

I n t e r n a t i o n a l M a n g a n e s e I n s t i t u t e



CONSORTIUM AGREEMENT

Having regard to

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18
December 2006 (“REACH”)

and

the Registration of manganese and certain manganese-containing Substances thereunder

THE AGREEMENT

This Agreement, creating the REACH Manganese Consortium, is made by and among the undersigned Parties

between

[Manufacturer 1, 2 etc.]

and

[Importer 1, 2 etc.]

hereinafter referred to as “Regular Members”

and

[Downstream user 1, 2 etc.]

hereinafter referred to as “Associate Members”

and

The International Manganese Institute (IMnI)

hereinafter referred to as the “Secretariat” or the “Trustee”

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1. PREAMBLE

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, (hereafter “the REACH Regulation” or “REACH”), aimed at ensuring a high level of protection for human health and the environment, whilst ensuring the efficient functioning of the internal market and stimulating innovation and competitiveness in the chemical industry;

Having regard in particular to the Registration requirements imposed by the REACH Regulation on Manufacturers and Importers of Substances as such, in Preparations or in Articles, and the financial and human effort implied by this obligation and the limited time to ensure compliance;

Having regard to the requirements of the REACH Regulation to share certain of the data required for Registration purposes; and to make joint submissions of Core Data when there are multiple Registrants;

Having regard to the fact that the REACH Regulation will affect directly or indirectly Manufacturers and Importers established both within and outside the EU;

Having regard to the obligations under the REACH Regulation to consider all stages of the life-cycle of the Substance resulting from the manufacture and Identified uses; and the specific duties and obligations imposed on Downstream users of Substances as well as Manufacturers and Importers;

Having regard to Information that has already been generated by the International Manganese Institute within the context of the Manganese Health Research Program; and as a result of work undertaken by the International Manganese Institute in relation to the formal establishment of Community Occupational Exposure Limits for manganese and its compounds within the context of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, and work undertaken already in preparation for the implementation of the REACH Regulation;

Having regard to the possibility within the REACH Regulation to apply a grouping and read-across approach to the assessment of structurally related Substances;

The Parties, having a common interest in fulfilling the requirements laid down by the REACH Regulation, agree to form a Consortium open to any other eligible entity, whether or not established in the EU, in order to share human and financial resources involved in complying with this Regulation and to develop and collate, in a timely and efficient manner, the sets of Information required for Registration.

2. DEFINITIONS

2.1. Any terms defined in Article 3 of the REACH Regulation shall have the same meaning in this Agreement, including the definitions of Agency, Manufacturer, Importer, Intermediate, Downstream user, Registrant, Study summary and Robust Study summary. For ease of reference Article 3 is reproduced in Appendix 8.

2.2. Furthermore, in this Agreement, the following terms shall have the following meanings:

2.2.1. “Administrative Costs” the costs of administering the Consortium, as more fully described in 9.1.1.1;

2.2.2. “Affiliate” (i) a Party’s ultimate controller and any company which is directly or indirectly controlled by that ultimate controller; and, in the case of a dual listed group of companies, includes the other holding company and any company which is directly or indirectly controlled by the other holding company and / or the ultimate controller and the other holding company;

For the purposes of this definition a particular entity is:

(a) directly controlled by another entity if that latter beneficially owns or controls more than fifty percent (50%) of the shares carrying the right to vote at the general meeting (or its equivalent) of the particular entity or has the right to exercise a dominant influence over the entity either by virtue of provisions contained in the entity’s memorandum or articles (or equivalent constitutional document) or by virtue of a contract; and

(b) indirectly controlled by an entity (hereinafter called “Parent”) if a series of entities exists, beginning with the Parent (or Parents) and ending with a particular entity, in which each entity of the series,

except the Parent or Parents, is directly controlled by one or more entities earlier in the series; or

- (ii) an entity in which a Regular Member has a shareholding of not less than 26% (twenty six percent) and which such Regular Member has nominated in writing to the Secretariat as its Affiliate;

2.2.3. “Agreement” this Agreement, including any annexures or appendices;

2.2.4. “Assembly” the body comprising all Consortium Members as more fully described in 6.1;

2.2.5. “Associate Member” any natural or legal person which :

- is a Downstream user or represents the interests of Downstream users of Substances covered by this Agreement; and
- can contribute to the objective pursued by the Consortium, in particular by providing scientific and technical data and data on Use; and
- is a Party to this Agreement at the Effective Date or is subsequently admitted as a new Associate Member by the Steering Committee; and
- is not an Affiliate of a Regular or Associate Member;

(and “Associate Membership” shall have a corresponding meaning);

2.2.6. “Chemical Safety Report” the report described in Article 14 of the REACH Regulation;

2.2.7. “Confidential Business Information” in accordance with Article 39.2 of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), all information which:

- (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally

deal with the kind of information in question;

- (b) has commercial value because it is secret; and
- (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

2.2.8. “Consortium” the Regular Members organised in a consortium without legal personality pursuant to this Agreement;

2.2.9. “Consortium Member” or “Member” an Associate Member or a Regular Member (and “Membership” shall bear a corresponding meaning);

2.2.10. “Core Data” data to be submitted jointly by Registrants pursuant to the REACH Regulation and which includes:

- classification and labelling of the Substances covered by this Agreement;
- summaries of Information derived from the application of Annexes VII to XI to the REACH Regulation;
- Robust Study summaries derived from the application of Annexes VII to XI, if so required under Annex I to the REACH Regulation;
- testing proposals where required by the application of Annexes IX to X to the REACH Regulation;
- Chemical Safety Reports (where appropriate);
- guidance on safe Use of the Substances listed in Appendix 1;

The scope of the Core Data shall correspond to the requirements of the REACH Regulation applicable to Regular Member(s) Manufacturing or Importing the Substance(s) covered by this Agreement;

2.2.11. “Disclosing Party” any natural or legal person that discloses Information in the framework of this Agreement;

- 2.2.12. “Effective Date” the date on which this Agreement comes into effect, as more specifically provided in 11.1.1;
- 2.2.13. “EU” the territory of the European Union, which comprises the current twenty-seven member states, as well as any future member state of the EU, as well as Iceland, Lichtenstein and Norway, all being European Economic Area countries;
- 2.2.14. “Executive Committee” the executive sub-committee of the Steering Committee established in accordance with 6.3;
- 2.2.15. “Founder Member” a Party who qualifies for Regular or Associate Membership and which has (either directly or through an Affiliate) made a financial and active contribution towards the operations of the Consortium before the Effective Date;
- 2.2.16. “Information” Studies, other tests, data and any information in any form whatsoever made available by a Consortium Member pursuant to 8.1.1, or licensed from third parties pursuant to 8.1.4 or developed pursuant to 8.2.1. It also includes :
- all statistics, information, data or conclusions that could be deduced from such Studies, other tests, data and information which might be written, oral or visual information;
 - Registration Dossiers;
 - technical dossiers comprising Studies, including test results, Study Summaries, proposals for testing, classification and labelling, guidance on safe Use, plus a Chemical Safety Report; and
 - draft Registration Dossiers, interim and working documents related to the preparation of the Registration Dossiers, know-how, technical information, research, methods, practices, procedures, processes, and formulae;
- 2.2.17. “Lead Registrant” as defined in Article 11(1) of the REACH Regulation;
- 2.2.18. “Letter of Access” a letter granting the rights to refer to a Study submitted to the Agency or to demonstrate

legitimate possession of the Study, or a copy thereof, by a Member or third party (a specimen of which is annexed as Appendix 4;

- 2.2.19. “Manager” a natural person appointed as such in terms of 6.4;
- 2.2.20. “Minor Breach” any breach of the Agreement that is not a Serious Material Breach;
- 2.2.21. “Non-EU Manufacturer” a natural or legal person established outside the EU who Manufactures a Substance on its own or in Preparations or in Articles, formulates a Preparation or produces an Article that is Imported into the EU;
- 2.2.22. “Observer” a natural or legal person who may have an interest in participating in the activity of the Consortium, including Manufacturers or Importers of Substances which are not covered by the scope of this Consortium Agreement. Observers are appointed by the Steering Committee at its sole discretion and may participate in the Steering Committee and Technical Working Group meetings under conditions to be established by the Steering Committee on an ad hoc basis;
- 2.2.23. “Only Representative” a natural or legal person established in the EU who has been appointed as such in accordance with Article 8 of the REACH Regulation by a Non-EU Manufacturer;
- 2.2.24. “Party” a party to this Agreement;
- 2.2.25. “Receiving Party” any Party to this Agreement to which Information is made available in any manner within the framework of this Agreement;
- 2.2.26. “Registration” submission of the relevant parts of a Registration Dossier to the Agency as described in Title II of the REACH Regulation (and “Register” shall have a similar meaning);
- 2.2.27. “Registration Dossier” a technical dossier (including a Chemical Safety Report where applicable) as required by the REACH Regulation;
- 2.2.28. “Regular Member” (i) an EU Manufacturer, Non-EU Manufacturer or Importer which is a Party to this Agreement and:
- has an interest in the scope and the

purpose of this Agreement; and

- is required to Register on its own or through an Only Representative Substances listed in Appendix 1 under the REACH Regulation; and
- (if it is an EU Manufacturer or Importer) will become a participant in the SIEF related to the Substance it has to Register; and
- is not an Affiliate of another Regular Member (save in circumstances where the Steering Committee has specifically approved such Membership in terms of 5.1.1.6); or

(ii) an Only Representative of a Non-EU Manufacturer (where the requirements of 5.1.1.7 have been satisfied);

(and “Regular Membership” shall have a corresponding meaning);

2.2.29. “Secretariat”

the International Manganese Institute (IMnI);

2.2.30. “Serious Material Breach”

a breach of a substantial obligation of this Agreement by a Party, including but not limited to:

- (1) provision of inaccurate information to the Secretariat in terms of 5.1.1.4;
- (2) breach of -
 - (i) an obligation related to payment;
 - (ii) an obligation to provide existing Studies and Information. Deliberate or reckless provision of inaccurate Studies or Information also constitutes a Serious Material Breach;
 - (iii) an obligation of confidentiality, including obligations contained in 5.1.1.7.6.4 (ii), 7 and Appendix 2 to this Agreement;
 - (iv) an obligation under 10 (liability); or
 - (v) an obligation under 12.1 (compliance with competition laws);

- 2.2.31. "SIEF" a Substance Information Exchange Forum as contemplated in the REACH Regulation;
- 2.2.32. "Steering Committee" the committee which provides strategic guidance on the development of the work plan of the Consortium. It will be responsible for advising the Consortium on the resources (human and budget), for the strategic and policy aspects and will play the role of referee in cases of disagreement or misunderstanding at the level of the Technical Working Group. It is composed in accordance with 6.2.1;
- 2.2.33. "Study" an investigation, test, or other examination, which relates to intrinsic properties or to the exposure assessment or to the risk characterisation of the Substance, and which, as such, is of relevance for Registration of the Substance pursuant to the REACH Regulation; a Study as defined also includes all statistics, Information, data or conclusions that could be deduced from such a Study, and the report of that Study in written or electronic form;
- 2.2.34. "Study Costs" expenses relating to the cost of Studies, as more fully described in 9.1.1.2;
- 2.2.35. "Substance" a Substance that conforms to the definition contained in Article 3(1) of the REACH Regulation and is listed in Appendix 1 to this Agreement;
- 2.2.36. "Technical Working Group" the group which provides technical guidance on the development of the work plan and support for the activities of the Consortium. It is composed in accordance with 6.5.1;
- 2.2.37. "Trustee" the International Manganese Institute / IMnI or any independent consultant appointed by the Steering Committee; the objective being to protect the confidentiality of Information and / or Confidential Business Information in the most effective way;
- 2.2.38. "Turnover" the deemed annual turnover of a Regular Member calculated in accordance with Appendix 5.

