committee according to the standard way of deliberation. The main tasks of the Consultants may be :

- To gather Data;
- To evaluate Data;
- To assess Hazard;
- To develop exposure scenario;
- Writing and revising of the Chemical Safety Report.

ARTICLE 5 Development of Core Data

5.1. Rights to existing Studies

5.1.1 Ownership and Licence to use of Studies: The ownership rights to existing unpublished studies made available for the purpose of joint submission in accordance with Articles 5 and 6 are retained by the Member who provides access to the respective studies and proof of their cost.

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 enclosed in Appendix 10. At the discretion of the Member owning the study, the letter of access can be delivered for free or against financial compensation in accordance with the cost key agreed upon in Appendix 7.

5.1.2. Relevant Studies: As soon as reasonably practicable, 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 Substance.

On the basis of competent analysis respecting the usability of the studies made available for registration in accordance with the previous paragraph, the Coordinator shall prepare a proposal for their financial value on the basis of the valuation rules indicated in Appendix 6. This proposal shall be agreed and adopted by the steering committee.

5.2. Rights on new Studies

5.2.1. Joint Ownership: The Regular Members shall have joint ownership of studies generated by the Consortium pursuant to Article 5.3 and Article6.2 (2) with respect to their rights and obligations under REACH, provided that those Regular Members share the cost of the studies in accordance with the cost key agreed upon in Appendix 7. Therefore, it means that the Regular Members shall have joint ownership pro rata to their respective financial contributions.

5.2.2. Licence to use new studies: Granting a right of access to the studies generated by the Consortium pursuant to Article 5.3 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 are not required for the purposes of REACH or that the studies will be misused.

5.3. Determination of New Test Data

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 the 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 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 (if any). 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 to undertake the testing. The Steering Committee then shall endorse the test proposal and the contract laboratories.

5.4. Test Data from Tests not involving Vertebrate Animals

Upon submitting the registration dossier, the Steering committee shall decide on the question as to whether or not test data from tests not involving vertebrate animals should be shared and under which conditions.

ARTICLE 6: Preparation of a Chemical Safety Report

6.1. Uses

Uses of the substance 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. Should the Steering Committee decides not to cover a specific use under the joint submission, each Regular Member may decide to do it on its own.

6.2. Development and Provision of Information Concerning Chemical Safety Assessment

(1) To the extent available, the Parties shall provide the Coordinator with the required studies, in particular with respect to information on exposure to the substance, 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.

6.3. 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 substance. The Steering Committee reviews and adopts the chemical safety report and the guidance on safe use of the subtances**.**

ARTICLE 7: Financial Rights and Obligations

7.1. Consortium Expenses

(1) The Parties shall bear the Consortium expenses jointly 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 includes:

a) Expenses to be paid to the Members in accordance with the valuation rules pursuant to Article 5.2 as reimbursement for existing studies made available by them.
b) Expenses for new studies decided upon and commissioned by the Steering Committee.
c) Running expenses incurred by the Consortium; these include, in particular: remuneration for coordination, expenses for External Experts according to the terms adopted by the Steering Committee.

d) Expenses for the constitution of the joint part (Core data) of the Registration Dossier.
e) Other expenses not otherwise specified provided that these expenses are agreed and approved by the Steering Committee.

(3) For the avoidance of doubt, expenses, other than expenses referred to in the Article 7.1 (2) incurred by Members in the performance of their individual duties cannot be recovered unless specifically approved by the Steering Committee. The Consortium expenses stated under (2) shall be allocated to the Parties in accordance with the cost key specified under Appendix 7..

(4) 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 Taxes reduction, refund or exemption. Payer shall be entitled to any refund of Withholding Taxes.

(5) Indirect Taxes – including but not limited to Value Added Tax (VAT), Goods and Service Tax (GST), Service Tax, Business Tax – as applicable pursuant to the relevant tax law, shall be borne by payer. However, payer is entitled to withhold any payment of indirect taxes unless payee has provided payer with a sufficient invoice for purposes of indirect taxation.

7.2. 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 a calendar year by 1st March of the respective following year, thereby taking into account changes having an effect on the past. These accounts shall be adopted by the Steering committee.
(2) Advance payments that are likely to be incurred by the Members in respect of which the Members wants to be reimbursed by the Consortium can be agreed through a resolution of the Steering Committee in accordance with the Steering Committee Rules of Procedure (Appendix 8).

