Consortium Agreement for Vinyl Chloride (VCM)

pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation,

Authorisation and Restriction of Chemicals (REACH)¹

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¹ OJ L 136 of 29.5.2007

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Consortium Agreement for Vinyl Chloride

Between

(1) ANWIL SA, a public company with limited liability under Polish law, whose registered office is at UI. Torunska 222, 87-805 Wloclawek, Poland

And

(2) Aragonesas Industrias y Energia S.A., a private company part of the Ercros Group with limited liability under Spanish law, whose registered office is at Avda. Diagonal no 595, 2nd floor, Barcelona (Spain). Postal Code: 08014

And

(3) Arkema France SA a public company with limited liability under French law, whose registered office is at 420 rue d 'Estienne d' Orves, 92700 ,Colombes, France

And

(4) BorsodChem Zrt., a private company limited by shares under Hungarian law, whose registered office is at 3700 Kazincbarcika, Bolyai tér 1, Hungary.

And

(5) Cires S.A., a public company with limited liability under Portuguese law, whose registered office is at P.O. Box 20, Samouqueiro – Avanca, P.3864-752 Estarreja, Portugal

And

(6) Dow Europe GmbH, a private company with limited liability under Swiss law, whose registered office is at Bachtobestr. 3, 8810 Horgen, Switzerland

And

(7) INEOS Vinyls (UK) Ltd, a private company with limited liability under British law, whose registered office is at PO Box 9, South Parade, Runcorn, Cheshire WA7 4JE, United Kingdom

And

(8) LVM N.V., a public company with limited liability under Belgian law, whose registered office is at Troonstraat 130, BE-1050 Brussels, Belgium

And

(9) Novacke Chemické Zavody a.s., a public company with limited liability under Slovak law, whose registered office is at ul. M.R. Stefanika1, 97271 Novaky, Slovak Republic

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And

(10) Oltchim S.A., a public company with limited liability under Romanian law, whose registered office is at Uzinei Street 1, 240050 Ramnicu Valcea, Valcea County, Romania

And

(11) Shin-Etsu PVC B.V., a private company with limited liability under Dutch law; whose registered office is at Noorderweg 68, 1221 AB Hilversum The Netherlands

And

(12) SolVin GmbH & Co KG, a private company with limited liability under German law, whose registered office is at Hans Boeckler Allee, 20, 30173 Hannover, Germany

And

(13) VESTOLIT GmbH & Co. KG, a private company with limited liability under German law, whose registered office is at Paul-Baumann-Strasse 1, 45772 Marl, Germany

And

(14) Vinnolit GmbH & Co. KG, a private company with limited liability under German law, whose registered office is at Carl-Zeiss-Ring 25, 85737 Ismaning, Germany

As "Regular Members",

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

Preamble

Whereas the Members are manufacturers/ importers/ only representatives or have Affiliates who are manufacturers and/or importers as defined in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals ("the REACH Regulation") of the Substance Vinyl Chloride, or have the obligation to register Vinyl Chloride by virtue of Article 6 § 3 of the above mentioned Regulation, on their own, in preparations or in articles with registered offices in the European Union or in other countries having adopted the REACH Regulation.

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Whereas the Substance has phase-in status according to Article 3 (20) of the REACH Regulation and each of the Members intend (has) to pre-register the substance individually.

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

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

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

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

THE MEMBERS HAVE AGREED UPON THE FOLLOWING:

Agreement

Article I. Definitions

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

Substance: Vinyl Chloride, as specified further in Annex 1 to this Agreement for which the Consortium is created.

Polyvinyl chloride homo- or co-polymer: The homo- or co-polymers having Vinyl Chloride as (one of) their monomer(s).

Members: Members of the Consortium being the above listed initial signatories to this Agreement as well as any other entity which becomes party to this Agreement in the future, including:

Regular Members: manufacturers/ importers/ only representatives or companies having Affiliates who are manufacturers and/or importers as defined in the REACH Regulation of the Substance on its own, in preparations or in articles, or having the obligation to register the Substance by virtue of Article 6 § 3 of Regulation (EC) No 1907/2006, and who are subject to the registration requirements pursuant to the REACH Regulation and who participate in the Consortium.

Associate Members: Downstream Users as defined in the REACH Regulation/ Industry associations/ Manufacturers not established within the European Union/ third parties holding information on the Substance (Data Holders), who are not subject to the registration requirements but have an

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interest in contributing to the achievement of the Purpose as defined in Article II and whose participation in the Consortium has been approved by the Steering Committee as specified in Article III of this Agreement.

Affiliates: Any legal entity controlling, controlled by, or under common control with a Regular Member. For these purposes, "control" shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of a person, whether through the ownership of voting rights, by contract or otherwise; or (ii) the ownership, directly or indirectly, of 50 % or more of the voting rights or other ownership interest of a person. Affiliates may or may not have registration obligations under REACH.

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

Deadline for registration: 30 November 2010.

Lead Company: the Regular Member who is responsible for submitting the Core Data to the European Chemicals Agency ("**Agency**") on behalf of the Regular Members and their Affiliates pursuant to Article 11 (1) of REACH.

Steering Committee: decision- making body of the Consortium.

Territory: all European Union Member States, as well as the countries of the European Economic Area having adopted the REACH regulation in their national legislation.

Trustee²: An independent third party who in view of the exchange of sensitive individual data, is appointed by the Steering Committee and who is a legal or natural person not directly or indirectly linked to a Member. A confidentiality agreement will ensure that the Trustee does not misuse any sensitive data (e.g. volumes, customers) it receives. The Trustee must ensure that specific internal procedures effectively protect any Information disclosed to him.

Study: reports, tests or evaluations in written or electronic form, including full study reports, summaries and robust study summaries as defined in the REACH Regulation, relating to intrinsic properties, exposure assessment and risk characterisation of the Substance and as such are of relevance for registration pursuant to Article 10 of the REACH Regulation, in existence before the 1 June 2008 ("Existing Study") or performed after that date ("New Study").

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

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² Trustee: See also Annex 7.

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

- Classification and labelling of the Substance pursuant to section 4 of Annex VI of the REACH Regulation;
- Study summaries of the information derived from the application of Annexes VII to XI of the REACH Regulation;
- Robust study summaries of the information derived from the application of Annexes VII to XI, if required in Annex I of the REACH Regulation;
- Proposals for testing where listed in Annexes IX and X of the REACH Regulation;

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

The Core Data also include

- the Chemical Safety Report where required under Article 14 of the REACH Regulation, in the format specified in Annex I of the REACH Regulation including the relevant use and exposure categories.
- the Guidance on safe use of the Substance as specified in section 5 of Annex VI of the REACH Regulation.

Letter of Access: a letter as set out under Annex 10 granting the rights to refer to a Study submitted to the Agency.

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

Article II. Purpose and Objectives

The Members undertake to cooperate and share human and financial resources in order to comply with the requirements of the REACH Regulation regarding the registration of VCM for manufacturing and use as monomer for the production of Polyvinyl chloride homopolymer or copolymer, by virtue of Article 6 § 3 of Regulation (EC) No 1907/2006i ("the Purpose"). In particular, they undertake to pursue jointly the following objectives:

- 1. Agreement on the identity and the sameness of the Substance and its regulatory status, as well as on other substances for which the available Information might be relevant for the Substance of interest for the Members.
- 2. Development of the Core Data for the Substance, including:
 - a) Gathering and assessing Existing Studies on the Substance individually held by the Members or third parties as well as any data in the public domain (literature, etc.);
 - b) Identification of data gaps between the Existing Studies gathered pursuant the previous point and the requirements of Annexes VI to XI of the REACH Regulation;

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- c) Development of read-across approach where possible;
- d) Assessment of opportunities for exposure-based waivers;
- e) Subject to obligations under Art. 30 of REACH Regulation carrying out of testing to close the data gaps identified in relation to Annexes VI to VIII of the REACH Regulation taking into account Annex XI;
- f) Preparation of study summaries and robust study summaries, where appropriate;
- g) Development of testing proposals as required according to Annexes IX and X of the REACH Regulation taking into account Annex XI;
- h) Development of uniform classification and labelling, according to GHS;
- i) Gathering information on use and exposure categories of the Substance, conditions of use and exposure to humans and environment. Identified uses of the Substance to be assessed in the Chemical Safety Report shall be listed in <u>Annex 2</u> to this Agreement. The Annex shall identify only uses based on information transmitted and aggregated by a Trustee.
- j) Performing a risk assessment according to the scientific principles as agreed by the Technical Committee with the intention to demonstrate safe manufacturing and use of the Substance(s) in the defined application areas and develop guidance on safe use.
- k) Initiating testing where a higher tier risk assessment is needed to demonstrate a safe use in a specific application or specific conditions of use in an application.
- 3. Submission of the Core Data for the purpose of Registration to the Agency by the Lead Company on behalf of Regular Members and their Affiliates at least six months before the deadline for registration applicable to the Regular Member(s) within the highest tonnage band. In order to have the Core Data submitted on behalf of their Affiliates, the Regular Member concerned notifies the names and addresses of its Affiliates to the Steering Committee in writing at least thirty (30) days before submission of the Core Data, so the Lead Company is able to include the names and addresses in the registration dossier as required in Annex VI Section 1.2 of the REACH Regulation.
- 4. Continuation of the cooperation contemplated herein during the dossier evaluation according to Title VI of the REACH Regulation, including supervising the performance of the testing proposals as authorized by the Agency.
- 5. Addressing technical and legal issues in relation to the Purpose.
- 6. Exercising the rights to the Studies in accordance with Articles IV and V of this Agreement.