3. PURPOSE AND SCOPE OF THE CONSORTIUM

- 3.1. The Consortium Members have become Parties to this Agreement in order to comply jointly with the requirements of the REACH Regulation for the Substances covered by this Agreement.
- 3.2. The activities of the Consortium shall be conducted on a not-for-profit basis. In addition, it is the intention of the Parties that nothing in this Agreement shall prejudice the not-for-profit character of the IMnI. If any provision of this Agreement tends or threatens to affect its not-for-profit character, the Parties agree to take such steps as may be required, including amending this Agreement, to ensure that the IMnI remains unaffected in its not-for-profit status.
- 3.3. The Parties to the Agreement shall make all reasonable efforts to ensure the appropriate and timely achievement of the Consortium's purposes.
- 3.4. In particular, the Consortium Members shall collectively, for the purposes set out below:

3.4.1. Pre-registration of Substances

- 3.4.1.1. share, for the sake of consistency and establishment of sameness, the names and identity codes of the Substances they intend to pre-Register;
- 3.4.1.2. identify the name(s) of other Substance(s) for which available Information is relevant for performing adaptations to the testing requirements, i.e. use of results from (Q)SAR models (Section 1.3 of Annex XI to the REACH Regulation) and read-across approach (Section 1.5 of Annex XI to the REACH regulation)

3.4.2. Registration of Substances

- 3.4.2.1. compile and assess all relevant existing Studies and identify data gaps;
- 3.4.2.2. prepare proposals for new testing needed to fill data-gaps related to the requirements specified in Annexes VII and VIII to the REACH Regulation, and have such tests performed;
- 3.4.2.3. prepare proposals for testing required to fill data-gaps related to the requirements specified in Annexes IX and X to the REACH Regulation; these proposals to be submitted to the Agency at the time of Registration of the Substance(s);
- 3.4.2.4. prepare the Core Data and ensure their reliability, relevance and adequacy;
- 3.4.2.5. address technical issues in relation to REACH Registration;
- 3.4.2.6. develop read-across approaches, as appropriate, based on data from tested Substances and/or surrogate data;

- 3.4.2.7. assess opportunities for exposure-based waivers from testing requirements;
- 3.4.2.8. develop hazard classification and labelling in accordance with the existing and future European Union rules (and, where applicable, with the Globally Harmonised System (“GHS”) of classification and labelling of chemicals);
- 3.4.2.9. coordinate, for each Substance, the joint submission of the Core Data, the Chemical Safety Report (where applicable) and the guidance on safe Use of the Substance by the Lead Registrant;
- 3.4.2.10. identify candidate Lead Registrants for each of the Substances to be Registered;
- 3.4.2.11. prepare the Core Data to be submitted by the Lead Registrants and Regular Members to the Agency for each Substance by not later than the earliest Registration deadline applicable to any of the Regular Members pursuant to the REACH Regulation;
- 3.4.2.12. ensure strict adherence to any working deadline or procedures set by the Steering Committee under this Agreement in view of the strict deadlines set by the REACH Regulation for the submission of the Core Data required for each Substance;
- 3.4.2.13. prepare and submit a Chemical Safety Report for all Substances in quantities of 10 tonnes or more per year per Registrant. In this regard:
 - 3.4.2.13.1. Regular and Associate Members shall provide the Trustee with the Information relating to Substance Uses and exposure in order to identify the Uses of a Substance to be covered by the Chemical Safety Report;
 - 3.4.2.13.2. the Consortium shall be allowed to prepare common Chemical Safety Reports only if the particular Uses are not considered Confidential Business Information by at least one of the relevant Parties;
 - 3.4.2.13.3. any Party shall be entitled to prepare and submit individually a Chemical Safety Report for Uses that it considers Confidential Business Information;

3.4.3. Evaluation by the Agency of the Registration Dossier and Authorisation

- 3.4.3.1. respond collectively to any request for further Information that may be made by the Agency in the context of Chapter 1 of Title VI of the REACH Regulation;

3.4.3.2. review the scope of the Consortium Agreement following submission by December 2010 of the initial Registration Dossiers for the Phase-in Substances to be Registered in terms of Article 23(1) of the REACH Regulation, and shall decide whether or not to extend it with a view to co-operation during any Authorisation process or any other follow-up process.

3.5. The Secretariat and the Trustee shall make any necessary effort to assist the Members in meeting their commitments under this Agreement and in achieving the purpose of the Consortium.

4. SUBSTANCES COVERED

The Substances covered by this Agreement are manganese and the manganese-containing Substances listed in Appendix 1. The list is not exhaustive and may be amended from time to time by decision of the Assembly upon the recommendation of the Steering Committee in terms of 6.1.4.3.6.2.

5. MEMBERSHIP

5.1. ADMISSION OF NEW CONSORTIUM MEMBERS

5.1.1. Admission of new Regular Members

5.1.1.1. Founder Members of the Consortium shall not be required to re-apply for Membership after this Agreement becomes effective.

5.1.1.2. Subject to 5.1.1.6 and 5.1.1.7, any natural or legal person who meets all the criteria for Regular Membership listed in 2.2.28 may become a Regular Member.

5.1.1.3. The Steering Committee shall consider all applications for Regular Membership and shall accept every application which meets all the criteria therefor, save where :

5.1.1.3.1. the applicant has previously been a Consortium Member and failed to comply with its obligations hereunder; or

5.1.1.3.2. the Steering Committee is entitled upon reasonable grounds to refuse Membership;

provided that refusal of an application for Regular Membership must in no circumstances constitute a breach of any competition law.

5.1.1.4. Every applicant for Regular Membership shall provide to the Secretariat in writing the names and number of its Affiliates which Manufacture in, and / or Import any of the Substances into, the EU,

and to the Trustee the tonnages of Substances so produced and / or Imported by such applicant and its Affiliates. For the purposes of determining the Regular Member's voting rights in the Assembly pursuant to 6.1.4.3 and its payment obligations pursuant to 9.3 and 9.4, the tonnages of Substances produced in and / or Imported into the EU by Affiliates of the Regular Member shall be attributed to the Regular Member. The Secretariat and the Trustee shall be entitled to require proof of the information provided in terms of this clause upon written request to the applicant, which shall include the right to audit such information in appropriate circumstances.

- 5.1.1.5. Regular Membership shall be conferred upon execution of this Agreement and payment of the fees and compensation required by this Agreement, including late Membership compensation in accordance with 9 and Appendix 5.
- 5.1.1.6. An Affiliate of a Regular Member shall only be entitled to Regular Membership if the Steering Committee is satisfied that there are special and compelling circumstances which justify the admission of the Affiliate to Regular Membership in addition to the Regular Member of which it is an Affiliate. In such an instance the Turnover of the Affiliate shall be allocated to the Affiliate and shall be deducted from the Turnover of the Regular Member for the purposes of determining their respective voting rights and financial contributions;
- 5.1.1.7. An Only Representative of a Non-EU Manufacturer shall only be entitled to Regular Membership under the following circumstances;
 - 5.1.1.7.1. The Non-EU Manufacturer which has appointed the Only Representative qualifies for Regular Membership but provides proof to the reasonable satisfaction of the Steering Committee that it is unable for reasons beyond its control to apply for Regular Membership itself;
 - 5.1.1.7.2. the Non-EU Manufacturer shall not become a Regular Member;
 - 5.1.1.7.3. the Only Representative must comply with the requirements set out in Article 8 of the REACH Regulation.
 - 5.1.1.7.4. the Only Representative shall only be permitted to represent a Non-EU Manufacturer who complies with the criteria set out in 5.1.1.7.1;
 - 5.1.1.7.5. the Only Representative shall provide the Secretariat (or, where applicable, the Trustee) with such written information as the Secretariat or Trustee may reasonably request with regard to both the Non-EU

Manufacturer and the Only Representative, including without limitation the information listed in 5.1.1.4;

5.1.1.7.6. the Non-EU Manufacturer which the Only Representative represents shall have provided to the Secretariat for the benefit of the Regular Members:

5.1.1.7.6.1. a written undertaking to be jointly and severally liable to the Consortium Members with the Only Representative for any breach of the Only Representative's obligations in terms of this Agreement;

5.1.1.7.6.2. such written guarantees with regard to the financial contributions and other obligations of the Only Representative pursuant to the Consortium Agreement as the Steering Committee may reasonably require;

5.1.1.7.6.3. written consent to submit to the dispute resolution provisions of this Agreement in the event of any dispute between the Non-EU Manufacturer on the one hand and the Only Representative and / or the Members of the Consortium on the other hand;

5.1.1.7.6.4. a letter of appointment of the Only Representative signed by the Non-EU Manufacturer and the Only Representative containing the following provisions:

- (i) an undertaking to provide the Only Representative with all information required pursuant to this Agreement in order to enable the Only Representative to fulfil its obligations in respect of data sharing within the Consortium;
- (ii) an undertaking to comply with the Confidentiality provisions in this Agreement;
- (iii) an undertaking by the Non-EU Manufacturer to the Only Representative and the Consortium Members to accept liability for any breach by the Non-EU Manufacturer of any of the

provisions contained in the letter of appointment;

- (iv) an undertaking by the Only Representative that it will, at the request of the Steering Committee, institute a claim against the Non-EU Manufacturer in the event of a breach of the Non-EU Manufacturer's obligations under the letter of appointment; and will transfer to the Secretariat for the benefit of all Regular Members any damages awarded as a result thereof;
- (v) a waiver by the Only Representative of any right to prevent the use of any data or Studies generated by or on behalf of the other Consortium Members which the Only Representative may have as co-owner of such data or Studies pursuant to this Agreement;

5.1.1.7.7. the Membership of the Only Representative shall automatically terminate if :

- 5.1.1.7.7.1. the Non-EU Manufacturer which it represents ceases to qualify for Regular Membership as provided in 2.2.28; or
- 5.1.1.7.7.2. the circumstance preventing the Non-EU Manufacturer from itself applying for Regular Membership ceases to exist, in which case Regular Membership shall automatically be deemed to be assigned by the Only Representative to the Non-EU Manufacturer with immediate effect;

5.1.1.8. An Only Representative shall only qualify as a Founder Member if it has disclosed the identity of the Non-EU Manufacturer which it represents before the Effective Date;

5.1.1.9. Notwithstanding the provisions of 5.1.1.7, the Steering Committee shall be entitled to set out additional objectively determinable criteria for Regular Membership of an Only Representative, and to reject any application for Membership by an Only Representative which fails to comply with such criteria. In such circumstances the

Non-EU Manufacturer shall be entitled to appoint an alternative Only Representative which does so comply.

5.1.2. Admission of new Associate Members

5.1.2.1. Any natural or legal person that meets all the criteria for Associate Membership listed in 2.2.5 may become an Associate Member.

5.1.2.2. The Steering Committee shall consider all applications for Associate Membership and shall accept every application which meets all the criteria therefor, save where :

5.1.2.2.1. the applicant has previously been a Consortium Member and failed to comply with its obligations hereunder; or

5.1.2.2.2. the Steering Committee is entitled upon reasonable grounds to refuse Membership;

provided that refusal of an application for Associate Membership must in no circumstances constitute a breach of any competition law.

5.1.2.3. Associate Membership shall be conferred upon execution of this Agreement. There will be no charge for Associate Membership.

5.1.3. Commitment of new Consortium Members

To become a Regular or Associate Member, an applicant must be subject to the REACH Regulation's requirements, and shall sign an undertaking to abide by all the terms and conditions as set out in this Agreement, including without limitation payment of the compensation described in 5.1.4; provided that a new Regular Member shall not be obliged to pay such compensation if it acquires Membership of the Consortium pursuant to 5.2.

5.1.4. Compensation due to existing Regular Members

5.1.4.1. Pursuant to the cost sharing formula set out in this Agreement, every new Regular Member shall pay a portion of the expenses incurred by the Consortium before the Effective Date as well as thereafter, up to the date on which the new Regular Member becomes a Party to this Agreement, by means of a proportionate reimbursement to the other Regular Members. The portion of expenses to be reimbursed shall be calculated in accordance with the cost sharing formula in 9.3.

5.1.4.2. The new Regular Member shall pay an additional Advantage Compensation (as detailed in Appendix 5) to the existing Regular Members to compensate for access to the know-how already acquired by them at the date of accession of the new Consortium Member.

- 5.1.4.3. The new Consortium Member shall have the rights and obligations attached to its status of Regular or Associate Member from the date of payment of its portion of expenses and Advantage Compensation, where applicable.

5.2. ASSIGNMENT OF MEMBERSHIP

5.2.1. Assignment of Regular Membership

A Regular Member shall be entitled to assign all (but not a part only) of its rights and obligations under this Agreement in the following circumstances:

5.2.1.1. Acquisition, merger or absorption of a Regular Member by or with a third party

Regular Membership can only be assigned if the Steering Committee is satisfied that:

- 5.2.1.1.1. the assignee meets all the requirements for Regular Membership; and
- 5.2.1.1.2. there are no grounds for refusal of Membership as set out in 5.1.1.3.