ARTICLE 8: Competition Law and Confidential Business Information

The activity of the Consortium shall be strictly limited to co-operation for compliance with REACH. In accordance with competition law, the Parties agree (i) not to provide others Members or Parties of the Consortium access to any confidential information which would enable a competitor to alter its commercial strategy and (ii) not to exchange sensitive market information such as volume, value of sales, market shares, division of markets, price increases, marketing strategies and others; information. If the Consortium Members or Parties need to provide information on volumes under the cost-sharing agreement; they must ensure

that these figures are communicated to the Trustee who is bound to keep this information confidential.

ARTICLE 9: Confidentiality

9.1 During the continuance of this Agreement and after its termination (howsoever termination may arise or occur) and for the purpose of this Agreement, the Parties undertake:

(a) to treat all Information made available to them in the context of any cooperation pursuant to this Agreement as strictly confidential and not to disclose it to any third parties without the prior written approval of the disclosing Party; and

(b) not use any such information for any purpose other than for the purposes of REACH and/or this Agreement.

9.2 The restrictions and prohibitions set out in clause 9.1 shall not apply to any Information which the receiving Party can show by documentary evidence:

(a) was known to it prior to disclosure by the disclosing Party;

(b) was in the public domain or the subject of public knowledge at the time of disclosure by the disclosing Party;

(c) becomes part of the public domain or the subject of public knowledge other than by reason of any act or omission of the receiving Party;

(d) is supplied or imparted to the receiving Party by a third party otherwise than in breach of any obligation of confidentiality owed to the disclosing Party; or

(e) is independently developed by the receiving Party without recourse to the Information.

9.3 Notwithstanding the aforesaid provisions of this Article 9, the receiving Party shall be entitled to disclose Information that it may receive from the disclosing Party pursuant to any legal or regulatory requirement or pursuant to any requirement of any governmental or competent regulatory authority, including but not limited to the requirement to supply others Members of a SIEF with relevant Studies for consideration. Each Party undertakes to ensure that its representatives, agents and affiliates comply with the same duty of confidentiality. Members are not under a duty of confidentiality in respect of their own data.

9.4 Upon the termination of this Agreement, each Receiving Party shall, to the extent reasonably practicable, cause all Information belonging to a Disclosing Party to be returned, deleted or destroyed according to the written instructions of said Disclosing Party.

9.5 The Parties agree to the Steering committee disclosing the information specified in Article 9.1 above to the Trustee, the Coordinator, the Industry Experts Panel and the External Experts nominated by the Steering Committee only to the extent that is absolutely necessary for their respective duties to be performed on behalf of the Consortium and provided that:

(a) Any disclosure to such Trustee, Coordinator, Industry Experts Panel and/or External Experts is made under obligations of confidentiality on terms substantially the same as those contained herein; and

(b) Such Trustee, Coordinator, Industry Experts Panel and/or External Experts to whom the confidential information is disclosed are obliged by their contracts of employment or service not to disclose the confidential information;

(c) The entity disclosing the information will be responsible for any breach of the obligations of confidentiality by such persons

(1) 9.6 The provisions of this Article 9 shall be in addition to and not in substitution for any confidentiality obligations imposed upon the Parties under REACH. The Parties shall fully comply with said confidentiality obligations and shall not be permitted to disclose Information under this Agreement where such disclosure would constitute a breach of the Agreement.

ARTICLE 10: No Partnership

Nothing in this Agreement shall constitute or be deemed to constitute a partnership, joint venture or association between Consortium Members or any of them and, except as expressly set out in this Agreement, none of the Consortium members shall have authority or power (nor represent themselves as having authority or power) to contract in the name of or to undertake any liability or obligation on behalf of any of the other Consortium Members.

The Consortium shall have no legal existence apart from the Consortium Members and the commitments created between them under this Agreement. It formally excludes any affectio societatis and any intention to share benefits or to contribute to losses.

ARTICLE 11: Duration and Dissolution of the Consortium

11.1. Duration

By mutual agreement, the entry into force date of this Agreement is 26 February 2009. The Consortium does not have a delimited period but shall exist until the date of completion of the scope of the Agreement such as described in Article 2 and such as certified by the Steering Committee.