Article III. Membership

1. General

Membership shall be open to any applicant who fulfils the membership criteria and is committed to pay the financial contribution as laid down in this Article.

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2. Regular Membership

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

Only Representatives of Manufacturers not established within the Territory must reveal the identity of the non Territory manufacturer they are representing. For the purpose of this Agreement an Only Representative shall count for each non Territory manufacturer he is representing as a separate Member.

3. Admission of new Regular Members

- 1. Any application for Regular Membership shall be in writing and shall be sent to the Secretariat. The admission of a new Member shall be subject to the majority vote of the Steering Committee, it being understood that such consent shall not be unreasonably withheld or delayed. The admission shall not be denied if the applicant fulfils the Regular Membership criteria specified above and has committed to pay the financial contribution referred to below.
- 2. Each new Regular Member shall financially compensate the existing Members for the expenses incurred as well as the accumulated experience and developed knowledge by the existing Members. This compensation shall consist of the following elements:
- a) a pro-rated refund determined pursuant to Article X and Annex 9 of this Agreement for the Studies made available or generated jointly under this Agreement by the Members. Unless agreed otherwise, the new Regular Member shall refund a share of costs only for the Studies he is required to submit within his tonnage band, and
- b) a non-discriminatory surcharge determined by the Steering Committee based on objective criteria to compensate for administrative and, if appropriate, other expenses incurred by the Members up to the date of admission.
- 3. Any decision refusing membership shall clearly state the reasons why the membership is not granted. The applicant whose application was turned down has the right to submit its observations in writing to the Steering Committee, which shall review the observations and reply in writing within 3 months. The non admitted applicant may be offered by the Members of the Consortium the access to the Studies or Core data necessary to fulfil his registration requirements in accordance with Article V 5 of this Agreement or may be included in the joint submission of data for the Substance subject to the financial compensation in accordance with Annex 9.
- 4. A new Regular Member shall fully adhere to the terms and conditions set out in this Agreement. Upon signature of a Declaration of Accession attached as Annex 11 and as of payment of the affiliation fee, the new Member shall have the same rights and obligations as any existing Regular Member.

4. Associate Members

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- 1. Associate membership shall be open to any Downstream Users as defined in the REACH Regulation/ Industry associations/ Manufacturers not established within the Territory/ third parties holding information on the Substance (Data Holders), who are not subject to the registration requirements but have an interest in contributing to the achievement of the Purpose as defined in Article II.
- 2. Any Associate Member established outside the Territory may appoint a natural or legal person established in the Community as his representative in the Consortium.

5. Admission of new Associate Members

- 1. Any application for Associate Membership shall be in writing and shall be sent to the Secretariat. The admission of a new Member shall be subject to the majority vote of the Steering Committee, it being understood that such consent shall not be unreasonably withheld or delayed. The admission shall not be denied if the applicant fulfils the conditions specified above and has committed to pay the financial contribution referred to below.
- 2. Associate Member shall contribute to the administrative costs of the Consortium in a fair and transparent proportion determined by the Steering Committee.

6. Transfer of membership

- 1. A Regular Member shall be entitled to transfer its membership including all its rights and obligations under this Agreement to a third party subject to prior majority vote of the Steering Committee which shall not be unreasonably withheld or delayed, provided that that third party meets the membership criteria as laid down in Article III 2 of this Agreement. The Steering Committee shall decide within two months of notification; the absence of a decision meaning acceptance. It is understood that after the transfer of its membership the former Regular Member shall cease to have any rights arising from this Agreement. The transfer by a Regular Member of individual rights or obligations arising from his membership to a third party shall not be permitted.
- 2. The consent of the Steering Committee shall not be required in case of a transfer of Membership to an Affiliate or restructuring within a group of companies or in case of a merger, a division or sale of a branch of activities, to the extent that the merged entity or branch of activities was a Member of the Consortium.
- 3. The Member shall notify the Secretariat by registered letter at least 60 days before the transfer of membership.

7. Withdrawal

At any time, a Member can terminate its membership in the Consortium if circumstances making the continued membership in the Consortium disproportionate and unjustified have durably occurred. Such termination is subject to a three months prior written notice to the Secretariat. A Member may terminate this Agreement without cause upon written notice with a notice period of one year. In any event, the effectiveness of termination is subject to the terminating Member having fulfilled all of its financial obligations up to the date of termination.

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8. Exclusion

- 1. Any Member may be excluded from the Consortium, without prejudice to any other rights the Members may have against the defaulting Member, if it does not meet or continue to meet the membership criteria as laid down in Article III or in the event of a serious material breach of this Agreement that has not been repaired within 30 calendar days after formal notice has been sent by the Secretariat by registered mail to the Member concerned.
- 2. The defaulting Member shall be excluded by a decision of the Steering Committee with a majority of two thirds of the votes of the Members present or represented and on the basis of an objective and documented justification in compliance with Articles 81 and 82 of the EC Treaty. The defaulting Member shall have the right to present its defence to the Steering Committee before a final decision is taken. The decision of the Steering Committee shall be immediately notified to the Member by registered mail and the exclusion shall be effective upon the date of receipt of this letter.

9. Consequences of withdrawal and exclusion

- 1. Subject to paragraph 4 hereunder, withdrawal or exclusion of a Member is without prejudice to the rights and obligations of the Member that is withdrawing or is excluded (hereafter exiting Member) which have accrued up to the date of effective withdrawal or exclusion provided that the exiting Member meets his payment obligations, including all payments related to Studies agreed on, which have arisen during the time of his membership. In particular, the exiting Member shall remain liable for the activities undertaken under this Agreement for the period of his membership. The exiting Member shall have no further rights to any results arising out of this Agreement in respect of which he has not fulfilled his financial contribution or to any compensation from new Members who have subsequently joined the Consortium for Studies developed before cessation of his membership.
- 2. The other Members shall continue to be entitled to make use of the Information made available by the exiting Member on the conditions specified in this Agreement and provided that that Member has been duly compensated under the conditions defined in this Agreement. Any recoverable damages suffered by the remaining Members as a result of the defaulting Member's actions shall be off set against any compensation payable to the exiting Member.
- 3. The exiting Member shall have no claims for reimbursement of his financial contribution to the Consortium for the period prior to his effective withdrawing or exclusion.
- 4. With regard to on-going Studies to which the exiting Member committed, the exiting Member shall financially contribute to all further costs of the Study as well as to all administrative costs incurred until the Study is completed and thereby acquire a joint ownership of the Study.
- 5. With regard to the Studies, the obligations specified in Article IV of this Agreement shall continue to apply to the exiting Member for a period of twelve (12) years following the initial submission to the Agency by a Member. With regard to all other Information, the obligations specified in Article IV shall continue to apply for a period of 10 years after withdrawal or exclusion.

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Article IV. Confidentiality

- 1. The Members shall:
 - a) Treat all Information as confidential and not to disclose it to third parties, unless legal disclosure requirements apply. Each Member shall advise immediately the other Members in writing of any disclosure or misuse by any Member or a third party of Information, as well as of any request by competent authorities relating to the disclosure of that Information.

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

- b) Use the Information only for the Purpose or otherwise as permitted under or in accordance with this Agreement.
- c) Disseminate the Information to their employees, Affiliates or external experts and/or consultants only on a need to know basis and only to the extent absolutely necessary for the Purpose or otherwise as permitted under or in accordance with this Agreement. Each Member shall have in place policies and procedures to ensure the confidentiality of Information, and require that its external experts and/or consultants also have such policies and procedures in place to ensure their compliance with these confidentiality obligations.
- 2. The obligations specified in Article IV.1 above shall not apply to Information for which the receiving Member can reasonably demonstrate that such Information
 - a) was known to the receiving Member on a non-confidential basis prior to its disclosure pursuant to this Agreement;
 - b) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this Agreement on the part of the receiving Member;
 - c) becomes known to the receiving Member through disclosure by sources other than the disclosing Member, having a right to disclose such Information,
 - d) was independently developed by the receiving Member without access to the disclosing Member's Information, as evidenced by documentary records,
 - e) becomes subject to disclosure to governmental agency/ authorities with lawful authority to seek such Information.

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

3. Affiliates and external experts and/or consultants (if bound by a confidentiality agreement) of any Regular Member are not regarded as third parties for the purpose of this Article. Each Member assumes full responsibility for compliance by its employees, Affiliates or external

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experts and/or consultants with the requirements of this Agreement in the respect of any Information received by those employees, Affiliates or external experts from that Member, unless the Affiliate in question is also a party to this Agreement.

4. In the event of non-compliance with the obligations set out in this Article the Members whose Information is disclosed shall have the remedies available under the applicable law notwithstanding the stipulations contained in this Agreement, notably Article XII.