5.2.1.2. Acquisition, merger or absorption of a Regular Member by or with another Regular Member

5.2.1.2.1. Regular Membership may be assigned without the prior approval of the Steering Committee to another Regular Member, provided that:

- 5.2.1.2.1.1. neither the assignor nor the assignee may be in breach of any of its obligations in terms of this Agreement;
- 5.2.1.2.1.2. the Regular Member which absorbs the other Regular Member or the new entity formed following the merger of the two Regular Members shall only have one voting right;
- 5.2.1.2.1.3. when a Regular Member becomes an Affiliate of another Regular Member, all the rights and obligations of one Affiliate shall be automatically assigned to the other of them. However, in such case, the voting right belonging to the assignor is not assigned to the assignee and shall cease to exist.

5.2.2. Assignment of Associate Membership

Assignment of Associate Membership must be approved in writing by the Steering Committee prior to such assignment including in the context of the absorption or merger of the Associate Member by or with a third party or by or with another Associate Member. The Steering Committee shall be entitled to refuse assignment to a third party in the circumstances contemplated in 5.1.2.2.

5.2.3. Notification to Steering Committee

A Party which wishes to assign its rights and obligations in terms of 5.2.1 or 5.2.2 must notify the Steering Committee in writing at least sixty (60) days in advance of the date of such proposed assignment. If the assignment is pursuant to 5.2.1.2.1.3, the notification must indicate which Party will retain its Regular Membership.

5.3. TERMINATION OF MEMBERSHIP

5.3.1. Withdrawal

A Consortium Member may withdraw from the Consortium by sending to the Secretariat written notice thereof at least 60 (sixty) days prior to withdrawal.

5.3.2. Failure to comply with criteria for Membership

A Consortium Member must notify the Secretariat immediately in writing if its circumstances change such that it no longer complies with the criteria for Membership set out in 2.2.5 or 2.2.28 (as the case may be), and its Membership will be deemed to have terminated automatically with effect from the date on which it ceased so to comply.

5.3.3. Assignment

A Consortium Member which has assigned its rights and obligations in terms of 5.2 shall cease to be a Consortium Member immediately upon such assignment becoming effective.

5.3.4. Expulsion

5.3.4.1. A Consortium Member may be expelled from the Consortium:

5.3.4.1.1. in the event of a Serious Material Breach that has not been remedied within 30 days after formal notice has been sent to it by Registered letter with return receipt:

5.3.4.1.1.1. by decision of the Steering Committee where such Serious Material Breach relates to default of a payment obligation; and

5.3.4.1.1.2. by decision of the Assembly in any other instance; and

5.3.4.1.2. by decision of the Assembly in the event of a Serious Material Breach described in 2.2.30(1) or 2.2.30(2)(iii), in which circumstances it shall not be necessary to give notice to remedy,

provided that the defaulting Consortium Member shall have been afforded a reasonable opportunity to submit reasons in writing why it should not be expelled from the Consortium.

5.3.4.2. Expulsion of a defaulting Member shall be without prejudice to any other legal or other remedy that may be available to any Party in terms of this Agreement or in law.

5.3.5. Consequences of termination of Membership

5.3.5.1. Upon termination of Membership in terms of 5.3.1, 5.3.2, 5.3.3 or 5.3.4 the rights and obligations of the Consortium Member in question shall cease to exist, save in respect of

5.3.5.1.1. any outstanding amounts due and payable to the Consortium or any Consortium Members;

5.3.5.1.2. the confidentiality provisions set out in this Agreement;

5.3.5.1.3. any liability incurred in terms of 10.1 during the time that it was a Member;

5.3.5.2. The Consortium Members and the other Parties to this Agreement shall be entitled to make use of the data made available by the former Member in accordance with the provisions specified in this Agreement provided that such data has been the subject of compensation as set out herein.

5.3.5.3. The former Consortium Member shall pay its contribution to the Consortium expenses, including all payments related to Studies agreed on during the time of its Membership; provided that a Consortium Member which has given written notice of withdrawal shall not be obliged to pay any contributions determined after the date of such notice to be payable by all Members.

5.3.5.4. A withdrawing or expelled Consortium Member shall not be entitled for any reason whatsoever to claim back any monies paid pursuant to this Agreement during the time of its Membership.

5.3.5.5. The former Consortium Member, except if it has been expelled for breach of its payment obligations, shall have access to the results of the Studies and the full reports prepared by the Consortium for which it has paid compensation pursuant to this Agreement, even if

such results are available after the date of termination of its Membership.

- 5.3.5.6. The former Member shall be entitled to a proportionate and transparent share of subsequent compensation for all the Studies completed and paid by it before the date of termination of its Membership.
- 5.3.5.7. The former Member shall have no right in respect of the Registration Dossier (including no right to refer to the Registration Dossier prepared by the Consortium for the purpose of Registration). If the withdrawing or expelled Consortium Member wishes to submit a Registration Dossier jointly with the Regular Members, it must do so in accordance with the provisions governing the joint submission of data under Article 11 of the REACH Regulation.

6. ORGANIZATION OF THE CONSORTIUM

6.1. ASSEMBLY

The Regular Members shall meet in an Assembly in order to make the decisions set out in 6.1.1.7 and 6.1.2.

6.1.1. Composition of the Assembly

- 6.1.1.1. The Assembly shall comprise all the Regular Members. Each Associate Member shall be entitled to designate one natural person to attend Assembly meetings as an observer.
- 6.1.1.2. Each Regular Member shall designate one natural person to act as the representative of that Regular Member in the Assembly.
- 6.1.1.3. The designated representative of the Regular Member shall have authority to commit the Regular Member in decisions to be taken by the Assembly; and must be able to produce duly executed original proof of such appointment.
- 6.1.1.4. Each Regular Member shall be entitled to replace its representative, either temporarily or permanently, provided that
 - 6.1.1.4.1. the replacing representative complies with the criteria set out in 6.1.1.3; and
 - 6.1.1.4.2. the Regular Member must promptly notify the Secretariat in writing of such replacement, whereafter the Secretariat shall promptly advise the other Regular Members thereof .

- 6.1.1.5. Each Regular Member or its representative or designated proxy shall participate in Assembly meetings in person or by teleconference.
- 6.1.1.6. The Secretariat shall serve as secretary of the Assembly and shall delegate one or more of its personnel to the Assembly for the purpose. The Secretariat shall have no voting right on the Assembly.
- 6.1.1.7. Members of the Assembly shall elect by majority vote a chairman and a vice-chairman for a period of one year at a time. Upon expiry of each term the chairman and vice-chairman will qualify for re-election. The chairman shall co-ordinate the Assembly with the assistance of the Secretariat.
- 6.1.1.8. The vice-chairman shall replace the chairman when s/he is unavailable.

6.1.2. Role of the Assembly

- 6.1.2.1. The Assembly shall take decisions in connection with the following:
 - 6.1.2.1.1. Approval of the Core Data before joint submission to the Agency;
 - 6.1.2.1.2. Approval of the Chemical Safety Report before joint submission to the Agency;
 - 6.1.2.1.3. Adaptation of the Agreement in light of legislative and technical adaptation of the REACH Regulation's requirements, (in particular the establishment of the SIEF) or the entry into force of the Globally Harmonised System Regulation;
 - 6.1.2.1.4. Modification of any provision as well as the Appendices to this Agreement, if and when needed;
 - 6.1.2.1.5. Expulsion of a Consortium Member, subject to 5.3.4.1;
 - 6.1.2.1.6. Nomination of the candidate Lead Registrant/s upon the recommendation of the Steering Committee;
 - 6.1.2.1.7. Annual ratification of the strategic programme of the Consortium;
 - 6.1.2.1.8. Approval of the annual budget and unbudgeted expenditure which exceeds the authority of the Steering Committee to approve in terms of 6.2.2.2;
 - 6.1.2.1.9. Approval of the annual accounts.

- 6.1.2.2. The Assembly shall elect the members of the Steering Committee in accordance with 6.2.1.1.

6.1.3. Meetings of the Assembly

6.1.3.1. Ordinary Meetings

- 6.1.3.1.1. Ordinary meetings in person of the Assembly shall be held at least once a year.

- 6.1.3.1.2. No business will be transacted at an ordinary meeting other than the items specified on the agenda. The Assembly may however, with the consent of

- 6.1.3.1.2.1. 50% plus one of the representatives of the Regular Members; and

- 6.1.3.1.2.2. Regular Members representing 50% of the total votes

present or represented at the meeting, bring forward any business which it considers requires decision or action by the Regular Members.

6.1.3.2. Extraordinary meetings

Extraordinary meetings of the Assembly may be convened at the request of the chairman of the Assembly or at the request of a majority of the Regular Members.

6.1.3.3. Organisation of Meetings

- 6.1.3.3.1. Meetings of the Assembly shall be held upon written notice given by the Secretariat for ordinary meetings and upon written notice given by the Secretariat on behalf of the chairman of the Assembly or of a majority of Regular Members for extraordinary meetings. The notice shall indicate the venue of the meeting and/or telephone conference details.

- 6.1.3.3.2. The notice period for ordinary and extraordinary meetings shall be 4 (four) weeks from issue of notice by the Secretariat, unless a shorter period is agreed by all Regular Members.

- 6.1.3.3.3. A Member's written submission on agenda matters received by the Secretariat 24 hours in advance of the opening of the Meeting, shall be taken into consideration by the Assembly.

- 6.1.3.3.4. The Manager as well as one or more representatives of the Secretariat, the Steering Committee and the

Technical Working Committee shall attend ordinary meetings of the Assembly, as appropriate, to report on their activities. The Manager may represent the Secretariat for the purposes hereof.

6.1.3.4. Minutes

Minutes of the Assembly meetings shall be prepared by the Secretariat which shall forward copies of them within two (2) weeks to all Regular Members. Such Members must notify the Secretariat within two (2) weeks after despatch of the minutes if there is anything contained in the minutes with which they disagree.

6.1.4. Procedure at meetings

6.1.4.1. Physical / non-physical meetings

Members of the Assembly or their designated proxies may attend meetings in person or by teleconference.

6.1.4.2. Quorum

6.1.4.2.1. A meeting of the Assembly can be held if a quorum of :

6.1.4.2.1.1. 50% plus one of the representatives of the Regular Members; and

6.1.4.2.1.2. Regular Members representing 50% of the total votes

are present or represented at the meeting.

6.1.4.2.2. If a quorum is not achieved within 30 minutes of the scheduled starting time of the meeting (unless the Regular Members present agree unanimously to extend that period), the meeting, if convened upon the requisition of Members, shall be dissolved; in any other case the Secretariat shall convene a subsequent meeting at least 3 calendar weeks later.

6.1.4.2.3. if at such subsequent meeting a quorum is not present within 30 minutes from the time appointed for the meeting (unless the Regular Members present agree unanimously to extend that period), those Members present shall be entitled to deliberate and take decisions as if a quorum were present.

6.1.4.2.4. The chairman may, with the consent of the Regular Members present at any meeting at which a quorum is present (and shall if so directed by such Members), adjourn the meeting from time to time and from place

to place, but no business shall be transacted at any adjourned meeting other than the business left unfinished at the meeting from which the adjournment took place.

6.1.4.2.5. The Assembly can deliberate on and take decisions related to the matters referred to in 6.1.2.1.3 and 6.1.2.1.4 only if all of the Regular Members are present or represented at a Assembly meeting. However, if all the Regular Members are not present or represented, the Regular Members who were absent from the meeting may be given the opportunity of approving the proposed decision by signing, together with the Regular Members who attended the meeting, a document circulated after such meeting and containing a detailed description of the proposed decision. If such decision is unanimously agreed and is signed by all Regular Members following such meeting, the decision shall immediately come into effect.

6.1.4.2.6. Regular Members may be represented at each meeting by another Regular Member provided the latter is able to show at the start of each such meeting an original proxy duly signed by the former. There shall be no limit to the number of proxies an individual representative may hold.

6.1.4.3. Voting rights

6.1.4.3.1. The Trustee shall determine the number of votes to which each Regular Member is entitled in advance of each Assembly meeting and shall notify the Secretariat and each Regular Member individually in writing. Each Regular Member's votes will be determined on the basis of its Turnover during the previous financial year calculated in accordance with the principles set out in Appendix 5, based on written information supplied by the Regular Member to the Secretariat and the Trustee upon application for Membership and updated annually thereafter.

6.1.4.3.2. Each representative is entitled to the number of votes allocated to the Regular Member/s which it represents on any decision taken at an Assembly meeting; provided however that he/she shall have no right to vote regarding decisions concerning a Substance in respect of which the Regular Member/s which he/she represents has/have no obligation to Register pursuant to the REACH Regulation.