11.2. 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 Article 2 has been fulfilled to its full extent.

11.3. 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 Consortium Members to the studies determined pursuant Articles 6 and 7 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 Parties arising from this Agreement that do not involve assets shall lapse. This does not apply to the obligations specified in Articles 9 and 11 for a period of 5 years following first registration of the substance(s) by a member.

ARTICLE 12: Concluding Provisions

12.1. 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. As a supplement, French law shall apply.
(2) Amendments to this Agreement are only effective in written form.

12.2. Juridictionnel venue, Arbitration

(1) The jurisdictional venue for disputes of the Consortium members is Paris, FRANCE.
(2) The members shall first attempt to settle amicably any dispute arising out of this Agreement. Should such amicable settlement fail, the dispute shall be resolved by arbitration under the rules of conciliation and arbitration of the International Chamber of Commerce in Paris. The decision of this Chamber shall be final and binding for all members. The arbitral tribunal consists of three arbitrators: each party 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 Parties 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 Parties in accordance to the outcome of arbitration. The language of the proceedings shall be English. The venue of arbitration shall be Paris, FRANCE. The arbitration shall be based on French law.

12.3. 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.

12.4. Copies of the Agreement

The Coordinator will make available the Consortium Agreements in an electronic format on the specific request of a Member. The consortium agreements are available and can be consulted in original by all parties at the social seat of Eurogypsum, rue de la Presse, 4-1000 Brussels.

Date

Place

LIST OF APPENDIXES

Appendix 1: Substance Specifications

Chemical name	EINECS	CAS	Formula	Typical content % (w/w)	Lower Content % (w/w)	Upper Content % (w/w)
Calcium Sulphate	231-900-3	7778-18-9	$CaSO_4$	87%	70%	100%

Impurities

Clays	0 % - 30 %
Calcite, dolomite	0 % - 30 %
Silica	0 % - 10 %
Celestine	0 % - 4 %
pH	5-9

Please note: Companies intending to register CaSO4 containing impurities not identified in this specification, even if present in quantities <0.1 %, that have an effect on the hazard classification of this substance are responsible for declaring these impurities and addressing any subsequent additional data or information requirements in their own registration dossier. This can be done using the PNECs and DNELS of the relevant substances when available.

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

I. REGULAR MEMBERS AND FOUNDING MEMBERS

Company name :

Address :

Legal entities :

-

-

-

Representative

Surname and first name :

Address :

Tel. :

E-mail :

Deputies

Surname and first name :

Address :

Tel. :

E-mail :

Company name :

Address :

Legal entities :

-

-

-

Representative

Surname and first name :

Address :

Tel. :

E-mail :

Deputies

Surname and first name :

Address :

Tel. :

E-mail :

II. ASSOCIATE MEMBERS

Company name : Address :   Representative Surname and first name : Address : Tel. : E-mail :

Appendix 3: Tonnage Bands of Regular Members (Manufacturers/Importers/Only-Representative)

The tonnage band shall be calculated as the average of the last 3 years (2006-2007-2008). Tonnage band shall be given in metric tonnes. This information should be provided to the independent trustee (on commencement and every --------- thereafter).

The tonnage band is as follows:

- 0 to 500.000 tons
- 500.000 to 1.000.000 tons
- 1.000.000 to 1.500.000 tons
- 1.500.000 to 2.000.000 tons ,etc
-

Company name :

Substance manufactured and/or imported	Tonnage band		
	0-500.000 tonnes	500.000-1.000.000 tonnes	1.000.000-1.500.000 tonnes etc ….

Company name :

Substance manufactured and/or imported	Tonnage band		
	0-500.000 tonnes	500.000-1.000.000 tonnes	1.000.000-1.500.000 tonnes etc ….