Article V. Ownership and use of Information

- 1. Within 4 weeks of the entry into effect of this Agreement, or within 4 weeks after joining the Consortium subsequently to the entry into effect of this Agreement, all Regular or Associate Members shall make available to the Secretariat a list of their Existing Studies and hard or electronic copy of these Studies. The Secretariat shall make a list of these Studies and shall make the necessary arrangements for the review of these studies by the Technical Committee.
- 2. Any intellectual property or ownership rights to any existing Information independently developed by a Member or any third party and made available to the Members in accordance with this Agreement shall remain unaffected by this Agreement. The other Members shall have for an indefinite period of time the non-transferable right to use the Information for registration pursuant to the REACH Regulation, including the right to refer to the full Study report, provided that they share in its cost in accordance with the cost allocation method agreed upon under Article X and Annex 9 of this Agreement.

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

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

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

- 3. Any Information generated or developed jointly by the Members in accordance with this Agreement shall be owned jointly by the Members provided that the individual Members have contributed to the costs thereof in accordance with the cost allocation method set out in Article X and Annex 9 of this Agreement. Each of the joint owners shall obtain a copy of the full Study report. The Information referred to in the first sentence may be used by the Members who have contributed to the costs thereof for complying with the requirements pursuant to the REACH Regulation and shall not for the period of 12 years from the date of initial submission to the Agency be sold, licensed or otherwise made available to third parties by any Member without prior written approval of a majority of 2/3 of remaining owners who have financially contributed to the costs thereof unless otherwise agreed by the Members.
- 4. Affiliates of a Regular Member shall have a royalty-free right on Information referred to in paragraph 2 and 3 provided that the relevant Regular Member to which they are affiliated has contributed to the costs thereof in accordance with the cost allocation method set out in Article X and Annex 9 of this Agreement.

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

Subject to provisions of paragraph 3, second sentence the Steering Committee shall take a decision whether or not to grant such rights and determine the amount of compensation payable in accordance with Article X and Annex 9 by simple majority of the Members present or represented] without undue delay. The Secretariat shall provide the requesting party the proof of cost within one week of the decision of the Steering Committee. The Secretariat shall issue a Letter of Access (Annex 10) within two weeks of receipt of payment of the compensation.

The terms and conditions of access will be set out in each case specifying the exact scope in accordance with the Letter of Access attached in Annex 10 to this Agreement.

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

Article VI. Organisation

1. Legal personality

This Agreement or the cooperation contemplated herein shall not constitute or be deemed to constitute a legal entity or partnership between the Members nor make a Member the agent or representative of another Member unless expressly stated otherwise. In its external relations, the Consortium will not act under its own name but as community of all its Members. The Members hold the rights and obligations of the Consortium jointly.

2. Bodies of the Consortium

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

In addition, in order to fulfill the Purpose, the Steering Committee shall be empowered to set up any necessary committees, groups and task forces, the composition, mandate, duration and rules of which shall be determined by the Steering Committee in accordance with the rules specified hereunder.

3. Steering Committee

- 1. The Regular Members shall meet in the Steering Committee in person, by telephone or video conference in order to take decisions on the overall organisation and activities of the Consortium.
- 2. The Steering Committee shall consist of one representative per Regular Member (the "representatives"). Substitutes for representatives may also be appointed. Replacements of representatives, proxies or substitutes shall be possible and shall be communicated in writing

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or electronically to the Secretariat who shall promptly advise the other Steering Committee members of the change. The representatives may be accompanied by external experts/consultants in meetings of the Steering Committee. The Chairman of the Steering Committee shall be the representative of the Lead Company.

Each Regular Member is entitled to one vote in the Steering Committee. Decisions of the Steering Committee shall be taken by a simple majority of the representatives present or represented, unless otherwise provided for in this Agreement. Decisions can be taken by the Steering Committee if at least half of its Members are present or represented. In the event that not at least half of its Members are present or represented, another Steering Committee meeting shall be held the same day with the same agenda. At this second meeting decisions can be taken by the Steering Committee without at least half of its Members being present or represented, on the basis of a majority vote of two thirds (2/3) of Members present or represented.

Decisions concerning the following aspects shall always be adopted on the basis of a 2/3 majority vote of the representatives present or represented unless otherwise set forth in this Agreement:

- Approval of the Core Data to be submitted to the Agency;
- Exclusion of a Member;
- Appointment of the Trustee if necessary for compliance with competition law:
- Decisions on the admission to the Consortium of a new Regular or Associate Member and determination of the financial contribution of such new Member

Upon unanimous decision, the Steering Committee is entitled to modify Annexes 1, 2, 6-11 to this Agreement. Annexes 3, 4 and 5 shall be adopted according to any changes notified to the Chairman of the Steering Committee by the Member concerned.

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

Associate Members are allowed to participate in the meetings of the Steering Committee without any voting rights.

- 3. The Steering Committee shall have all powers and make all decisions necessary to ensure that the Purpose is achieved. The tasks of the Steering Committee may include inter alia the following:
 - Appointment of a Secretariat and Task Forces where appropriate;
 - Decisions on funding, scope and matters of policy;
 - Appointment and directing the Technical Committee;
 - Decisions to carry out and on proposals for testing;

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- Decisions on working and finance plan and management of financial resources of the Consortium, including budgeting, funding collection and accountancy;
- Decisions on coordination of and guidance for data collection concerning the Substance;
- Appointment of external consultants to perform technical and scientific tasks;
- Approval of the Core Data to be submitted jointly to the Agency; as well as determination of the Information which shall be subject to a request for confidentiality according to Article 119 of the REACH Regulation.
- Coordination and supervision of activities of the Secretariat and the Lead Company;
- Arbitration in cases of disagreement or disparities within the Technical Committee;
- Decisions on admission to the Consortium of new Regular or Associate Member and determination of the financial contribution of such new Member;
- Decision on the exclusion of a Member:
- Appointment of a Trustee.
- 4. Meetings of the Steering Committee shall be convened every 6 months or more to review, on the basis of the technical and financial progress reports of the Secretariat and the progress relative to the work schedule and the budget.

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

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

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

- 5. Decisions by the Steering Committee may exceptionally be made in writing on the initiative of the Secretariat/ Technical Committee/ Task Force/ Majority of the Regular Members when a decision cannot be deferred until the following meeting of the Steering Committee but is not sufficiently important to justify an extraordinary meeting of the Steering Committee. Except in urgent cases, replies must be given to the Secretariat, within 14 days of the date the written consultation was sent. The absence of the reply within this period shall mean acceptance. Any decision taken by written consultation shall be submitted for confirmation at the subsequent Steering Committee meeting.
- 6. Extraordinary meetings of the Steering Committee will be convened by the Secretariat at the request of the majority of the Regular Members wherever the agreed deadlines or estimated budget are overrun or when other extraordinary circumstances occur. The Members of the Consortium shall have the opportunity on that occasion to consider their participation in the Consortium based on documented reasons.

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4. Technical Committee

- 1. The Technical Committee shall consist of at least three representatives nominated by the Regular Members and shall take decisions by simple majority vote of the representatives present or represented at the meeting. The Members of the Technical Committee shall jointly elect a Chairman who shall organise meetings and report to the Steering Committee.
- 2. The tasks of the Technical Committee shall be directed by the Steering Committee and may include, inter alia, the following:
 - Steering the technical work;
 - Developing work plans;
 - Delegating and directing sub-tasks;
 - Selecting external consultants, if and when required and subject to approval of the Steering Committee;
 - Proposing test plans to the Steering Committee;
 - Executing approved test plans;
 - Overseeing the progress reporting deviations to the Steering Committee;
 - Collecting and evaluating the Substance related Information to be shared;
 - Giving input/ guidance to the Secretariat on the value of knowledge developed;
 - Estimating financial resources required to comply with REACH requirements;
 - Preparing the Core Data for registration, including the determination of data gaps, waivers and surrogate data as well as completion of data gaps in compliance with the legal requirements laid down by the REACH Regulation regarding data sharing;
 - Preparing CSR, if appropriate; in particular collecting and evaluating the uses and exposure scenarios;
 - Collecting classification and labelling data from all Members and preparing harmonised classification and labelling in accordance with the GHS;
 - Supervising performance of the testing
- 3. The meeting of the Technical Committee shall be convened by the Chairman of the Technical Committee upon necessity to review the progress relative to the work schedule and the budget.

5. Task Forces

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- 1. In order to pursue the Purpose of the Consortium, the Steering Committee may establish Task Forces, whenever necessary, including for the development of Core Data required for each specific Substance covered by the Consortium, others, e.g. prepare harmonised classification and labelling, prepare proposals for further testing and data gathering, advise on the selection of external laboratories to conduct the testing programme, supervise performance of the testing programme, advise on potential new Members to join the Task Force.
- 2. The Steering Committee shall specify the scope, composition and budget of the Task Forces in writing.
- 3. Each Task Force shall be chaired by one of its members appointed for such task by the Steering Committee. The Task Forces may rely on the Secretariat to assist in the work which is entrusted to them, provided that the costs involved fall within the budget of the Task Force as approved by the Steering Committee.