6.1.4.3.3. The Assembly Members shall strive for consensus.

- 6.1.4.3.4. In the case of equality of votes, the motion shall fail. The chairman shall not have a casting vote.
- 6.1.4.3.5. Associate Members shall have no voting rights on the Assembly.
- 6.1.4.3.6. Decisions shall be taken by a majority of 50% + 1 (fifty percent plus one) votes of Regular Members present or represented at the meeting except:
 - 6.1.4.3.6.1. Decisions to expel a Regular Member from the Consortium, which must be taken by a majority of 66% of votes by the Regular Members present or represented at the meeting, and
 - 6.1.4.3.6.2. Decisions related to 6.1.2.1.3 and / or 6.1.2.1.4, which must be taken by a majority of 75% of votes by the Regular Members present or represented at the meeting (for avoidance of doubt, such decisions once taken with the required number of votes shall be binding on all Members, unless the Regular Members who voted against the decision can demonstrate that such decision discriminates unfairly against any or all of them).

6.2. STEERING COMMITTEE

Decisions on the organisation of the Consortium shall be taken by a Steering Committee consisting *inter alia* of elected representatives of the Regular Members.

6.2.1. Composition of the Steering Committee

6.2.1.1. Participants in the Steering Committee

The Steering Committee shall be elected by the Regular Members in accordance with 6.2.1.4 and shall be composed as follows:

- 6.2.1.1.1. seven (7) Regular Members elected by the Regular Members in the Consortium; and
 - 6.2.1.1.2. One (1) Associate Member elected by the Associate Members of the Consortium, and acting as an observer in the Steering Committee.
- 6.2.1.2. If two or more Affiliates are Regular Members pursuant to 5.1.1.6, only one such Regular Member will be eligible for election to the Steering Committee.

- 6.2.1.3. For avoidance of doubt, an Only Representative which has been admitted to Regular Membership of the Consortium shall be eligible for election to the Steering Committee.
- 6.2.1.4. A Regular Member will only be entitled to stand as a candidate for membership of the Steering Committee if it possesses personnel with sufficient technical expertise to make a positive contribution to the work of the Technical Working Group.
- 6.2.1.5. The first election of members of the Steering Committee shall take place within 60 (sixty) days after the Effective Date of this Agreement, and elections shall take place annually thereafter.
- 6.2.1.6. Each Regular Member shall be entitled to the number of votes allocated to it by the Secretariat in terms of 6.1.4.3.1 for the purposes of electing members of the Steering Committee.
- 6.2.1.7. When electing members of the Steering Committee, Regular Members should endeavour to ensure that Manufacturers / Importers of each of the major Substance groups set out in Appendix 1 are represented thereon.
- 6.2.1.8. The Steering Committee shall be entitled to invite such additional Regular Members to the Steering Committee as observers as it sees fit.
- 6.2.1.9. Substitutes for representatives may also be appointed in writing.
- 6.2.1.10. Replacements of representatives as well as substitutes shall be possible.
- 6.2.1.11. The members of the Steering Committee and their representatives shall -
 - 6.2.1.11.1. serve in their respective positions for no compensation or remuneration whatsoever; and
 - 6.2.1.11.2. in carrying out their functions as members of the Steering Committee in good faith take into account the interests of all Regular Members, irrespective of whether or not such Regular Members are represented on the Steering Committee.
- 6.2.1.12. The Secretariat shall serve as secretary of the Steering Committee and shall delegate one or more of its personnel to the Steering Committee for the purpose. The Secretariat shall have no voting right on the Steering Committee.
- 6.2.1.13. Chairman and vice-chairman of the Steering Committee
 - 6.2.1.13.1. Members of the Steering Committee shall elect by majority vote a chairman and a vice-chairman for a

period of one year. The chairman shall coordinate the Steering Committee and organize its work with the assistance of the Secretariat.

6.2.1.13.2. The vice-chairman shall replace the chairman when s/he is unavailable.

6.2.2. Role of the Steering Committee

6.2.2.1. Within the Steering Committee, Regular Members shall take the necessary decisions relating to the Consortium and its objectives and shall in this regard particularly, but not exclusively, deal with the following:

6.2.2.1.1. Management of financial resources of the Consortium, including budget, funding collection and accounts;

6.2.2.1.2. Establishment of a Technical Working Group as per 6.5.1.1;

6.2.2.1.3. Coordination of and guidance for the preparation of the Registration Dossier for the Substances covered by Appendix 1, including following proposals by the Technical Working Group, the acceptance of relevant and reliable existing Studies and Information and any decisions to develop new Studies and Information;

6.2.2.1.4. Approval of testing programs;

6.2.2.1.5. Appointment of external consultants to perform technical and scientific tasks and as proposed by the relevant Technical Working Group (when requiring a budget);

6.2.2.1.6. Coordination and supervision of activities of the Secretariat, the Manager, the Technical Working Group and the Lead Registrant/s;

6.2.2.1.7. Arbitration in cases of disagreement or disparities within or between the Technical Working Group;

6.2.2.1.8. Decisions regarding admission of any new Regular or Associate Member;

6.2.2.1.9. Review and approval of each of the following stages after completion by the Technical Working Group:

6.2.2.1.9.1. Process for defining data gaps, including the development of waivers and use of surrogate and read-across data;

6.2.2.1.9.2. Defining test plans;

- 6.2.2.1.9.3. Analysis of tests results;
- 6.2.2.1.9.4. Compilation of Core Data;
- 6.2.2.1.9.5. Nomination of the candidate Lead Registrants to the Assembly pursuant to 6.8.1;
- 6.2.2.1.9.6. Submission of Core Data to the Agency;
- 6.2.2.1.9.7. Response to request(s) for further information by the Agency.

The review shall include a financial report of the collective work completed during the relevant stage.

- 6.2.2.2. The Steering Committee shall approve working and finance plans prepared by the Secretariat concerning the planned activities until submission of the Registration Dossier, in particular concerning the development of Information. The Steering Committee shall be entitled to approve:
 - 6.2.2.2.1. all expenditure (whether Study or Administrative Costs) which does not exceed the approved budgeted amount therefor by more than 10% (ten percent) (expenditure which exceeds the approved budgeted amount by more than 10% (ten percent) must be approved or rejected by the Assembly within thirty (30) days of a written request for such approval); and
 - 6.2.2.2.2. unbudgeted Study Costs not exceeding one hundred thousand euros (€100 000) (Unbudgeted Study Costs exceeding €100 000 must be approved or rejected by the Assembly within thirty (30) days of a written request for such approval).
- 6.2.2.3. The Steering Committee may appoint legal or technical experts to provide assistance on an *ad hoc* or regular basis.
- 6.2.2.4. The Steering Committee may approve the participation of other interested parties at meetings of the Steering Committee and / or of the Technical Working Group as Observers, subject to the signature of a non-disclosure agreement and on such terms and conditions as the Steering Committee shall determine.
- 6.2.2.5. Associate Members and Observers may be informed about Identified Uses which will be covered by a Registration Dossier and may be given an opportunity to request the inclusion of additional Uses. Such requests may be taken into consideration by the Steering Committee if appropriately substantiated.

- 6.2.2.6. The Steering Committee shall be entitled to appoint sub-committees for such purposes as it may deem appropriate.

6.2.3. Meetings of the Steering Committee

6.2.3.1. Ordinary Meetings

The Steering Committee shall hold ordinary meetings at least every 6 (six) months to review, on the basis of the technical and financial progress reports of the Secretariat, the progress according to the work schedule and the budget.

6.2.3.2. Extraordinary meetings

Extraordinary meetings of the Steering Committee may be convened:

- 6.2.3.2.1. at the request of the chairman of the Steering Committee; or
- 6.2.3.2.2. by the Secretariat upon written request by
 - 6.2.3.2.2.1. at least two members of the Steering Committee; or
 - 6.2.3.2.2.2. a majority of Regular Members.

6.2.3.3. Organisation of Meetings

- 6.2.3.3.1. Meetings of the Steering Committee shall be held upon written notice given by the Secretariat for ordinary and extraordinary meetings.
- 6.2.3.3.2. The notice period shall be 4 calendar weeks from issue of notice by the Secretariat, except if a shorter period is agreed by all members of the Steering Committee.
- 6.2.3.3.3. When meetings of the Steering Committee shall be held in person, the Secretariat's notice shall also indicate the address of the meeting place.
- 6.2.3.3.4. A Consortium Member's written submission on agenda matters received by the Secretariat 24 hours in advance of the opening of the Meeting shall be taken into consideration by the Steering Committee.

6.2.3.4. Minutes

Minutes of the Steering Committee meetings shall be prepared by the Secretariat which shall forward copies promptly to all Regular Members once the minutes have been signed by the chairman of the Steering Committee.

6.2.4. Decision procedures

6.2.4.1. Physical / non-physical meetings

- 6.2.4.1.1. Except when meetings must be held in person pursuant to other provisions of this Agreement, decisions of the Steering Committee may be taken by means of a document to be circulated and signed by the members of the Steering Committee.
- 6.2.4.1.2. Members of the Steering Committee may attend meetings in person or by teleconference.

6.2.4.2. Quorum

- 6.2.4.2.1. A meeting of the Steering Committee can be held if a quorum of 50% plus one of the representatives of the Regular Members is present or represented at the meeting.
- 6.2.4.2.2. If a quorum is not achieved within 30 minutes of the scheduled starting time of the meeting, the Secretariat shall convene another Steering Committee meeting at least 3 calendar weeks later (the "Second Meeting").
- 6.2.4.2.3. The Steering Committee shall be entitled to take decisions even if a quorum is not achieved during the Second Meeting.
- 6.2.4.2.4. Regular Members may be represented at each meeting by another Regular Member provided the latter is able to show at the start of each such meeting an original proxy duly signed by the former.

6.2.4.3. Voting rights

- 6.2.4.3.1. Subject to 6.2.4.3.4, each representative is entitled to one vote on any decision taken at a Steering Committee meeting.
- 6.2.4.3.2. The members of the Steering Committee shall always strive for consensus.
- 6.2.4.3.3. In the case of equality of votes, the motion shall fail. The chairman shall not have a casting vote.
- 6.2.4.3.4. One representative of all Associate Members may participate in the meetings of the Steering Committee as an observer without voting rights. This representative shall be elected by the other Associate Members by simple majority.

- 6.2.4.3.5. Subject to 6.2.4.3.2, decisions shall be taken by a majority of 50% + 1 (fifty percent plus one) vote of Regular Members present or represented at the meeting.

6.3. EXECUTIVE COMMITTEE

The Executive Committee shall be made up of the chairman, the vice-chairman, the Manager and another representative of the Secretariat. The Executive Committee will meet from time to time, as is necessary, to discuss and take action on matters of particular importance and urgency for the day-to-day functioning of the Consortium. The Executive Committee shall advise the Steering Committee of its decisions as soon as possible.

6.4. MANAGER

- 6.4.1. The Steering Committee shall appoint the Manager. The Steering Committee shall determine the necessary qualifications required of the Manager, as well as his/her duties and remuneration. The Manager shall report directly to the Steering Committee.
- 6.4.2. For the purposes of this Agreement, the Manager shall be deemed to be a member of the Secretariat.

6.5. TECHNICAL WORKING GROUP

6.5.1. Composition

- 6.5.1.1. In order to pursue the purposes of the Consortium, the Steering Committee shall establish a Technical Working Group, composed of suitably qualified representatives of the Regular Members and / or Associate Members and / or Observers.
- 6.5.1.2. All Regular Members shall be entitled to nominate suitably qualified persons for appointment to the Technical Working Group. The Steering Committee shall appoint the members of the Technical Working Group on the recommendation of the co-chairmen thereof.
- 6.5.1.3. The participants in the Technical Working Group and their representatives shall serve in their respective positions for no compensation or remuneration whatsoever.