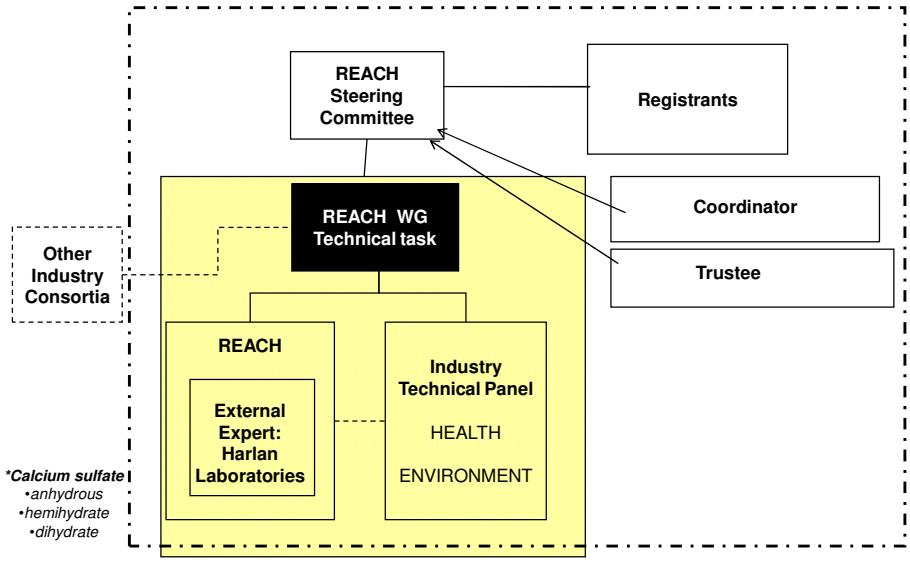
Appendix 4: Code of Conduct


Code of Conduct

Appendix 5: Consortium Structure & Membership

I. Consortium structure

Calcium sulfate* REACH Consortium Organisation Chart



II. Consortium membership

Appendix 6: 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 practice[2]:

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.
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.[3] method

[2] www.cesio2004.de

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

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 information contained in reports from the latter two categories is classified as useless. Rather, the owners are asked to make such information available free of charge.

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

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 provision[4] 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.

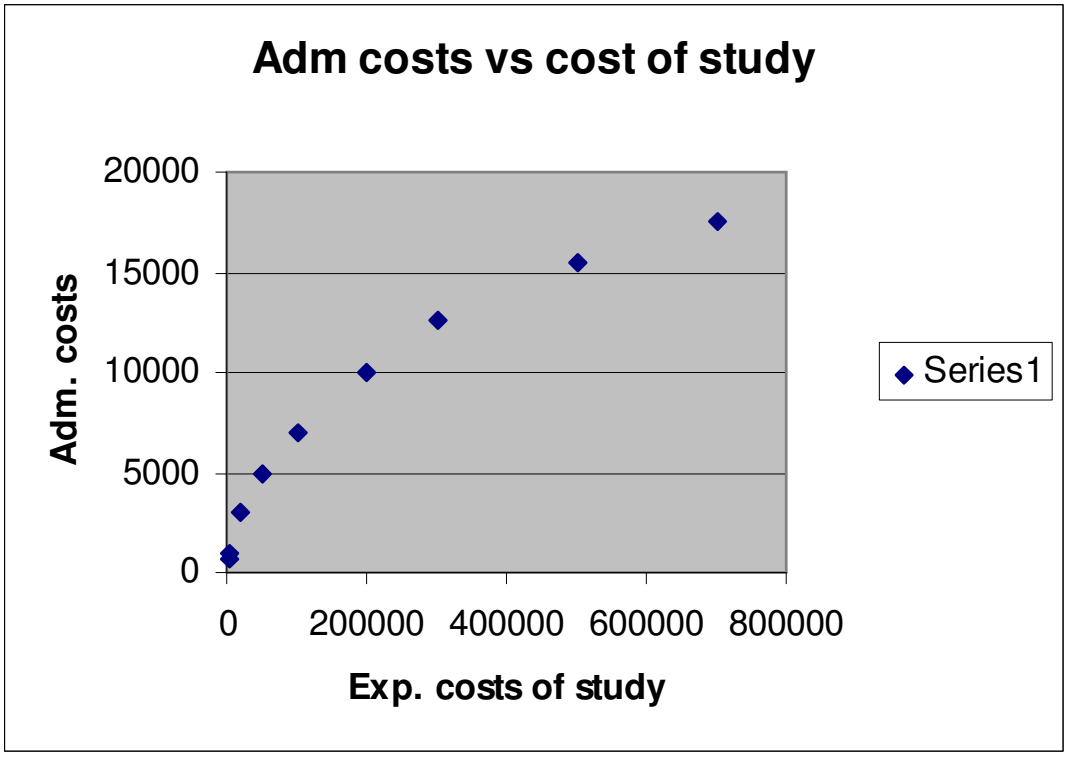
2.10. The decision to conduct a study involves the risk that the study results could adversely affect or prevent future substance marketing; hence, the individual member contributing a

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

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.