6. The Secretariat

- 1. The Secretariat shall be ensured by ECVM 2010, an international non-profit association governed by the Belgian statute of 25 October 1919, as amended by the laws of 6 December 1954 and 3 June 2000, and replaced by the law of 27 June 1921, as amended by the law of 2 May 2002. The registered office of ECVM 2010 is currently located at Avenue E. Van Nieuwenhuyse 4, Brussels, Belgium.
- 2. The Secretariat shall be responsible for daily management of the Members of the Consortium. The Secretariat is appointed by the Steering Committee to conduct all normal business of the Consortium, to the exclusion of strategic activities exclusively attributed to the Steering Committee, and shall in this regard deal particularly with the following:
 - Proposing the working and finance plan;
 - Organising and convening meetings, distribution of agenda and making minutes, archiving, and distribution of information;
 - Keeping archives for a minimum period of twelve years and notifying the Members before the archive will be disposed of;
 - Ensuring compliance with competition laws;
 - Handling of Information (production volumes, capacities, markets etc.)
 - Supervising the external consultants and experts;
 - Following up the legislative and technical development of the REACH Regulation and informing the Technical Committee, Task Forces and Steering Committee about relevant new developments;
 - Following up on progress in the technical activities of the Consortium and reporting on the technical and financial aspects to the bodies of the Consortium;
 - Providing technical and administrative support for the Technical Committee, Task Forces;



- Coordinating and providing guidance for data collection concerning the Substance;
- Performing sub-tasks as agreed by the Technical Committee;
- Processing of purchase orders/contracts for studies/work in line with the approved test plans;
- Handling financial matters and being responsible for the accounting, including budgeting, invoicing, keeping track of costs/value of information;
- Keeping an updated list of Regular Members, Associate Members and their representatives;
- Preparing the budget and the annual accounts of the Consortium.
- Communicating to organisations, associations and potential new Members.
- 3. The Secretariat may, upon prior approval of the Steering Committee, sign all contracts with external consultants, experts, including the laboratories, to perform technical and scientific tasks, in its own name but on account of the Members who are required to submit the Study according to their tonnage band. Only the Members who are required to submit the Study according to their tonnage band shall be listed as parties to the agreement and shall be liable for the expenses incurred.
- 4. The Secretariat is accountable to the Steering Committee.

7. Representation and activities in relation to third parties

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

8. Working language

The working language of the Consortium shall be English.

Article VII. Lead Company

- 1. The Lead Company shall be Ineos Vinyls UK ltd. The decision to either terminate or change the Lead Company shall require a majority of two thirds (2/3) of the votes of the Members present or represented at the Steering Committee notwithstanding the right of the Lead Company to resign upon written notice to the Steering Committee with a notice period of six months. Such resignation, however, is only admissible if not endangering the Purpose of the Consortium.
- 2. The Lead Company, with the assistance of the Secretariat and other bodies of the Consortium, shall prepare and submit to the Agency, in the agreement of and on behalf of the Members of Consortium Members and their Affiliates and in the format specified by the

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Agency the Core Data, and the Chemical safety Report/ Guidance on safe use for the purpose of registering the substance at least six months before the deadline for registration applicable to the Regular Member(s) within the highest tonnage band.

The Lead Company shall pay its fee as invoiced by the Agency after submission of the Core Data without undue delay. The Lead Company shall further communicate the registration number as obtained by the Agency after payment of the fee to the other Members of the Consortium without undue delay.

- 3. The Lead Company undertakes to inform the Members regularly on the developments of the registration dossier. In addition, the Lead Company shall forward in writing to the Secretariat, within 5 calendar days, any communication received either from the Agency or a Member State or any other authority regarding the joint submission.
- 4. The Lead Company shall if required and approved by the majority of Steering Committee Members, appeal any adverse decisions of the Agency or the Member States relating to the jointly submitted registration dossier.

Article VIII. Individual obligations

- 1. The Members undertake to make all reasonable efforts to ensure the appropriate and timely achievement of the Purpose. In particular, each Member shall:
 - Observe and comply with the provisions of this Agreement;
 - Timely provide any available Information, including Existing Studies, on the Substance(s), to the extent necessary for the Purpose;
 - Allocate human and financial resources to the Steering and Technical Committees and other Consortium bodies;
 - Participate in the work of the Steering and Technical Committees;
 - Fund the agreed work plans and other agreed actions;
 - Inform the Chairman of the Steering Committee/ Secretariat of any significant change with respect to legal status or organization;
 - Keep the Chairman of the Steering Committee/ Secretariat continuously informed of a responsible contact person for the duration of this Agreement which hence leads to an update of Annex 3.
- 2. Each Member is responsible for observing its rights and obligations pursuant to the REACH Regulation, in as much as these rights and obligations are not observed by the Members of the Consortium in accordance with this Agreement. This applies, in particular, to information that is to be submitted to the Agency within the registration dossier in due time by each Member as well as any information communicated by the Members to customers, suppliers and other third parties, such as Safety Data Sheets.

Article IX. Competition law compliance

1. The Members acknowledge that any activities carried out under this Agreement have to be

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carried out in full compliance with EU competition law, in particular but not limited to Articles 81 and 82 EC Treaty as well as any applicable national laws. The Members explicitly agree to observe Cefic REACH competition law compliance guidance attached as <u>Annex 7</u> to this Agreement.

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

Article X. Definition of costs and cost allocation

1. Valuation of Existing Studies

The value of Existing Studies made available by the Member to other Members shall be determined by the Steering Committee on the basis of an evaluation of the scientific quality, adequacy and relevance in relation to the achievement of the Purpose, in accordance with rules laid down in Annex 8.

2. Cost sharing principles

- 1. The following costs shall be shared between the Members:
 - a) Administrative expenses reasonably incurred by the management of the Consortium, including secretarial services, management of confidential data or external experts which have been approved by the Steering Committee. Any such costs shall not include any out-of-pocket expenses incurred by the Members unless approved in advance by the Steering Committee;
 - b) Acquisition of rights to Existing Studies valued under conditions specified above provided that the Member needs to submit the Study according to its tonnage band;
 - c) Costs for new Studies to be jointly developed according to Annexes VI to VIII of the REACH Regulation, provided that the Member needs to submit the Study according to its tonnage band and provided that no study will be initiated without a budget approved by the Steering Committee;
 - d) Costs for New Studies to be jointly developed pursuant to the evaluation of testing proposals by the Agency, provided that the Member needs to submit the Study according to its tonnage band and provided that no study will be initiated without a budget approved by the Steering Committee.
- 2. Other costs incurred by the Members in the context of this Agreement shall not be compensated unless agreed by the Steering Committee.
- 3. Expenses referred to under 2. 1a) shall be allocated to all Members equally.
- 4. The expenses referred to under 2.1 b), c) and d) shall be allocated to Regular Members in accordance with the cost allocation principles under Annex 9.
- 5. All payments due hereunder shall be net payments, i.e. free of any bank or transfer charges or similar charges and without deduction of any taxes, levies or other dues payable If payer is required to withhold any tax or to make any other deduction from any such payments, then the said payments shall be increased to the extent necessary to ensure that,

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after making of the required deduction or withholding, payee receives and retains (free from any liability in respect of any such deduction or withholding) a net sum equal to the sum which it would have received and so retained had no such deduction or withholding been made or required to be made (gross-up amount). If upon application of the beneficiary any Withholding Tax can be reduced, or refunded, or an exemption from Withholding Tax is granted, payer shall file on behalf of payee for such reduction, refund or exemption. Payee shall render any assistance to payer to obtain such Withholding Tax reduction, refund or exemption. Payer shall be entitled to any refund of Withholding Taxes.

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

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Article XI. Administration & Reporting of costs

- 1. The Secretariat shall administer and keep records of all expenses incurred including allocation and cost-splitting as well as credits and present a costs overview to the Steering Committee on a monthly / quarterly basis.
- 2. The Secretariat shall administer invoices and the compensation payable to Members or from the Members based on their respective verification. The Secretariat shall keep records of the full value of the data obtained/generated.
- 3. Until disbursed pursuant to this Agreement, all the funds of the Consortium shall be maintained by the Secretariat in guaranteed accounts approved by the Steering Committee, which preserve the principal while providing a reasonable rate of return. The Secretariat shall be responsible for making any disbursement relevant for the activities of the Consortium, subject to prior approval of the expense by the Steering Committee. All earnings shall be credited by the Secretariat to the account of the Consortium.
- 4. The Steering Committee shall base decisions on contributions and payments on the principle that provided Information shall be assessed and incurred costs shall be split in a fair, transparent and non discriminatory way.
- 5. The financial year shall run from 1 January to 31 December of each calendar year.
- 6. Each year the Secretariat shall submit to the Steering Committee for approval the accounts of the past financial year and the budget for the following year.

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

- 7. When for appropriate reasons the budget agreed by the Steering Committee has to be increased in the course of the financial year, such budget increase shall be subject to prior approval by the Steering Committee at its next meeting.
- 8. A favourable vote of at least two-thirds (2/3) of the Members present or represented shall be required for all decisions concerning financial matters.