6.5.2. Role

- 6.5.2.1. The activities of the Technical Working Group may include the following:
- 6.5.2.1.1. Finalising the initial list of Substances to be covered by this Agreement and developing preparatory groupings of these Substances;

- 6.5.2.1.2. Submitting proposals for updating the list of Substances to the Steering Committee for final approval by the Assembly if / when necessary;
- 6.5.2.1.3. Advising Regular Members on pre-registration and Registration requirements for their Substances;
- 6.5.2.1.4. Identifying and recommending to the Steering Committee potential Lead Registrants for the Substances;
- 6.5.2.1.5. Assisting in the preparation of the technical aspects of the working plan and estimating the financial resources required to comply with REACH requirements;
- 6.5.2.1.6. Determining cost allocation for risk assessment in the different Substance groups and advising the Steering Committee;
- 6.5.2.1.7. Overseeing the execution of the working plan, especially with regard to timing and taking corrective actions when / if necessary;
- 6.5.2.1.8. Reviewing and evaluating existing Studies and Information, including any submitted by third parties to the Trustee or to the Secretariat, and proposing to the Steering Committee which of the submitted Studies and Information will be necessary for the purpose of Registration of one or more of the Substances;
- 6.5.2.1.9. Determining, where appropriate, the financial value of existing Studies and Information, and advising the Secretariat and Steering Committee regarding proposed payments to Consortium Members for submitted Studies and/or Information and proposed payments to third parties for Studies to be acquired;
- 6.5.2.1.10. Preparing the Technical Dossier for Registration, including the determination of data gaps, waivers and surrogate data and any proposals for further testing where data gaps may need to be filled with tests listed in REACH Annexes IX and/or X;
- 6.5.2.1.11. Preparing the Chemical Safety Report and the guidance on safe Use;
- 6.5.2.1.12. Preparing harmonised classification and labelling in accordance with the EU rules on classification and labelling;

- 6.5.2.1.13. Preparing proposals for further testing and Information gathering for approval by the Steering Committee;
- 6.5.2.1.14. Advising on the selection of external laboratories to conduct the testing programme;
- 6.5.2.1.15. Supervision of performance of the testing programme and Information gathering and maintaining financial control (actual spending against budget) and reporting on these matters to the Steering Committee;
- 6.5.2.1.16. Assessing the results of new Studies and of new Information;
- 6.5.2.1.17. Considering requests of Observers or Associate Members for inclusion of additional Uses;
- 6.5.2.1.18. Regularly communicating progress on all of the above, and any other activities related to REACH and the Registration of the Substances, to the Steering Committee.

6.5.2.2. The Secretariat shall provide the Technical Working Group with such administrative and technical support as is necessary to enable the Technical Working Group to fulfil its functions.

6.5.3. Co-chairmen of the Technical Working Group

6.5.3.1. Appointment

The Steering Committee shall appoint the two co-chairmen of the Technical Working Group for an initial period of one year. Both co-chairmen may be re-appointed for a period to be decided by the Steering Committee.

6.5.3.2. Role

The co-chairmen of the Technical Working Group shall:

- 6.5.3.2.1. make recommendations to the Steering Committee on the composition and membership of the Technical Working Group; and
- 6.5.3.2.2. co-ordinate and organize the work of the Technical Working Group with the assistance of the Secretariat, and supervise reporting to the Steering Committee.

6.5.4. Technical sub-committees

The Steering Committee shall be entitled to create one or more technical sub-committees, for example in relation to a specific Substance or group of

Substances or to pursue the acquisition and/or assessment of particular Information.

6.6. THE SECRETARIAT

The Secretariat shall :

- 6.6.1. be responsible for daily management and external representation of the Consortium within the mandate given in terms of this Agreement;
- 6.6.2. conduct all normal business of the Consortium in the framework of this Agreement, other than activities which shall be the exclusive competence of the Steering Committee, and shall in particular:
 - 6.6.2.1. follow up the legislative and technical development of the REACH Regulation and inform the Technical Working Group and Steering Committee about relevant new developments;
 - 6.6.2.2. follow up progress in the activities of the Consortium and report the progress as well as the financial aspects related to these activities to the Steering Committee;
 - 6.6.2.3. provide technical and administrative support to the Steering Committee and the Technical Working Group;
 - 6.6.2.4. supervise external consultants and experts appointed by the Steering Committee;
 - 6.6.2.5. co-ordinate and provide guidance for data collection concerning Substances covered in 4;
 - 6.6.2.6. establish budget proposals;
 - 6.6.2.7. establish annual accounts; and
- 6.6.3. prepare reports for the Steering Committee on the achievement of the purposes of the Consortium as defined in 3.

6.7. THE TRUSTEE

- 6.7.1. The Secretariat shall act as Trustee to the Consortium in relation to receiving, recording and aggregating Confidential Business Information on the basis of stringent procedures that protect effectively the confidentiality required by the Consortium Members or by third parties.
- 6.7.2. Notwithstanding 6.7.1, the Steering Committee may decide to appoint an appropriately qualified independent third party to perform some or all of the functions of the Trustee when a higher degree of confidentiality is required.

6.7.3. The Trustee shall:

- 6.7.3.1. be able to guarantee independence and absence of conflicts of interest;
- 6.7.3.2. be able to demonstrate appropriate ability and capacity to receive, record and aggregate Confidential Business Information and Information on the basis of stringent procedures that will protect the confidentiality thereof;
- 6.7.3.3. comply with the provisions of Appendix 3.

6.8. LEAD REGISTRANT

6.8.1. Nomination

The Steering Committee shall nominate an applicant for Lead Registrant from amongst the Regular Members for each Substance listed in Appendix 1. Nomination of a Lead Registrant must be supported by a qualified majority of sixty six percent (66%) of the votes of the representatives of the Regular Members present at the meeting of the Assembly.

6.8.2. Non-preferential treatment and confidentiality

- 6.8.2.1. The nominated Lead Registrant shall continue to be subject to all the rights and obligations of a Regular Member under this Agreement.
- 6.8.2.2. The nominated Lead Registrant shall strictly abide by the confidentiality obligations set out in 7 and Appendix 2 of this Agreement.

6.8.3. Submission of Registration Dossier

- 6.8.3.1. The nominated Lead Registrant shall, if subsequently appointed as such by the members of the SIEF, submit the Registration Dossier to the Agency on behalf of the Regular Members (including their Affiliates concerned by the Substance to be Registered) and the other members of the SIEF and in the format specified by the Agency, on the date determined by the Steering Committee. The nominated Lead Registrant shall ensure that all confidential Information in the Registration Dossier is marked as such and shall submit to the Agency any requested justification for non-disclosure of Registration Dossier Information.
- 6.8.3.2. Nothing contained in this Agreement shall prevent a Regular Member from submitting the Chemical Safety Report and the guidance on safe Use individually. In such case, the Regular Member shall inform the Secretariat and the Lead Registrant of its decision within a reasonable period which is at least sufficient to

enable amendments of the Registration Dossier prior to its submission to the Agency.

6.8.4. Liability

To the greatest extent possible under the laws of the relevant jurisdiction, the nominated Lead Registrant shall not be liable for, and the Regular Members shall indemnify the nominated Lead Registrant against and hold it harmless from, all liabilities and claims (including reasonable attorneys' fees and expenses in defending against such liabilities and claims) against the nominated Lead Registrant in connection with the matters contemplated by this Agreement other than liabilities attributable to the gross negligence or wilful misconduct of the nominated Lead Registrant or a breach by the nominated Lead Registrant of the confidentiality provisions contained in 6.8.2.

6.8.5. Communications received from the European Chemicals Agency (ECHA)

The nominated Lead Registrant shall forward within five (5) business days any communications received from the Agency to the Regular Members through the Secretariat.

6.8.6. Appeals

The nominated Lead Registrant shall use all reasonable efforts to make any appeals under the REACH Regulation in the case of any rejection, objection, or request by the Agency relating to the Consortium Members' compliance with the requirements of the REACH Regulation. This does not preclude the right of any Regular Member, to which a decision of the Commission is directed, to make an appeal under REACH, subject to prior notification to the Secretariat and the Lead Registrant.

7. CONFIDENTIALITY

7.1. CONFIDENTIAL BUSINESS INFORMATION

7.1.1. Nothing contained in this Agreement shall oblige any Party to disclose any information which it considers to be Confidential Business Information.

7.1.2. Each Regular and Associate Member shall, and shall procure that its Affiliates, officers, directors, employees, agents and contractors (and, in the case of a Regular Member which is an Only Representative, the Non-EU Manufacturer which has appointed it, as well as the latter's Affiliates, officers, directors, employees, agents and contractors) shall, not disclose Confidential Business Information to any person not expressly authorized to receive such information under this Agreement. This obligation extends to the Secretariat and the Trustee, as well as, if relevant, any other external technical, scientific, financial or legal consultant.

- 7.1.3. The non-disclosure obligation covers Confidential Business Information that is disclosed by a Party to the Trustee or any other external technical, scientific, financial or legal consultant.
- 7.1.4. Persons not expressly authorized to access Confidential Business Information under this Agreement include, where appropriate, but without limitation, any third party to this Agreement or any Party to this Agreement which has not shared the cost of a Study in accordance with the cost sharing formula agreed upon in this Agreement.
- 7.1.5. Consortium Members may provide the Trustee in confidence with Confidential Business Information relating to Uses of and exposure to a Substance for the purpose of producing a Chemical Safety Report in respect thereof. The Trustee shall thereafter -
- 7.1.5.1. receive and compile information on all Uses from Members;
 - 7.1.5.2. identify Uses common to all the Members; and
 - 7.1.5.3. inform each Member of the Uses which are peculiar to that Member,
- in order to enable a decision to be taken on the production of one or more Chemical Safety Reports.

7.2. INFORMATION

- 7.2.1. The Parties to this Agreement and their Affiliates shall not disclose and shall protect the confidentiality of Information in accordance with the terms and conditions set out in Appendix 2.
- 7.2.2. Information disclosed to the Trustee is subject to a higher degree of confidentiality as set out in Appendix 3.
- 7.2.3. Each Regular and Associate Member shall, and shall procure that its Affiliates, officers, directors, employees, agents and contractors (and, in the case of a Regular Member which is an Only Representative, the Non-EU Manufacturer which has appointed it, as well as the latter's Affiliates, officers, directors, employees, agents and contractors) shall, maintain in strict confidence and not disclose any Information to any third party (with the exception of necessary submission to the Agency, the European Commission and/or state or public authorities, including judicial and arbitral tribunals or except as otherwise provided by law, regulations or this Agreement) without the prior written authorisation of the Steering Committee.
- 7.2.4. The non-disclosure obligation covers Information that is disclosed by a Party to the Trustee or any other external technical, scientific, financial or legal consultant.
- 7.2.5. Persons not expressly authorized to access Information under this Agreement include, where appropriate, but without limitation, any third party to this

Agreement or any Party to this Agreement which has not shared the cost of a Study in accordance with the cost sharing formula agreed upon in this Agreement.

- 7.2.6. This obligation of confidentiality is subject to applicable EU laws and shall remain in effect until the Steering Committee decides on any public disclosure of the Information and subject to consent to disclosure by individual owners of the Information who have provided it to the Consortium (if any) as well as any conditions the Steering Committee may impose.

8. DATA SHARING

8.1. EXISTING STUDIES AND INFORMATION

8.1.1. Obligation to provide existing Studies and Information

- 8.1.1.1. The Parties to this Agreement undertake to provide the Secretariat or, when a higher degree of confidentiality is required, to provide the Trustee with any existing Studies or Information of interest for achieving the purposes of the Consortium.
- 8.1.1.2. The existing Studies provided shall meet the criteria set out in the Technical Guidance Document provided by the European Commission.
- 8.1.1.3. Each Party shall inform the Secretariat or the Trustee of any Studies or Information that cannot be made public, in particular pursuant to Article 119 of the REACH Regulation.
- 8.1.1.4. Upon receipt of the existing Studies and existing Information, the Secretariat and the Trustee, as the case may be, shall provide the Steering Committee with a list of these Studies and Information. The Steering Committee shall then select, under the guidance of the Technical Working Group, the Studies and Information which will be necessary for the purpose of Registration.

8.1.2. Ownership of existing Studies

Intellectual property rights applicable to an existing Study or Information made available in accordance with this Agreement shall remain with the Party which provided such Study or Information.

8.1.3. Use of existing Studies

- 8.1.3.1. The Parties shall have the right to use the Study or Information jointly for the purpose of complying with the requirements of the REACH Regulation, provided that they have shared the cost of the Study or Information in accordance with the cost sharing formula agreed upon in this Agreement.
- 8.1.3.2. This right shall extend to Affiliates of these Parties.

- 8.1.3.3. The Party who granted the right to use its existing Studies or Information to the other Parties may extend the right of other Parties to use or refer to these Studies or Information, for purposes other than REACH requirements.

8.1.4. License of existing Studies from third parties

- 8.1.4.1. Subject to budgetary constraints, the Steering Committee may decide to license from any third party existing Studies or Information that can assist in satisfying Registration requirements. Such a license shall be concluded by the Secretariat on behalf of the Regular Members, under the conditions agreed by the Steering Committee.
- 8.1.4.2. The Parties to this Agreement shall have the right to use such jointly licensed Study or Information for the purposes of complying with the REACH requirements to the extent that they share individually the license costs in accordance with the cost sharing formula agreed upon in this Agreement.
- 8.1.4.3. As a condition of licensing any Study or Information, the license to be concluded must provide that the same right to use such Study or Information for the purposes of complying with the REACH requirements shall extend to Affiliates of the Regular Members.