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



Appendix-7: Cost Allocation Key

COSTS ALLOCATION

The total costs of the Consortium will be shared by the Regular Members. Each Regular member will be charged a fix fee for the coordinator costs and trustee costs of ----- € per represented legal entity plus a proportional fee calculated on a pro-rata basis of the declared tonnage band for the technical costs and test costs.

TONNAGE INFORMATION

All Consortium Members shall declare their production (i.e. manufacture and imports) tonnage to the Trustee of the Consortium on a confidential basis according to the principles described in the Agreement. The tonnage shall be calculated as an average of the last 3 years (2006-2007-2008).

Appendix 8: Steering Committee Rules of Procedure

Open list

All invoices sent by the Coordinator or the Trustee are payable within 30 days. After this delay, a reminder will be sent and the amount of the invoice will be automatically increased by 5%. Should an invoice not be settled within 6 months by a Member, the Member will be expulsed from the Consortium.

Appendix 9: Article 3 of REACH (L 396/56 EN Official Journal of the European Union 30.12.2006)

Article 3
Definitions
For the purposes of this Regulation:
1) **Substance**: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
2) **Preparation:** means a mixture or solution composed of two or more substances;
3) **Article:** means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
(4) **Producer of an article:** means any natural or legal person who makes or assembles an article within the Community;
5) **Polymer:** means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

(b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a "monomer unit" means the reacted form of a monomer substance in a polymer;
6) **Monomer:** means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;
7) **Registrant:** means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;
8) **Manufacturing:** means production or extraction of substances in the natural state;
9) **Manufacturer:** means any natural or legal person established within the Community who manufactures a substance within the Community;
10) **Import:** means the physical introduction into the customs territory of the Community;
11) **Importer:** means any natural or legal person established within the Community who is responsible for import;
12) **Placing on the market:** means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;
13) **Downstream user:** means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;
14) **Distributor:** means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;
15) **Intermediate:** means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis"):

(a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment

through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipe work for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;

(b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

(c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

16**) Site:** means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;

17) **Actors in the supply chain:** means all manufacturers and/or importers and/or downstream users in a supply chain;

18) **Agency:** means the European Chemicals Agency as established by this Regulation;

19) Competent authority: means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

20) **Phase-in substance:** means a substance which meets at least one of the following criteria:

(a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);

(b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;

(c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this;

21) **Notified substance:** means a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC;

22) **Product and process orientated research and development**: means any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;

23) **Scientific research and development:** means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year;

24) **Use**: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization;

25) **Registrant's own use**: means an industrial or professional use by the registrant;

26) **Identified use:** means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;

27) **Full study report:** means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed;

28) **Robust study summary:** means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimizing the need to consult the full study report;

29) **Study summary:** means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study;
30) **Per year:** means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;
31) **Restriction:** means any condition for or prohibition of the manufacture, use or placing on the market;
32) **Supplier of a substance or a preparation:** means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;
33) **Supplier of an article:** means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;
34) **Recipient of a substance or a preparation:** means a downstream user or a distributor being supplied with a substance or a preparation;
35) **Recipient of an article:** means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;
36) **SME:** means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises**1**;
37) **Exposure scenario:** means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;
38) **Use and exposure category:** means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;
39) **Substances which occur in nature:** means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;
40) **Not chemically modified substance:** means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;
41) **Alloy:** means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.

Appendix 10: Standard letter of access

Letter of Access for the registration of calcium sulphate under *REACH Regulation*

Whereas, ----------. acting as coordinator of the consortium on calcium sulphate for the registration under REACH Regulation;

Whereas ----------. has been lawfully licensed by the legal data owner(s) to deliver letters of access.

---------- 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 calcium sulphate

(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 ----------