Article XII. Limitation of liability

- 1. The Members shall undertake their Purpose related activities specified hereunder in good faith and according to all applicable laws and regulations, and they shall use all reasonable endeavours to ensure the best possible results based on the evidence, methods and techniques known at the time.
- 2. Subject to paragraph 3 each Member shall assume liability for the correctness of the Study which he makes available to other Members and that he is authorised to do so. No warranty for acceptance of the Study by the Agency at the dossier evaluation (according to Title VI REACH) is given.

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- 3. The Member who submits a Study to other Members will indemnify them in respect of any claims for unauthorised use or breach of the intellectual property rights of any third party relating to that Study.
- 4. None of the Members, including the Lead Company, shall be held liable for any direct, indirect or consequential loss or damage incurred by another Member in connection with the activities contemplated in this Agreement, unless caused by gross negligence or wilful misconduct.
- 5. Each Member shall be liable vis-à-vis third parties within the scope of its responsibility. The other Members of the Consortium shall support to the extent possible and reasonable, any Member against whom a liability claim has been made by a third party in its defence against such claim.
- 6. The Secretariat acts entirely in its capacity as representative of the Members and bears no individual responsibility or liability for its actions taken in this capacity, with the exception of gross negligence or wilful misconduct.

Article XIII. Duration, termination and amendments to the Agreement

1. This Agreement shall enter into force as from the date of the first signature. The Consortium shall be formed for the duration necessary to achieve the Purpose.

Upon achievement of the Purpose the Consortium can be terminated by a majority decision of the Steering Committee.

Prior to that date the Consortium may only be dissolved by a 80 % majority vote decision of the Regular Members.

- 2. This Article and the provisions relating to the protection of confidentiality (Article IV), ownership and use of Information (Article V), dispute resolution and applicable law (Article XIV) and limitation of the liability (Article XII) shall survive the termination of this Agreement. With regard to the Studies, the obligations specified in Article IV of this Agreement shall survive for a period of twelve (12) years following the initial submission to the Agency by a Member. With regard to all other Information, the obligations specified in Article IV shall survive for a period of 10 years after dissolution.
- 3. Upon termination of the Consortium and after payment of all obligations of any kind to or by the Members, the Steering Committee shall decide on the method of liquidation and the distribution of the Consortium's fund. Before dissolution or termination of the Consortium all remaining joint and severable rights and obligations of the Members resulting from this Agreement shall be settled.
- 4. Amendments to this Agreement must be in written form to be effective.

Article XIV. Dispute resolution and applicable law

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

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If differences remain, each Member shall have the right to submit its observations in writing to the Steering Committee, which shall have to reply in writing stating the reasons for the decision within 3 months.

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

- 2. This Agreement shall be governed by the laws of Belgium.
- 3. If at any time any provision of this Agreement is or becomes invalid or illegal in any respect, this shall have no effect on the validity of the remaining contractual provisions. The invalid provisions are to be replaced, backdated to the time of their becoming ineffective, by provisions which come closest to achieving their objective.
- 4. This Agreement constitutes the entire agreement and supersedes all other prior agreements and understandings, both written and oral, between the Members with respect to the subject matter hereof.

He for

pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

This Agreement has been made in 15 copies, each Member as well as ECVM 2010 receiving one copy.

The only modification in this version, compared to the version dated 14/01/2009 which was signed by all members, is the addition of the following clause in the second paragraph of Chapter VI, Section 3.2:

"In the event that not at least half of its Members are present or represented, another Steering Committee meeting shall be held the same day with the same agenda. At this second meeting decisions can be taken by the Steering Committee without at least half of its Members being present or represented, on the basis of a majority vote of two thirds (2/3) of Members present or represented."

The undersigned herewith declares agreeing with this modification

For and on behalf of
ANWIL SA
Signature:
Name: Krzysztof Kaminski
Member of the Executive Board
Date:
Signature:
Name: Jan Zielinski
Director of the PVC Complex
Date:

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pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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The undersigned herewith declares agreeing with this modification

For and on behalf of Aragonesas Industrias y Energia, S.A.

Signature:	
Name: José Miguel Falcón Sanz	
Director of Plastics Division	
Date:	



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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For and on be	ehalf of	
Arkema France S.A.		
Signature:		
Name: Deni	s TUAL	
President Chlo	orine & Caustic Soda Business Unit	
Date:		



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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The undersigned herewith declares agreeing with this modification

For and on behalf of	
BorsodChem Zrt	
Signature:	
Name: László Szentmiklóssy	
EHS Director	
Date:	
Signature:	
Name: Laszlo Nagy	
VCM factory manager	
Date:	

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For and on behalf of		
Cires S.A.		
Signatu	·e·	
Oigilatai	o	-
Name:	Luis Montelobo	
Vice-Pre	esident	
Date:		



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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For and on behalf of		
Dow Europe GmbH		
Signature:		
Name: Ralf Brinkmann		
Commercial Vice President Basic & Performance Chemicals		
Date:		



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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For and on behalf of		
INEOS Vinyls (UK) Ltd		
Signature:		
Name: Ashley Reed		
Commercial Director		
Date:		



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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For and on behalf of	
LVM N.V.	
Signature:	
Name: Pol Deturck	
Director Business Group Chemicals	
Date:	



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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For and on behalf of		
Novacke chemicke zavody, a.s.		
Signatur	e:	
Name:	MARIÁN KARKUŠ	
General	Director	
Date:		



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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For and on behalf of	
Oltchim	
Signature:	
Name: Constantin Roibu	
General Manager	
Date:	



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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For and on behalf of	
Shin-Etsu PVC B.V.	
Signature:	
Name:	Toshiaki Maruyama
Technical Director	
Date:	



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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The undersigned herewith declares agreeing with this modification

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For and on behalf of				
SolVin GmbH & Co.				
Signature:				
Name: Pierre Tucoulat				
CEO				
CLO				
Date:				



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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The undersigned herewith declares agreeing with this modification

Signatur	e:
Name:	Arno Knebelkamp
Managin	g Director (CEO)

For and on behalf of

VESTOLIT GmbH & Co. KG

the fund

Date:

pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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The undersigned herewith declares agreeing with this modification

Vinnolit GmbH & Co. KG
Signature:
Name: Josef Ertl
Managing Director (CEO)
Date:

For and on behalf of



pursuant to requirements of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

The only modification in this version, compared to the version dated 14/01/2009 which was signed by all members, is the addition of the following clause in the second paragraph of Chapter VI, Section 3.2:

"In the event that not at least half of its Members are present or represented, another Steering Committee meeting shall be held the same day with the same agenda. At this second meeting decisions can be taken by the Steering Committee without at least half of its Members being present or represented, on the basis of a majority vote of two thirds (2/3) of Members present or represented."

The undersigned herewith declares agreeing with this modification

This Agreement has been made in 15 copies, each Member as well as ECVM 2010 receiving one copy.

This Agreement is endorsed by ECVM 2010 as far as its involvement is concerned and ECVM 2010 hereby confirms that it will fulfil the role as the Secretariat.

For and on behalf of the Secretariat

Signature:

Name: J.P. De Grève

Executive Director

Date: 30 April 2009

List of Annexes:

- 1. Substance identification
- 2. Identified uses to be included in Chemical Safety Report
- 3. Names, addresses, representatives and tonnage bands of Consortium Members
- 4. Affiliated companies of Regular Members
- 5. List of Existing Studies provided by Consortium Members
- 6. Confidentiality Agreements (two-way and one-way)
- 7. Guidance on competition compliance
- 8. Value of studies valuation rules
- 9. Cost allocation
- 10. Letter of Access
- 11. Declaration of Accession

Annex 1: Substance identification

The Substance(s) covered by this Agreement is Vinyl Chloride (EINECS name chloroethene, CAS number 75-01-4, EINECS number 200-831-0)



Annex 2: Identified uses to be included in the Chemical Safety Assessment

Use as a monomer for polymerisation into Polyvinyl Chloride homopolymer or copolymer.



Annex 3: Names, addresses, representatives and tonnage bands of Consortium Members

ANWIL SA UI. Torunska 222, 87-805 Wloclawek, Poland

Representatives:

Andrzej Blasiak <u>blasiaka@anwil.pl</u>

Tonnage Bands: more than 1000t/a for each legal entity

Arkema France S.A. 420 rue d' Estienne d' Orves, 92700 Colombes, France

Representatives:

Patrice Guesnet
Celine Poujoulas
Isabelle Gaou
JeanClaude Besson
François Vanney:

patrice.guesnet@arkema.com
celine.poujoulas@arkema.com
isabelle.gaou@arkema.com
jean-claude.besson@arkema.com
francois.vanney@arkema.com

Tonnage Bands: more than 1000 t/a for each legal entity

Aragonesas Industrias y Energia S.A. Avda. Diagonal nº 595, 2nd floor,

Barcelona (Spain). Postal Code: 08014

Representative:

Juan Alsina Martí jalsina@ercros.es

Tonnage Bands: more than 1000t/a for each legal entity

BorsodChem Zrt. 3700 Kazincbarcika, Bolyai tér 1, Hungary

Representative:

László Szentmiklóssy laszlo.szentmiklossy@borsodchem.hu

Tonnage Bands: more than 1000 t/a for each legal entity

Cires S.A

Representative:

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REACH Consortium Agreement for VCM, amended version, 23/03/2009

Rui Batista <u>rui.batista@cires.pt</u>

Tonnage Bands: more than 1000 t/a for each legal entity

Dow Europe GmbHBachtobestr. 3, 8810 Horgen, Switzerland

Representative:

Silke Tenbrock <u>STenbrock@DOW.com</u>

Jan Wilmer jwilmer@dow.com

Tonnage Bands: more than 1000 t/a for each legal entity

INEOS Vinyls (UK) Ltd O Box 9, South Parade, Runcorn,

Cheshire WA7 4JE, United Kingdom

Representatives:

Chris Howick chris.howick@ineosvinyls.com david.farrar@ineoschlor.com

Tonnage Bands: more than 1000t/a for each legal entity

LVM N.V. Troonstraat 130, BE-1050 Brussels, Belgium

Representative:

Jo Vandormael jo.vandormael@tessenderlo.com

Tonnage Bands: more than 1000 t/a for each legal entity

Novacke Chemické Zavody a.s ul. M.R. Stefanika, 1 97271 Novaky,

Slovak Republic

Representative:

Ludmila Korenova <u>ludmila.korenova@nchz.sk</u>

Tonnage Bands: more than 1000 t/a for each legal entity

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REACH Consortium Agreement for VCM, amended version, 23/03/2009

Oltchim S.A.