8.2. DEVELOPMENT OF NEW STUDIES

8.2.1. Ownership of new Studies or new Information

- 8.2.1.1. The Steering Committee can authorise the development of new Studies and Information.
- 8.2.1.2. The Regular Members shall have joint ownership pro rata to their respective financial contributions of the Studies or Information generated or developed by the Consortium pursuant to this Agreement.
- 8.2.1.3. Each Regular Member authorises the other Regular Members and their Affiliates to use the new Studies or Information and authorises the Steering Committee to license the right to refer to the new Studies or Information to third parties pursuant to the provisions of the Agreement.

8.2.2. Use of new Studies and new Information

8.2.2.1. Use by Associate Members

Associate Members shall only have the right to refer to new Studies and Information for the purpose of complying with the requirement of the REACH Regulation if :

- 8.2.2.1.1. they have shared in payment of the cost of the Studies or Information in accordance with the cost sharing formula agreed upon in this Agreement; or
- 8.2.2.1.2. they have paid the licence fee and complied with the terms and conditions determined by the Steering Committee in terms of 8.2.2.3.

8.2.2.2. Use by Affiliates of a Regular Member

Affiliates of a Regular Member shall have the right to use the new Studies and Information without any additional payment therefor, *inter alia* for the purpose of fulfilment of their obligations pursuant to the REACH Regulation.

8.2.2.3. Use by third parties

In accordance with 8.2.1.3, the Steering Committee may give to third parties the right to refer to new Studies and Information in support of the Registration of chemical Substances in the EU under the terms and conditions and subject to the appropriate license fee that the Steering Committee shall determine. The Steering Committee shall execute a "Letter of access for referral" in the form attached to this Agreement in Appendix 4 where required.

9. FINANCIAL RIGHTS AND OBLIGATIONS

9.1. EXPENSES / COSTS

9.1.1. The Consortium expenses will comprise:

9.1.1.1. Administrative Costs, including :

- 9.1.1.1.1. costs incurred by the Secretariat in performing its obligations hereunder;
- 9.1.1.1.2. remuneration of the Trustee;
- 9.1.1.1.3. remuneration of external experts;
- 9.1.1.1.4. remuneration of external accountants, auditors, lawyers;

9.1.1.2. Study Costs, including

- 9.1.1.2.1. expenses related to the use of Studies or Information provided by the Consortium Members (financial value of a Study): The Steering Committee shall approve the financial value of an existing Study made available by a Party pursuant to this Agreement on the basis of an evaluation of the scientific quality and relevance of the

Study in relation to the achievement of the purpose of the Consortium. The Steering Committee may take into account the actual cost or the replacement value of the Studies, including the Administrative cost of preparing and implementing the testing programme;

9.1.1.2.2. expenses related to the procurement of new Studies and Information decided by the Steering Committee;

9.1.1.2.3. expenses related to Studies or Information licensed from third parties;

9.1.1.3. costs of joint submission of Core Data.

9.1.2. Consortium expenses shall not include any charges against the Consortium for any overhead expenses or charges of the offices of the Consortium Members or their Affiliates for time which may be expended in connection with the activities of the Consortium by any of the Consortium Members or their officers, employees or representatives or of their Affiliates, except as may be approved by the Steering Committee (excluding the representative of the interested Party).

9.2. ACCOUNTS / ANNUAL BUDGET

9.2.1. The Secretariat shall

9.2.1.1. be responsible for the accounts of the Consortium. It shall establish (i) the annual accounts of the Consortium and submit them to the Steering Committee up to the end of each calendar year by March of the following year; and (ii) a statement of charge and discharge for each Consortium Member; and

9.2.1.2. annually establish a budget proposal for the next year, including if necessary advance payments to be made by the Consortium Members, and submit this proposal to the Steering Committee, which will thereafter present it to the Assembly for approval. The budget proposal shall be circulated by the Secretariat among the members of the Steering Committee at least three (3) months before the end of each financial year for pre-approval examination.

9.2.2. If there is an excess of funds during a certain year, this excess shall be carried over to the following year and applied towards fulfilment of that following year's budget, provided that the Consortium still exists.

9.2.3. The Secretariat shall maintain full and accurate books, records and accounts that shall, in reasonable detail, accurately and fairly reflect the cost sharing accounts of the Consortium Members and all transactions within the framework of the Consortium.

9.3. COST SHARING

- 9.3.1. The Members shall share the costs of the Consortium by means of contributions approved annually by the Assembly on proposals from the Secretariat according to the budget. The financial year shall extend from 1 January to 31 December of each year.
- 9.3.2. The Consortium Members shall bear the Consortium expenses jointly as follows:
- 9.3.2.1. Administrative Costs and Study Costs shall be allocated among Regular Members on a pro rata to Turnover basis in accordance with the principles set out in Appendix 5. When a service or an activity only benefits a certain group of Members, the costs of that service or activity shall be paid only by the Consortium Members benefiting from the service or activity.
- 9.3.2.2. The costs associated with the submission of Core Data for a particular Substance shall be shared pro rata to their Turnover among all Regular Members who Manufacture the Substance in, or Import it into, the EU.
- 9.3.2.3. Associate Members shall not be required to contribute to the Consortium's expenses.
- 9.3.3. The funding principles to be used by the Steering Committee are listed in Appendix 5.

9.4. PAYMENT

- 9.4.1. Not later than thirty (30) days before the beginning of each financial year, the Secretariat shall send to each Member a fund raising appeal for its respective share determined in accordance with 9.3.2 of the total cost of the activities projected to be incurred during the subsequent year.
- 9.4.2. Each fund raising appeal shall be paid within thirty (30) days of its release by the Secretariat. If a fund raising appeal is not received by a Member within thirty (30) days before the beginning of the financial year the Member shall notify the chairman in writing, who shall instruct the Secretariat to re-issue the fund raising appeal, which shall be paid within thirty (30) days of its release.
- 9.4.3. Consortium Members may be reasonably requested by the Secretariat from time to time to pay, and shall pay within a reasonable period to the Secretariat, additional unbudgeted expenses and costs, provided such unbudgeted expenses have been approved by the Steering Committee in accordance with 6.2.2.2 or by the Assembly if the unbudgeted expenses exceed the authority of the Steering Committee pursuant to 6.2.2.2. Payment of such costs shall be allocated among the Regular Members in accordance with 9.3 (or, if such costs are not categorised as Administrative Costs or Study Costs, as reasonably determined by the Steering Committee).

9.5. AUDIT OF THE ACCOUNTS

The accounts of the Consortium shall be subject to external and independent audit on a yearly basis, based on recognized accounting standards and procedures. These audits must result in an annual financial statement being made available to all the Consortium Members.

10. LIABILITY

10.1. LIABILITY OF CONSORTIUM MEMBERS

10.1.1. Liability to other Members

10.1.1.1. The liability of each Consortium Member for the expenses and liabilities of the Consortium shall be several and not joint.

10.1.1.2. The Consortium Members shall exercise due care and diligence vis-à-vis other Consortium Members in observing the rights and obligations related to, or arising out of this Agreement.

10.1.1.3. Subject to 10.1.1.4:

10.1.1.3.1. each Consortium Member agrees not to take any legal or other action against any other Consortium Member for liabilities arising in connection with the matters contemplated by this Agreement in case of Minor Breach if the accumulated amount of a claim or claims is less than €50.000;

10.1.1.3.2. no Consortium Member shall be responsible to another for indirect or consequential loss or damage such as but not limited to loss of profit or loss of revenue.

10.1.1.4. The threshold and limit of liability set out in 10.1.1.3 do not apply in case of wilful misconduct or Serious Material Breach.

10.1.2. Liability to third parties

Each Consortium Member shall be solely liable to third parties and shall indemnify any other Consortium Member against and hold any other Consortium Member harmless from all liabilities and claims (including reasonable attorneys fees and expenses in defending against such liabilities and claims) in connection with any loss, damage or injury to third parties resulting from its own fault or negligence.

10.1.3. Liability related to the use of Studies

The Consortium Members shall not be held liable for misuse of data developed under the Consortium program by one or more Regular or Associate Members.

10.1.4. Liability related to the provided Studies

Any Consortium Member who knowingly or recklessly provides inaccurate Studies under 8.1.1 shall indemnify the receiving Consortium Member/s for any loss, damage or injury caused thereby.

10.1.5. Liability related to the fulfilment of the REACH Regulation requirements

Each Party to this Agreement is and remains responsible for complying with its rights and obligations under the REACH Regulation in as much as these rights and obligations are not expressly transferred to the Consortium in accordance with this Agreement. This applies, in particular, to Information which is to be submitted to the Agency within the pre-registration and Registration Dossier in due time by each Member, as well as to communication with Downstream users in the supply chain.

10.2. LIABILITY OF THE SECRETARIAT

10.2.1. Secretariat's liability to third parties

The Secretariat shall act solely in its capacity as representative of the Consortium Members and shall bear no individual responsibility or liability for its actions taken in this capacity, with the exception of intentionally unlawful acts or gross negligence incompatible with its mandate.

10.2.2. Secretariat's liability to Consortium Members

The Secretariat is accountable to the Steering Committee alone.

10.3. LIABILITY OF THE TRUSTEE

The Trustee shall be responsible for any breach of its obligations as set out in this Agreement, with particular reference to Appendix 3.

11. DURATION OF THE AGREEMENT

11.1. ENTRY INTO EFFECT AND TERM

11.1.1. This Agreement shall enter into force on the date when five (5) Regular Members shall have signed the Agreement.

11.1.2. The expiry date of the Agreement shall be the date of completion of the purposes of the Agreement as determined by the Assembly in terms of 6.1.4.3.6.2 on the recommendation of the Steering Committee.

11.2. EFFECTS OF DISSOLUTION

11.2.1. Before dissolution or termination of the Consortium, any remaining joint and several rights and obligations of Consortium Members resulting from this Agreement and in relation to third parties shall be settled by the Steering

Committee. However, upon dissolution, all rights and obligations of the Consortium Members arising from this Agreement that do not involve assets shall lapse. After payment of all expenses and liabilities as authorised by the Steering Committee, any balance remaining of amounts paid by the Consortium Members or amounts derived from the granting of licenses to third parties, shall either be (i) returned to the Consortium Members in a pro rata manner based upon the Consortium Members' respective share in the Consortium expenses as at the time of termination, or (ii) transferred to the IMnI, as directed by the Steering Committee.

- 11.2.2. The provisions relating to the obligations of confidentiality, data ownership, ownership of intellectual property rights, settlement of disputes as well as those provisions of this Agreement which by their nature extend beyond the expiration or earlier termination of the Agreement will survive and remain in effect.

12. GENERAL PROVISIONS

12.1. COMPLIANCE WITH COMPETITION LAWS

- 12.1.1. Neither this Agreement nor anything contained in this Agreement is intended to restrict competition in any manner whatsoever. The Parties expressly undertake to comply with applicable rules on competition law, in particular but not limited to Articles 81 and 82 of the EC Treaty, as well as any applicable national laws.
- 12.1.2. The exchange of information required to operate this Agreement shall be limited to what is strictly necessary for achieving the purpose of the Consortium.
- 12.1.3. In particular, each Consortium Member agrees not to disclose to any other Consortium Member any information that relates in any way to production capacities, production volumes, sales volumes, Import volumes, market shares, clients, pricing information or future business plans.
- 12.1.4. Should it become apparent at any time that, notwithstanding their commitment, this Agreement or any provision thereof, or activity or decision of the Consortium can have a potentially restrictive effect on open and fair competition, in breach of any statutory provision, each Party to this Agreement undertakes to take the steps necessary to remedy that situation immediately so that it is lawful.

12.2. REPRESENTATIONS AND WARRANTIES

Each Party represents and warrants to each other Party that:

- 12.2.1. it is a duly organized, validly existing entity of the type described in the introduction to this Agreement and is in good standing under the laws of the jurisdiction of its formation, and that it has all requisite power and authority to enter into and to perform its obligations under this Agreement;

- 12.2.2. execution, delivery, and performance of this Agreement have been duly authorized, and do not and will not;
- 12.2.2.1. contravene any law, rules, regulation, order, or decree applicable to it; or
- 12.2.2.2. contravene its organizational rules or documents;
- 12.2.3. this Agreement is a legal and binding obligation of that Party, enforceable against that Party in accordance with its terms, except to the extent enforceability is modified by bankruptcy, reorganization and other similar laws affecting the rights of creditors generally and by general principles of equity; and
- 12.2.4. there is no litigation pending or, to the best of its knowledge, threatened to which such Party or any of its Affiliates is a party that, if adversely determined, would have a material adverse effect on the financial condition, prospects, or purposes of the Consortium, or that Party's ability to perform its obligations under this Agreement.