Uzinei Street 1, 240050 Ramnicu Valcea,

Valcea County, Romania

Representative:

Radu Olaru (Deputy General Manager) <u>olaru@oltchim.ro</u>

Tonnage Bands: more than 1000 t/a for each legal entity

Shin-Etsu PVC B.V. Noorderweg 68, 1221 AB Hilversum, The Netherlands

Representative:

Albert Keukens <u>albert.keukens@shinetsu.nl</u>

Tonnage Bands: more than 1000 t/a for each legal entity

SolVin GmbH & Co KG

Representatives:

Jean-Paul Bindelle <u>jean-paul.bindelle@solvay.com</u>
Bruno Schmit <u>bruno.schmit@solvay.com</u>

Tonnage Bands: more than 1000t/a for each legal entity

VESTOLIT GmbH & Co. KG, Paul-Baumann-Strasse 1, 45772 Marl, Germany

Representative:

Wilfried Schmitt: wilfried.schmitt@vestolit.de

Tonnage Bands : more than 1000t/a for each legal entity

Vinnolit GmbH & Co. KG Carl-Zeiss-Ring 25, 85737 Ismaning,

Germany

Representative:

Michael Suess michael.suess@vinnolit.com

Tonnage Bands: more than 1000t/a for each legal entity

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Annex 4: Affiliated companies of Regular Members

ANWIL SA

• SPOLANA a.s. Neratovice ul. Prace 657, 27 111 Neratovice, Czech Republic

ARKEMA FRANCE S.A.

- Vinylfos
 420 rue d' Estienne d' Orves, 92700 ,Colombes, FRANCE
- Arkema Quimica SA
 12 Avenida de Burgos, 7p, 28036, Madrid, SPAIN

DOW EUROPE GMBH

- Dow Olefinverbund GmbH, D-06258 Schkopau, Germany
- Dow Benelux B.V., HERBERT H. DOWWEG 5, PO BOX 48, 4530 AA Terneuzen,
 The Netherlands
- The Dow Chemical Company, 2030 Dow Center, Midland Michigan 48674, USA

INEOS VINYLS (UK) LTD.

Affiliates engaged in both the manufacture and use (for polymerisation operations) of vinyl chloride:

- INEOS Vinyls Deutschland GmbH, Inhausersieler Straße 25, 26388 Wilhelmshaven, Germany
- INEOS Vinyls Italia SpA, Via della Chimica 5, 30175 Venezia-Marghera, Italy
- INEOS Vinyls Italia SpA, Zona Industriale La Marinella, 07046 Porto Torres (SS), Italy
- INEOS Sverige AB, SE.44483 Stenungsund, Sweden
- INEOS Norge AS, Rafnes, N-3966 Stathelle, Norway

In addition, the following affiliates are engaged in the use only of vinyl chloride in polymerization operations:

 INEOS Vinyls UK Ltd, Sully Moors Road, Sully, Penarth (Barry), South Glamorgan CF64 5RP, United Kingdom

- INEOS Newton Aycliffe Limited, School Aycliffe Lane, Newton Aycliffe, Co. Durham DL5 6EA, United Kingdom
- INEOS Vinyls Deutschland GmbH, Werk Schkopau, Gebäude O 160, 06258
 Schkopau, Germany
- INEOS Vinyls Italia SpA, Via Baiona 107/111, 48100 Ravenna, Italy

LVM N.V.

- Société Artésienne de Vinyle SAS, Chemin des Soldats, BP 49 ; FR-62160 Bully-les-Mines France
- LVM Limburg BV, Koolwaterstofstraat, 1 NL-6161 RA Geleen, Netherlands

SHIN-ETSU PVC B.V.

- Shin-Etsu Chemical Co., Ltd. 6-1, Ohtemachi 2-chome, Chiyoda-ku, Tokyo 100-0004, Japan
- Shintech Inc. 3 Greenway Plaza, Suite 1150 Houston, Texas 77046, U.S.A.
- Shin-Etsu International Europe B.V. World Trade Center Amsterdam, Strawinskylaan B-827, 1077 XX Amsterdam, The Netherlands

SOLVIN GMBH & CO K.G.

Solvay-Electrolyse-France 25 RUE DE CLICHY S.A.S. (Paris) F-75009 PARIS

Solvin GmbH & Co. KG LUDWIGSTRASSE 12 (Hannover) D-47495 RHEINBERG
Affiliate of Solvin GmbH & Co. RUE DU PRINCE ALBERT, 44

KG (Hannover)

B-1050 BRUXELLES

Solvic SA (Ixelles)

Affiliate of Solvin GmbH & Co. AVENUE DE LA REPUBLIQUE Solvin France KG (Hannover) F-39500 TAVAUX S.A. (Paris)

Affiliate of Solvin GmbH & Co. RUE DE RANSBEEK, 310
KG (Hannover)
B-1120 BRUXELLES
Solvin SA (NOH)

Affiliate of Solvin GmbH & Co.MARIE CURIE, 1-3-5

KG (Hannover) E-08760 MARTORELL (BARCELONA) Vinilis S.A.(Martorell)

Affiliate of Solvin GmbH & Co. VIA G.MARCONI, 73 Vinyloop Ferrara KG (Hannover) I-44100 FERRARA FE S.p.A. (Ferrara

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VINNOLIT GMBH & CO K.G.

In addition to the producing sites of VINNOLIT GMBH & CO. KG, the following affiliates are engaged in the use only of Vinyl Chloride in polymerisation operations:

- VINNOLIT Hillhouse Ltd., Hillhouse International Business Park, Thornton-Cleveleys, Lancashire, FY5 4QD United Kingdom
- VINNOLIT Schkopau GmbH, Dow Value Park, An der B91, D 06258 Schkopau, Germany

Annex 5: List of Existing Studies provided by Consortium Members

Established on the basis of Annex 4 of RIP 3.4



Annex 6: Confidentiality Agreements



Annex 6 Secrecy one way.doc



Annex 6 Secrecy two way.doc

REACH - TEMPLATE

SECRECY AGREEMENT - One way

I NIS	Agreement	is by	and between	HAA XXXX	. AA ("XXXX"), naving	a piace	OT	business	aı
,	, and BB	YYYY	BB ("YYYY")	, having a p	lace of busine	ess at,			.	

XXXX represents that it owns valuable proprietary business and technical information relating to **[(this should be made more specific as needed for particular disclosures)** chemical elements and/or compounds and/or mixtures or solutions thereof] produced and/or imported and/or used in the Territory by XXXX or its affiliates ("INFORMATION").

YYYY desires to evaluate the INFORMATION for the purposes of enabling YYYY to perform health, safety, and environmental hazard assessments for its own tiered assessment screening and to enable health, safety, and environmental reporting, in compliance with applicable European Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") obligations and use the INFORMATION according to the purpose as defined in Article II of the Consortium Agreement (collectively, "PURPOSE").

For the above PURPOSE, XXXX is willing to provide YYYY access to INFORMATION under the terms and conditions set forth herein.

In consideration of the promises and conditions set forth herein, the parties agree as follows:

- 1. XXXX in its sole discretion shall disclose to YYYY certain INFORMATION for the PURPOSE stated above. INFORMATION provided by XXXX hereunder shall explicitly refer to the present Agreement. All INFORMATION shall be treated as confidential by YYYY, whether disclosed in writing, orally, or by observation; provided that in order to be treated as confidential, INFORMATION disclosed orally or by observation shall be identified by XXXX as confidential at the time of the disclosure or observation and reduced to a writing marked as confidential and provided to YYYY within thirty (30) days.
- 2. YYYY agrees to hold the INFORMATION provided by XXXX in confidence for a period of __ () [to be decided on case by case basis e.g. 15, 20, 25 years, depending on value/sensitivity of INFORMATION] years from the date of disclosure of the INFORMATION and to use the INFORMATION solely for the PURPOSE stated above. In no event during the period of confidentiality shall any disclosure of the INFORMATION be made to any third party, or be made in any patent application, or otherwise be made in any form without the prior written approval of XXXX.

- 3. YYYY shall have no confidentiality or use restriction regarding any information or material which:
 - (i) is or hereafter becomes, through no fault of YYYY, part of the public domain by publication or otherwise,
 - (ii) YYYY can show was received by it from a third party as a matter of right without any restriction on disclosure,
 - (iii) YYYY can prove was in its possession at the time of disclosure by XXXX and was not previously acquired directly or indirectly from XXXX, or
 - (iv) YYYY can show was developed by its employees who did not have access or recourse to INFORMATION.

Information disclosed under this Agreement shall not be deemed to be within the foregoing exceptions merely because such information is embraced by more general information in the public domain or in the possession of YYYY. Neither will a combination of features be deemed within the foregoing exceptions merely because individual features are in the public domain or in YYYY's possession, unless the combination itself is in the public domain or in YYYY's possession.

4. Notwithstanding the provisions of Paragraphs 2 and 3, in the event YYYY makes reasonable determination that it is required to disclose the INFORMATION pursuant to a governmental and/or judicial obligation or order, including an obligation to disclose to the European Chemical Agency under REACH, YYYY shall be permitted to do so provided that written notice of such requirement is promptly provided to XXXX to enable XXXX to seek from a court a protective order relating to the disclosure of said INFORMATION.

In any event, in the case where YYYY discloses INFORMATION under this Paragraph 4, it shall furnish only that portion of the INFORMATION that its legal counsel reasonably determines it is legally required to disclose.

- 5. YYYY may disclose the INFORMATION to those of its affiliates bound by the confidentiality and use restrictions as set out in this Agreement who are needed to work with YYYY in accordance with the PURPOSE ("YYYY AFFILIATES") and remains liable to XXXX for unauthorized disclosure or misuse of the INFORMATION by YYYY AFFILIATES. For the avoidance of doubt, the parties agree that XXXX may provide INFORMATION directly to YYYY AFFILIATES and that YYYY and its AFFILIATES may exchange INFORMATION directly with each other.
- 6. YYYY shall destroy or return to XXXX, upon XXXX's request, all documents received from XXXX containing INFORMATION, including documents in electronic format and the like, under this Agreement, provided that YYYY is under no obligation to destroy INFORMATION that is contained on electronic back-up data generated automatically in the data center. YYYY shall provide written confirmation of any such destruction. However, in any event, YYYY may retain in continuing confidence one secured copy of the documents for record keeping purposes only.
- 7. Nothing in this Agreement shall be construed as granting or obligating XXXX to grant to YYYY any license under any existing or future patent right, or other intellectual property right or confidential information of XXXX or its affiliates.
- 9. YYYY shall not furnish, deliver, or release the INFORMATION made available to it hereunder to any individual, entity, or destination, or for any use, except, *[optional: with the*



prior written consent of XXXXJ, in full accordance with all applicable laws, regulations, and requirements of the United Nations, the Territory or any member state thereof and the United States with respect to export control and trade sanctions. YYYY agrees and understands it shall be responsible for ongoing compliance with all such applicable laws, regulations, and requirements.

- 10. The provisions of paragraphs 2 to 9 shall survive termination of this Agreement
- 11. This Agreement shall be effective as of the date it is signed by both parties and shall terminate __ (_) [e.g. 5, 10, 15, 20 or 25] years thereafter [to be decided on a case by case basis depending on the sensivity of the INFORMATION], unless it is extended by mutual written consent, or earlier terminated by either party by giving at least thirty (30) days' prior written notice to the other party. In case of early termination, the provisions of this Agreement shall survive for the period set forth herein
- 12. This Agreement constitutes the entire agreement between the parties as to its subject matter. No representations have been made by either of the parties except as are specifically set forth herein. No rights or obligations other than those expressly recited herein are to be implied from this Agreement.

In Witness Whereof, the parties have caused this Agreement to be duly executed.

	AA XXXX AA	BB YYYY BB
Ву:	Signature	By: Signature
Title:	Print	Print Title:
Date:		Date:

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REACH - TEMPLATE

SECRECY AGREEMENT - Two Way

This Agreement is by and between AA XXXX AA ("XXXX"), having a place of business

at	,, and BB YY	AAA BB ("AAAA.	"), naving a pia	ice of business a
<u> </u>				
XXXX representinformation relating to	ts that it owns or contr chemical elements ar	•		
thereof produced and/ ("XXXX INFORMATION		sed in the Ter	ritory by XXXX	K or its affiliates

YYYY represents that it owns or controls valuable proprietary business and technical information relating to chemical elements and/or compounds and/or mixtures or solutions thereof produced and/or imported and/or used in the Territory by YYYY or its affiliates ("YYYY INFORMATION").

YYYY and XXXX desire to exchange INFORMATION for the purposes of enabling each party to evaluate and use the INFORMATION according to the purpose as defined in Article II of the Consortium Agreement, perform health, safety, and environmental hazard assessments for its own tiered assessment screening and to enable health, safety, and environmental reporting in compliance with applicable European Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") obligations (collectively, "PURPOSE").

For the above PURPOSE XXXX and YYYY is each willing to provide access to its INFORMATION to the other under the terms and conditions set forth herein

In consideration of the promises and conditions set forth herein, the parties agree as follows:

- 1. XXXX in its sole discretion shall disclose to YYYY certain XXXX INFORMATION for the PURPOSE stated above. XXXX INFORMATION provided by XXXX hereunder shall explicitly refer to the present Agreement. All XXXX INFORMATION shall be treated as confidential by YYYY, whether disclosed in writing, orally, or by observation; provided that in order to be treated as confidential, XXXX INFORMATION disclosed orally or by observation shall be identified by XXXX as confidential at the time of the disclosure or observation and reduced to a writing marked as confidential and provided to YYYY within thirty (30) days.
- 2. YYYY in its sole discretion shall disclose to XXXX certain YYYY INFORMATION for the PURPOSE stated above. YYYY INFORMATION provided by YYYY hereunder shall explicitly refer to the present Agreement. All YYYY INFORMATION shall be treated as confidential by XXXX, whether disclosed in writing, orally, or by observation; provided that in order to be treated as confidential, YYYY INFORMATION disclosed orally or by observation shall be identified by YYYY as confidential at the time of the disclosure or observation and reduced to a writing marked as confidential and provided to XXXX within thirty (30) days.

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- 3. With regard to the INFORMATION of the other, each party agrees to hold the INFORMATION in confidence for a period of __ (_) [to be decided on case by case basis e.g. 15, 20, 25 years, depending on value/sensitivity of INFORMATION] years from the date of disclosure of the INFORMATION and to use the INFORMATION solely for the PURPOSE stated above. In no event during the period of confidentiality shall any disclosure of such INFORMATION be made to any third party, or be made in any patent application, or otherwise be made in any form without the prior written approval of the owner of the INFORMATION.
- 4. Neither party, as recipient ("RECIPIENT") of the INFORMATION of the other ("PROVIDER"), shall have any confidentiality or use restriction regarding any information or material which:
 - (i) is or hereafter becomes, through no fault of RECIPIENT, part of the public domain by publication or otherwise,
 - (ii) RECIPIENT can show was received by it from a third party as a matter of right without any restriction on disclosure,
 - (iii) RECIPIENT can prove was in its possession at the time of disclosure by PROVIDER and was not previously acquired directly or indirectly from PROVIDER, or
 - (iv) RECIPIENT can show was developed by its employees who did not have access or recourse to INFORMATION.

Information disclosed under this Agreement shall not be deemed to be within the foregoing exceptions merely because such information is embraced by more general information in the public domain or in the possession of RECIPIENT. Neither will a combination of features be deemed within the foregoing exceptions merely because individual features are in the public domain or in RECIPIENT's possession, unless the combination itself is in the public domain or in RECIPIENT's possession.

5. Notwithstanding the provisions of Paragraphs 3 and 4, in the event either party, as RECIPIENT of the INFORMATION of the other party ("PROVIDER"), makes reasonable determination that it is required to disclose PROVIDER's INFORMATION pursuant to a governmental and/or judicial obligation or order, including an obligation to disclose to the European Chemical Agency under REACH, RECIPIENT shall be permitted to do so provided that written notice of such requirement is promptly provided to the PROVIDER to enable the PROVIDER to seek from a court a protective order relating to the disclosure of said INFORMATION.

In any event, in the case where RECIPIENT discloses PROVIDER's INFORMATION under this Paragraph 5, it shall furnish only that portion of PROVIDER's INFORMATION that its legal counsel reasonably determines it is legally required to disclose.

- 6. Each RECIPIENT may disclose the PROVIDER'S INFORMATION to those of its affiliates bound by the confidentiality and use restrictions as set out in this Agreement who are needed to work with RECIPIENT in accordance with the PURPOSE ("AFFILIATES") and RECIPIENT remains liable to PROVIDER for unauthorized disclosure or misuse of PROVIDER'S INFORMATION by RECIPIENT'S AFFILIATES. For the avoidance of doubt, each party agrees that it and its AFFILIATES may exchange INFORMATION directly with each other and with the other party and with the other party's AFFILIATES.
- 7. RECIPIENT shall destroy or return to PROVIDER, upon PROVIDER's request, all documents received from PROVIDER containing PROVIDER's INFORMATION, including documents in electronic format and the like, under this Agreement, provided that YYYY is under no obligation to destroy INFORMATION that is contained on electronic back-up data generated automatically in the data center. RECIPIENT shall provide written confirmation of

any such destruction. However, in any event, RECIPIENT may retain in continuing confidence one secured copy of such documents for record keeping purposes only.