12.3. SEVERABILITY

If any one or more of the provisions of this Agreement or any part or parts of it, shall be declared or adjudged to be illegal, invalid or unenforceable under any applicable law, such illegality, invalidity or unenforceability shall not vitiate the remainder of this Agreement, and this Agreement shall be construed as if such illegal, invalid and unenforceable passages were omitted.

12.4. NO PARTNERSHIP

No Consortium Member shall be deemed an employee, agent, partner, or joint venturer of any other. Except as authorised by this Agreement, no Consortium Member shall make any commitment, by contract or otherwise, binding upon any other Consortium Member nor represent that it has any authority to do so. Except as expressly authorised by this Agreement, neither the Consortium, nor any Consortium Member, whether acting through the Steering Committee or otherwise, shall have the authority to act for or to assume any obligation or responsibility on behalf of any other Consortium Member.

12.5. NOTICES

- 12.5.1. Except as expressly set forth to the contrary in this Agreement, all notices, requests or consents provided for or permitted to be given under this Agreement must be in writing and must be delivered to the recipient in person, by courier or mail or by facsimile, telegram, cablegram or similar transmission; and a notice, request or consent given under this Agreement is effective:
- 12.5.1.1. upon receipt if sent by personal delivery, mail, courier, telegram or cablegram; or

12.5.1.2. upon the sender's receipt of electronic confirmation of transmission, if sent by telex or facsimile during regular business hours on a Business Day or (if not sent during regular business hours or on a Business Day, on the next succeeding Business Day).

12.5.2. All notices, requests and consents to be sent to a Party must be sent to or made at the address(es) given by that Party upon signature of this Agreement or such other address as that Party may specify by notice in writing to the Secretariat who shall circulate it to other Consortium Members.

12.6. LEGAL STATUS

12.6.1. This Agreement shall not be interpreted or regarded as creating either a company (including a company in fact or a company in participation) or a legal person. This Agreement is based on the solidarity of operators subject to regulatory challenges. It formally excludes any *affectio societatis* and any intention to share benefits or to contribute to losses.

12.6.2. The rights, duties, obligations and liabilities of the Parties under this Agreement shall be several and, not joint or collective. It is not the intention of the Parties to create, nor shall this Agreement be deemed or construed to create, a partnership, joint venture or association.

12.6.3. This Agreement shall not be deemed or construed to authorise any Party to act as an agent, servant or employee for any other Party for any purpose whatsoever except as explicitly set forth in this Agreement.

12.7. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the Parties and supersedes all prior contracts or agreements among such parties with respect to such matters, whether oral or written. There are no understandings, obligations, representations or warranties except as herein provided and no rights are granted except as expressly set forth herein.

12.8. EFFECT OF WAIVER OR CONSENT.

A waiver or consent, express or implied, to or of any breach or default by any Party in the performance by that Party of its obligations with respect to this Agreement is not a consent or waiver to or of any other breach or default in the performance by that Party of the same or any other obligations of that Party with respect to this Agreement. Failure on the part of a Party to complain of any act of any Party or to declare any Party in default with respect to this Agreement, irrespective of how long that failure continues, does not constitute a waiver by that Party of its rights with respect to that default until the applicable limitation period has expired.

12.9. GOOD FAITH

Each Party shall perform its obligations under this Agreement in good faith in dealing with the other Parties and shall not do anything which would prejudice the objectives of the Consortium.

12.10. DISPUTE RESOLUTION

Except for the purpose of obtaining injunctive or other provisional relief in a court of competent jurisdiction, all disputes, controversies or claims which may arise between the Parties in connection with the interpretation of any provision of this Agreement or its validity or enforceability, or its breach or termination, or the performance or non performance of any obligations hereunder shall be resolved as follows:

12.10.1. The Parties shall endeavour to settle all disputes, controversies or claims which do not require urgent injunctive or other provisional relief by an amicable effort on the part of the Parties. An attempt to arrive at a settlement shall be deemed to have failed as soon as one of the Parties so notifies the other Party in writing.

12.10.2. If an attempt at settlement has failed, the Parties will (unless otherwise agreed) submit the dispute, controversy or claim to non-binding mediation, before a single mediator, chosen jointly by the Parties. If the Parties have agreed not to submit the dispute, controversy or claim to mediation, or if it cannot be resolved by mediation, the dispute, controversy or claim shall (unless otherwise agreed) be finally settled by three (3) arbitrators in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce, Paris.

12.10.3. The decision of the arbitrator shall be final and binding. The cost of arbitration shall be paid equally by the Parties involved and any out-of-court costs shall be borne by the Party incurring said costs. The arbitrator shall decide which Party(ies) shall pay particular costs of arbitration including out-of-court costs incurred by the parties in accordance with the outcome of the arbitration. The language of the arbitration proceedings shall be English. The venue of arbitration shall be Paris (unless otherwise agreed).

12.10.4. During the period of any arbitration proceedings, the Parties shall continue to perform their respective obligations under this Agreement insofar as the circumstances will allow it but without prejudice to a final adjustment in accordance with the arbitral award.

12.11. LAW

All disputes or claims relating to this Consortium and any legal issues arising from the Agreement shall be governed exclusively by French law without regard to its conflict of laws rules.

12.12. COUNTERPARTS

This Agreement will be executed in a number of counterparts, which shall together constitute a single agreement. Each undersigned Consortium Member shall execute two (2) signature pages, retain one for its file and communicate the other to the Secretariat.

IN WITNESS WHEREOF, the undersigned, by their duly authorised representatives, have executed and delivered this Agreement.

SIGNED AT THIS DAY OF

AS WITNESS:

Witness' signature For and on behalf of

Witness' name Name of Member

Name of authorised signatory

SIGNED AT THIS DAY OF

AS WITNESS:

Witness' signature For and on behalf of

Witness' name Name of Member

Name of authorised signatory

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SUBSTANCES COVERED BY THE AGREEMENT

Reference name	Formula	EINECS Number	CAS Number	Tonnage Band	Notes; other Substances names; status (S, SP, I)*
Group I: metallic (manganese and Alloys)					
Manganese	Mn	231-105-1	7439-96-5	>1000	S
Alloys					
Ferromanganese	Mixture of Fe and Mn	Not applicable	12604-53-4	>1000	Alloys are not themselves subject to Registration: the named component elements have to be registered i.e. manganese (as above) will be registered by the Mn Consortium. SP
Silicomanganese	Mixture of Si, Fe and Mn	Not applicable	None found	>1000	
Group II: oxides (manganese oxides, ore sinter and slags)					
Manganese (II) oxide	MnO	215-695-8	1344-43-0	>1000	Manganous oxide; Mn monoxide S
Manganese (IV) oxide	MnO ₂	215-202-6	1313-13-9	>1000	Manganese dioxide S
Manganese (II, III) oxide	Mn ₃ O ₄	215-266-5	1317-35-7	>1000	Tri-manganese tetraoxide S
Manganese (III) oxide	Mn ₂ O ₃	215-264-4	1317-34-6	<1000	Di-manganese trioxide S
Mixture of manganese (II) oxide, manganese (II, III) oxide and manganese (II) silicate (Manganese ore sinter)	Mixture of MnO, Mn ₃ O ₄ and Mn ₂ SiO ₄	Mixture as indicated by formula	Mixture as indicated by formula	>1000	May contain Ca ₂ SiO ₄ instead of Mn ₂ SiO ₄ . Not a simple mixture but an agglomerate. I
Slags					
(Slags, ferromanganese-Manufacturing)	Mixture of oxides	273-728-1	69012-28-8	>1000	Reference name and formula to be defined S
(Slags, silicomanganese-Manufacturing)	Mixture of oxides	273-733-9	69012-33-5	>1000	Reference name and formula to be defined S

*S =Substance, SP = special Preparation, I =Intermediate (NB Intermediates are Substances)

Reference name	Formula	EINECS Number	CAS Number	Tonnage Band	Notes; other Substances names; status (S, SP, I)*
Group III: manganese salts and other compounds					
Manganese (II) carbonate	MnCO ₃	209-942-9	598-62-9	>1000	Manganese carbonate S
Manganese (II) sulphate	MnSO ₄	232-089-9	7785-87-7 10034-96-5	>1000	Hydrated salts considered as “same” but may have different CAS no. S
Manganese (II) nitrate	Mn(NO ₃) ₂	233-828-8	10377-66-9	>1000	Manganese dinitrate S
Manganese (II) chloride	MnCl ₂	231-869-6	7773-01-5	<1000	Manganese dichloride; hydrated salts considered as “same” S
Manganese (II) phosphate	Mn(H ₂ PO ₄) ₂	242-520-2	18718-07-5	<1000	Mn bis(dihydrogen phosphate) S
Manganese (II) acetate	Mn(CH ₃ COO) ₂	211-334-3	638-38-0	<1000	Manganese di(acetate) S
Other compounds					
Manganese (II) silicate	Mn ₂ SiO ₄	231-848-1	7759-00-4	>1000	Component of manganese ore sinter S
Manganese (II) sulphide	MnS	242-599-3	18820-29-6	<1000	Manganese sulphide S
(Zinc manganic oxide)	ZnMn ₂ O ₄	None	None found	>1000	Reference name to be defined S
Lithium manganese (III, IV) oxide*	LiMn ₂ O ₄	None	12057-17-9	<1000	Lithium manganate S
(Lithium manganese phosphate)**	(Li,Mn) PO ₄	None	None found	<1000	Reference name to be defined S
(Mixed metal oxide)**	Li(Ni,Mn,Co)O ₂	None	None found	<1000	Reference name to be defined S

*S =Substance, SP = special Preparation, I = Intermediate (NB Intermediates are Substances)

** For pre-registration, provisional for Registration

CONFIDENTIALITY

1. OBLIGATIONS OF THE RECEIVING PARTY

1.1. The Receiving Party agrees:

1.1.1. not to disclose and to protect the confidentiality of the Information (including any notes, summaries, reports, analyses or other material derived by the Receiving Party, its Affiliates or its or their Representatives (defined below) in whole or in part and in whatever form maintained (collectively, "Notes");

1.1.2. to use the Information and Notes only for the purpose of this Agreement as contemplated hereby;

1.1.3. to treat the Information and Notes with the same degree of care as it treats its own Confidential Business Information, which shall be at least a reasonable standard of care, to prevent disclosure of the Information and Notes, except to its Affiliates and its or their officers, directors, employees, agents and contractors (collectively, "Representatives"), to the extent necessary for the fulfilment of the obligations of the Receiving Party and its Affiliates pursuant to the REACH Regulation.

1.1.4. that prior to disclosing any Information and Notes to its Affiliates or its or their Representatives as provided above, such Affiliates and their Representatives will be advised of the confidential nature of the Information and/or Notes, and will be provided a copy of this Appendix and directed to abide by its terms.

1.1.5. to be responsible for any breach of this Appendix by it, its Affiliates or its or their Representatives.

1.1.6. not to copy or otherwise reproduce nor duplicate the Information or Notes in whole or in part where such copying, reproduction or duplication has not been specifically authorized by this Agreement or otherwise approved in writing by the Steering Committee or the Secretariat.

1.2. Obligations in this clause 1 shall continue for twelve (12) years from the date of Registration of each of the Substances listed in Appendix 1.

1.3. Nothing herein is intended to, and shall not limit or abridge the protection of any trade secret under applicable trade secrets law, and trade secrets shall be maintained as such until they fall into the public domain.

1.4. The Receiving Party acknowledges that the covenants of non-disclosure and non-use in this Agreement shall be effective in every county and territory in the world.

1.5. In the event of loss or theft of any Information and Notes, the Secretariat must be notified by the Receiving Party who shall take all reasonable action and cooperate fully in remedying same.