- 8. Nothing in this Agreement shall be construed as the grant to, or an obligation on PROVIDER to grant to, RECIPIENT of any license under any existing or future patent right or other intellectual property right or confidential information of PROVIDER or its affiliates.
- 9. The validity, interpretation and effect of this Agreement shall be governed by the procedural and substantive laws of [......] without regard to its choice of law provisions. In the event of dispute, the Courts of [......] shall have exclusive jurisdiction.
- 10. RECIPIENT shall not furnish, deliver, or release the INFORMATION made available to it hereunder to any individual, entity, or destination, or for any use, except, [optional: with the prior written consent of PROVIDER], in full accordance with all applicable laws, regulations, and requirements of the United Nations, the Territory or any member state thereof and the United States with respect to export control and trade sanctions. RECIPIENT agrees and understands it shall be responsible for ongoing compliance with all such applicable laws, regulations, and requirements.
- 11. The provisions of Paragraphs 3 to 10 shall survive termination of this Agreement.
- 12. This Agreement shall be effective as of the date it is signed by both parties and shall terminate ___(_) [e.g. 5, 10, 15, 20 or 25] years thereafter [to be decided on a case by case basis depending on the sensivity of the INFORMATION],, unless it is extended by mutual written consent, or earlier terminated by either party by giving at least thirty (30) days' prior written notice to the other party. In case of early termination, the provisions of this Agreement shall survive for the period set forth herein.
- 13. This Agreement constitutes the entire agreement between the parties as to its subject matter. No representations have been made by either of the parties except as are specifically set forth herein. No rights or obligations other than those expressly recited herein are to be implied from this Agreement.

In Witness Whereof, the parties have caused this Agreement to be duly executed.

AA XX	XXX AA		BB YYYY BB	
Ву:	Signature	By:	Signature	
	Print		Print	
Title:		Title:		
Date:		Date:		

the for

Annex 7: Guidance on competition compliance



the for

Annex 8

Value of studies - valuation rules

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

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

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

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

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

RIP 3.4 takes as a basis Klimish rating (adequacy, relevance and reliability). The valuation rules described below have been based on RIP 3.4 recommendations and rules previously developed in practice³:

³ www.cesio2004.de

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

- a) The aforementioned reports are initially evaluated with respect to their scientific value. In a second step, their financial value is calculated through the use of various mark-ups and deductions.
- b) The object of the valuation is to ensure that adequate compensation is paid to the report owner for the provision of preliminary services and that the recipients' requirement for a high quality report is satisfied.

1. Scientific Evaluation

- 1.1. For reports, which are contributed by individual members of the consortium, the supplier provides the consortium with the report itself and existing and available summaries in the form of an IUCLID data set and a robust summary. The robust summary may also be integrated into the IUCLID data set.
- 1.2. The quality of the reports is determined by the Technical Committee, or experts commissioned by the latter, in accordance with the Klimisch et al.⁴ method by classifying the report into one of the following categories: (1) reliable without restriction, (2) reliable with restrictions, (3) not reliable, (4) not assignable.
- 1.3. The allocation to the four categories must be accompanied by appropriate substantiation in accordance with the requirements described in the chapter "Documentation of reliability categories in data sheets (IUCLID)" of the Klimisch et al. publication.
- 1.4. The quality of the robust summaries and IUCLID datasets is determined by the Technical Committee, or experts commissioned by the latter.
- 1.5. If the documents (IUCLID data set and/or robust summary) submitted by a party supplying a report are not in conformity with the state of the art or missing the Technical Committee or experts commissioned by the latter, should develop a robust summary and an IUCLID update.

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



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

2. Financial Valuation

- 1.7.From a scientific viewpoint, reports in category (1) "reliable without restriction" and (2) "reliable with restrictions" qualify for financial compensation, whereas reports in categories (3) "not reliable" and (4) "not assignable" are deselected from the subsequent procedure. This does not mean that the information contained in reports from the latter two categories is classified as useless. Rather, the owners are asked to make such information available free of charge.
- 1.8. The assessment basis for determination of the financial value of a given report is the replacement value of the report as of the valuation date. Included in this value are expenses for setting up the test ,e.g.:
 - i) Preliminary testing for determining test concentrations
 - ii) Substance testing according to the standard protocol
 - iii) Development of suitable analytical methods
 - iv) Supplementary analyses
 - i) Substance characterization
 - ii) Stability in test medium
 - iii) Concentration in test medium
 - v) Administrative expenses, e.g.:
 - i) Processing and professional support by the commissioning party
 - ii) Travel expenses
 - iii) Archival of the test substance and raw data
 - iv) Preparation of IUCLID data set and robust summary.
 - vi) The calculation only includes expenses, which are documented by verifiable documentation or, if such documentation is not available, expenses that can be justified with sufficient plausibility.
- 1.9. The expenses for preliminary testing and substance testing according to the standard protocol are calculated as the arithmetic average of the prices charged by the following three European testing institutes according to their price lists:

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

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

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

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

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

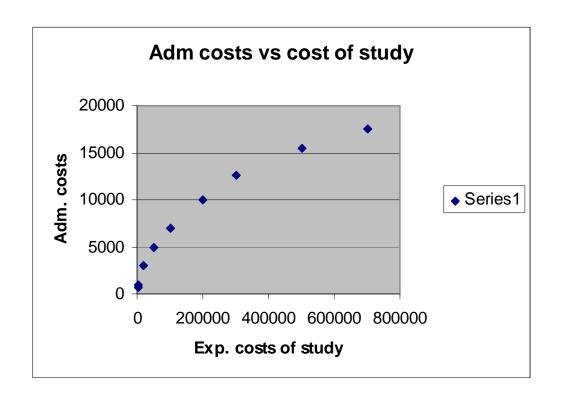
- 1.13. The calculation of expenses for substance analysis, for which no market prices are available, requires the following information from the party supplying the report for each analytical procedure:
 - i) Brief description of the procedure or method, including the limit of detection
 - ii) Estimated costs for the development or provision⁵ of the procedure or method
 - iii) Costs per analysis
 - iv) Number of analyses performed
 - v) The development and provision costs can also be included in the costs for each analysis.
- 1.14. Robust summaries contributed by the supplier or developed by experts commissioned by the Technical Committee should be compensated by 30% of the value of the admin costs according to 2.9.
- 1.15. A surcharge to the sum total of experimental costs (substance testing and analysis) is charged for administrative expenses (processing, monitoring and professional support by the commissioning party, travel expenses, archival of the test substance and raw data). The surcharge depends on the experimental value of the study according to Attachment 3b. In the case of significant amounts in excess of the above surcharge, the expenses are to be substantiated and documented individually.
- 1.16. The decision to conduct a study involves the risk that the study results could adversely affect or prevent future substance marketing; hence, the individual member contributing a report to the consortium was exposed to the risk that the investments made in the study are of minor or no benefit. The other members of the consortium, new parties or parties wishing to acquire a specific study are not exposed to this risk since they already know the study result. Therefore, the contributing member(s) is granted a fixed surcharge of 30% of experimental costs.
- 1.17. The current value of a given report is comprised of the experimental and administrative expenses, as well as the risk premium specified above.

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

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



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

the fund

Annex 9: Cost allocation



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Annex 10: Letter of Access⁶

Letter of Access for the registration of the substance vinyl chloride under REACH Regulation

By this letter, the Members of the Consortium⁷ on the registration of the substance Vinyl Chloride under *REACH* (hereafter referred to as "the Consortium") agree that the data, studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments specified in detail below owned by Members of the Consortium and submitted by the Consortium in support of the registration under REACH on

<u>Substance</u> Vinyl chloride (EINECS name chloroethene, CAS number 75-01-4, EINECS number 200-831-0)

(hereinafter collectively referred to as the "Registration 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]

It is agreed that:

- 1. The right to refer is restricted only for the registration purpose as specified above.
- 2. The right of refer is solely granted in favour of *Company XYZ* and is not transferable to any other entity or person.



⁶ www.cesio2004.de

- 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.⁸
- 4. This Letter of Access shall in no event be construed as granting *Company XYZ* any property rights whatsoever in the Dossier.

Signature: Authorised Representative of the Consortium

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⁸ Depending on the contract between the Consortium and *Company XYZ* the latter may receive the results and/or summaries/robust summaries of studies directly from the Consortium.

Annex 11: Declaration of Accession

The company:
Name Address/ seat of incorporation Represented by
Hereby declares that wishes to join as Regular Member the present Consortium Agreement pursuant to REACH legislation, dealing with the Substance Vinyl Chloride and thereby recognises by signing this Declaration of Accession that it is bound by the terms and conditions set out in the Consortium Agreement as of [date]duly signed by the following parties:
[list all the Members signatories to the Consortium Agreement]
Date Signature