2. EXCEPTION TO CONFIDENTIALITY PROTECTION

- 2.1. Notwithstanding 1.1, the Receiving Party may provide its customers, to the extent that it is necessary to comply with the Receiving Party's legal obligations, with (i) Safety Data Sheets as defined in the REACH Regulation, (ii) relevant Exposure scenarios or (iii) other available and relevant Information about the Substance covered by this Agreement, that is necessary to enable appropriate risk management measures to be identified and applied, but only so long as the Receiving Party's customer does not manufacture, Import into the EU or sell such Substances.
- 2.2. Notwithstanding 1.1:
- 2.2.1. the Receiving Party may disclose the Information if and to the extent that such disclosure is required by law or court order, provided that the Receiving Party notifies the Disclosing Party and the Secretariat; and
- 2.2.2. the Receiving Party and its Affiliates may use the Information to achieve compliance with laws and regulations in other non EU jurisdictions provided that the confidentiality of the Information and Notes is guaranteed and in compliance with the Agreement. Any disclosure of the Information for purposes of compliance with non-EU regulatory requirements that could result in public disclosure of the Information or Notes shall only be permissible after prior approval from the Steering Committee.
- 2.3. 1.1 shall not apply to those particular portions of Information disclosed by the Disclosing Party if such Information:
- 2.3.1. is or becomes generally available to the public other than as a result of disclosure by the Receiving Party, its Affiliates or its or their Representatives to which it has been made available;
- 2.3.2. was available on a non-confidential basis prior to its disclosure to the Receiving Party;
- 2.3.3. is or becomes available to the Receiving Party, its Affiliates or its or their Representatives on a non-confidential basis from a source other than the Disclosing Party when such source is not, to the best of the Receiving Party's knowledge, subject to a confidentiality obligation with the Disclosing Party;
- 2.3.4. was independently developed by the Receiving Party, its Affiliates or its or their Representatives, without reference to the Information, and the Receiving Party can prove such independent development of the Information with written documentation;
- 2.3.5. is approved for release by the Steering Committee in compliance with Article 119 of the REACH Regulation (as amended or replaced) on electronic public access with the decision for submission of a Registration Dossier; or
- 2.3.6. is approved for public disclosure by written authorisation of the Steering Committee subject to any directions of the Steering Committee with respect

to the extent, timing, and manner in which the Information shall be publicly disclosed.

3. NO LICENCE AND INDEMNITY

- 3.1. Nothing in this Agreement is intended to and shall not grant any right to the Receiving Party under any patent, copyright or any other intellectual property right, nor shall this Agreement grant the Receiving Party any rights in or to the Information except as expressly set forth in the Agreement.
- 3.2. The Receiving Party acknowledges and agrees that any breach of the confidentiality provisions of the Agreement and particularly this Appendix 2 would cause immediate and irreparable injury to the Consortium and the Consortium Members. Should the Receiving Party violate any of the terms and conditions of confidentiality in this Agreement, the Consortium Members shall be entitled, in addition to any other remedies that maybe available, in law, in equity or otherwise, to obtain injunctive relief against the threatened breach of the confidentiality provisions of the Agreement or the continuation of any such breach, without the necessity of proving actual damage.

TRUSTEE UNDERTAKINGS

When a higher degree of confidentiality is required by a Disclosing Party, this Disclosing Party may disclose Information or Confidential Business Information to the Trustee only and the Trustee shall treat such information as follows.

1. DISCLOSURE PROCEDURE

- 1.1. Any Information or Confidential Business Information disclosed to the Trustee shall be marked prominently on each page “Extremely Confidential – BUSINESS SECRETS OF [NAME OF DISCLOSING PARTY]”.
- 1.2. Information or Confidential Business Information provided to the Trustee may only be included as an Annex to any Registration Dossier or Study after the Steering Committee has approved the relevant Information / Confidential Business Information / Registration Dossier but without the Steering Committee seeing such information. The Trustee may make a non-confidential summary of this extremely confidential information if s/he considers it necessary for other Consortium Members to see some of it for the purpose of Registration of the Substances covered by this Agreement. In particular, the Trustee shall aggregate any Information or Confidential Business Information provided to the Trustee so that it does not enable any Member to infer the sales, market shares, market or sales performance or trends therein of any other Member. The Trustee shall give the Disclosing Party reasonable opportunity to comment on any such summary the Trustee may make, before it is distributed. The Trustee may seek the advice of legal counsel before releasing such a summary to the Consortium Members.

2. OBLIGATIONS OF THE TRUSTEE

The Trustee is responsible for receiving, collecting, recording and aggregating any information, including confidential and proprietary information, as well as sensitive business secrets and other information which if disclosed to another Member(s) might be regarded as a breach of competition law, and thereafter circulating and disclosing sufficient and appropriate information, following the procedures in 1, as required for the purposes of the Agreement.

LETTER OF ACCESS FOR REFERRAL

European Chemicals Agency
[address of Agency]
Helsinki, Finland

Letter of Access for the Registration of the Substance[insert the short name of the Substance to be Registered] under Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisations and Restrictions of Chemicals, hereinafter “REACH”.

Dear Sirs,

The consortium¹ for the Registration of the Substance [insert the short name of the Substance to be Registered] under REACH (hereinafter referred to as "the Consortium") agrees 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 of

Substance [insert the exact name of the Substance to be Registered]

¹ At the date of issue of this Letter of Access the Members of the consortium are:[insert names of the Members of the consortium]

(hereinafter collectively referred to as the “Dossier”), may be referred by Applicant: Company XYZ 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]*

The right to refer to the Dossier is subject to the following restrictions:

1. The right of referral is only in respect of the Dossier of the Substance for the Registration as specified above.
2. The right of referral is granted solely in favour of *Company XYZ* and is not transferable or assignable to any other entity or person.
3. *Company XYZ* is not authorised to receive any copies of the Dossier nor is *Company XYZ* 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 *Company XYZ* any property or other rights whatsoever in the Dossier or any part thereof.
5. Nothing in this letter shall require the Consortium to file any additional data.

Signature: [Authorized Representative of the Consortium]

FUNDING PRINCIPLES**1. MINIMUM CONTRIBUTIONS**

Notwithstanding anything to the contrary contained herein, every Regular Member will be required to contribute annually until the time of submission of the Registration Dossiers an amount of fifty thousand euros (€50 000) or its share of costs calculated in terms of this Agreement, whichever amount is greater. Thereafter the Parties will review the Members' contributions in good faith.

2. ADMINISTRATIVE COSTS

2.1. These will be shared pro rata to their Turnover amongst the Regular Members. New Members will contribute pro rata to their Turnover to costs incurred by the Consortium before they join, and the existing Regular Members will be reimbursed annually by means of a credit in their favour at the end of the year.

2.2. Associate Members will not be required to contribute to Administrative Costs.

3. SUBMISSION OF CORE DATA

These costs will be shared pro rata to their Turnover amongst the Regular Members who are obliged to Register the Substance to which the Core Data applies.

4. COSTS OF STUDIES**4.1. REIMBURSEMENT OF COSTS OF EXISTING STUDIES**

The reimbursement value of each Study will be determined by the Steering Committee in accordance with transparent and objectively determined principles taking into account the recommendations of the Technical Working Group; provided that no member of the Steering Committee shall be party to a decision in respect of a Study/Studies which it has provided.

4.2. NEW STUDIES**4.2.1. Regular Members**

4.2.1.1. No Regular Member will be required to contribute to Study Costs in respect of Substances which it (and its Affiliate/s) is not obliged to Register.

4.2.1.2. If a Study is required by all the Regular Members of the Consortium, the cost of such Study shall be shared amongst them in proportion to their respective Turnover during the year/s in which the cost of the Study is incurred.

- 4.2.1.3. If a Study is required for the purposes of Registration of one or more but not all Substances, the cost of such Study will be shared amongst the Regular Members obliged to Register such Substance/s in proportion to their respective Turnover during the year/s in which the cost of the Study is incurred.
- 4.2.1.4. Study Costs will be shared in proportion to the Turnover attributed to a Regular Member which Manufactures or Imports the Substance in question. Members' Turnover for the purposes of this clause will be calculated annually on the basis of –
- 4.2.1.4.1. the total tonnage Imported (customs cleared) into, or produced in, the EU of the Substance in question by the Regular Member and its Affiliates during the previous financial year, as disclosed to the Trustee; and
- 4.2.1.4.2. the average delivered market price of the Substance in the EU during the previous financial year, as determined by the Trustee.
- 4.2.1.5. The Trustee will annually determine a reference price for each Substance based on average prices contained in published information wherever possible. The most recent CRU published prices will be used for the purposes of determining manganese Alloy prices. If no published reference price is available for a particular Substance the Trustee will determine a deemed price based on such verifiable information as is available to it. The deemed Turnover of each of the Regular Members will be determined by the Trustee and each Regular Member will be notified individually of the number of its votes and its contribution.

4.2.2. Associate Members

An Associate Member who wishes to Register a Substance shall contribute to the costs of Studies required for the purposes of such Substance *mutatis mutandis* on the same basis as Regular Members in terms of 4.2.1, save that its contribution shall be calculated on the aggregate annual value of the Substance purchased by it in the EU during the previous year. Irrespective of the price actually paid by such Associate Member for the Substance in question, the price shall be deemed to be the price determined by the Secretariat in terms of 4.2.1.4.2.

4.2.3. Verification of charges

The Secretariat shall procure that its auditors shall annually review and verify the amounts claimed from each Member in terms hereof.

5. MEMBERS WHO JOIN THE CONSORTIUM AFTER ITS INCEPTION

- 5.1. If a Regular Member joins the Consortium more than six (6) months after the Consortium has been in operation, such Regular Member shall pay, in addition to its pro rata share of the Administrative Costs and the Study Costs for which it is liable, an “Advantage Compensation” calculated as a percentage of its pro rata share of the total cost of the Study as follows:

Members who join after 30 June 2008 but before 30 June 2009	10%
Members who join after 30 June 2009 but before 30 June 2010	25%
Members who join after 30 June 2010 but before 30 June 2011	35%
Members who join after 30 June 2011	50%

- 5.2. The Advantage Compensation paid pursuant to 5.1 shall be credited :

5.2.1. first, to the accounts with the Secretariat of the Founder Members on a pro rata basis corresponding to their respective contributions before 1 January 2008 until such contributions have been reimbursed in full; and thereafter

5.2.2. to the accounts with the Secretariat of the existing Regular Members (including Founder Members) on a pro rata basis corresponding to the respective Turnover of each Member.

- 5.3. Notwithstanding 5.1, an applicant for Regular Membership which has not produced the Substance in question anywhere in the world before the calendar year during which it applies for Membership shall not be liable to pay the Advantage Compensation.

- 5.4. For the avoidance of doubt, a Regular Member who is admitted to Membership of the Consortium after its inception shall be liable to pay -

5.4.1. the greater of :

5.4.1.1. €25 000; or

5.4.1.2. its pro rata share of Costs,

in respect of each year that the Consortium has been in operation; plus

5.4.2. the Advantage Compensation described in 5.1 (subject to 5.3).

6. FUND RAISING APPEALING AND CREDITS

Fund raising appeal will be issued annually. At the end of each year the Secretariat will calculate the actual expenses incurred that year and issue a debit or credit against the Members’ accounts, taking into account payments received from new Members who have joined during the year in question.

7. REGISTRATION COSTS

Each Member shall be personally responsible for its own costs incurred in the Registration of a Substance which it is required to Register.

**RECOMMENDATIONS FOR COMPLIANCE WITH
COMPETITION LAW**

Each Party to the REACH Manganese Consortium is liable for ensuring strict compliance with competition. The following advice, which does not constitute an exhaustive list, should be implemented by each Party, whether in the context of Consortium meetings or social gatherings incidental to these meetings.

Supervise strictly

- Ensure that the actual activities of the Consortium are in line with its purposes, structures and authorities, as described in the Agreement
- Restrict cooperation to the purpose and scope defined in the Agreement
- Ensure legal counsel is present at each meeting
- Limit meeting discussions to agenda topics
- Provide each attendee who accompanies you with a copy of this checklist
- Have a copy of these rules available for reference at all meetings
- Consult with internal or external legal counsel if you have any doubt as to the application of these guidelines or any Consortium activity

Keep detailed records

- Ensure that the agenda and the minutes accurately reflect the matters which occur
- Make sure that data is exchanged on a need to know basis and only for the objectives pursued by the Consortium
- Archive the agenda, the minutes and any relevant documents and ensure that they can be made available on request
- Ensure that any individual company data is reviewed by legal counsel prior to disclosure

Be vigilant

- Object to any discussion or meeting activities which appear to contravene this checklist
- Require those activities to be stopped so that a check can be made by legal counsel
- Dissociate from such discussion or activity and from the attendees who conduct them
- Leave any meeting in which they continue and have it recorded in the minutes

- Ensure that data which is commercially sensitive is not shared between competitors, but placed in confidential annexes by legal counsel
 - Involve the Trustee for exchange of information likely to affect competition
-

ARTICLE 3 OF THE REACH REGULATION

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 pipework 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 utilisation;
- 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 minimising 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;
- 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.
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