

## **Results of the project:**

### **Model Agreements for Consortia and other Forms of Data Sharing according to REACH Reg.**

compiled by the law firm of REDEKER SELLNER DAHS & WIDMAIER<sup>1</sup>  
with the collaboration of the members of the project group<sup>2</sup> formed for this project

## **→→ Appendix C**

### **Model Agreement on the Formation of a Consortium pursuant to REACH Requirements (Consortium Agreement)**

Frankfurt, October 2007

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<sup>1</sup> [www.redeker.de](http://www.redeker.de).

<sup>2</sup> See listing of the members in the attachment labelled "Members of the Project Group and Contact Persons of the relevant Law Firm".

## ***Note***

*This Model Consortium Agreement was developed on the basis of the practical and legal experience of the aforementioned law firm and the Project Group. Consideration was given to the practical need for brief and simple provisions. Thereby, other conceivable (more) detailed provisions were omitted. Consequently, the Model Agreement cannot and does not reflect all possible constellations and problems occurring under actual conditions. Therefore, the Model may not be used as a standardised form for a consortium agreement. Rather, it is to be used as a guideline and sample. In each specific case, a separate review must be conducted to determine whether the provisions of the relevant Model Agreement are appropriate under practical and legal aspects and whether any other provisions are required and suitable.*

*The Model Agreement is based on Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 and on the European law in force (legislation and court rulings). Adjustments may be necessary in order to comply with the national law applicable according to Section VIII. par. 2.1 of the Model Agreement.*

### **CONSORTIUM AGREEMENT FOR REACH**

**between**

**Manufacturer 1, 2** etc. ....

[optional: and

**Importer 1, 2** etc. ....

[optional: and

**Only Representatives 1, 2** etc. ....

as “Regular Members”

[optional: and

**Downstream User 1, 2** etc. ....

as “Associate Members”

– all hereinafter referred to as “Members of the Consortium” –

**Kommentar [1]:** The wording in brackets “[...]” represents options to or alternatives for the Agreement.

**Kommentar [2]:** According to Article 8 REACH Reg. the “Only Representative” may be appointed by a manufacturer established outside the European Community. This “Only Representative” will then have the same obligations as an importer and will as such be able to participate in a consortium.

**Kommentar [3]:** Manufacturers of preparations and other downstream users are not subject to registration requirements. Consequently, there must be special reasons for their participation as “associate members” of a consortium.

**Kommentar [4]:** Practical experience has shown that a consortium usually consists of 5 to 10 members. The Model Agreement is tailored to this size. If more than 10 members are involved, the model may lead to an impractical consortium structure.

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## I. Preamble

The Members are manufacturers [*optional*: or importers as well as only representatives] [*optional*: or downstream users pursuant to Article 3 No. 13 REACH] of the substance ... [*designation of the substance with its substance name*] [*optional*: of substances in the category ... [*designation of the category with its substance name*]] described in **Annex 1** – hereinafter: “the Substance” – with registered head offices in the European Union.

According to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals [hereinafter “REACH”], manufacturers [*optional*: and importers as well as only representatives] are obliged to register the Substance within the prescribed deadlines [*optional*: pursuant to **Annex 2**]. Each of them will [*optional*: has] pre-register [*optional*: pre-registered] the Substance according to Article 28 REACH.

The Substance has phase-in status according to Article 3 No. 20 REACH.

Articles 11 and 19 REACH require Core Data on the same substance to be submitted jointly during registration.

Now, therefore, in consideration of the above, the Members agree as follows:

## II. General Provisions

### 1. Definitions

- (1) *Regular Members*: manufacturers, importers and/or Only Representatives who are subject to a registration requirement according to REACH and who belong to the Consortium as founding Members or as Members who joined the Consortium at a later date.
- (2) [*optional*: *Associate Members*: downstream users within the meaning of Article 3 No. 11 REACH.]
- (3) *Affiliate*: a corporation, which controls, is controlled by or is under common control with a Regular Member, with control meaning at least 50 % of the voting

**Kommentar [5]:** Annex 1 must include precise specification of the substance and/or category of substances in order to enable exact definition for purposes of the consortium. This is the only means of clearly differentiating between the manufacturers and/or importers of other substances. For non-identical substances of a substance the core data may be jointly prepared within a consortium. However, a joint submission according to Articles 11 and 19 requires substance identity.

**Kommentar [6]:** Annex 2 indicates the tonnage bands of the respective manufacturer or importer (Article 12 REACH Reg.) and the deadlines for registration pursuant to Article 23 REACH Reg. If all members act within the same tonnage band, Annex 2 does not need to be completed.

**Kommentar [7]:** Experience shows that the formation of consortia is negotiated prior to Title II REACH Reg. entering into force (01.06.2008) and thus before pre-registration becomes possible (pre-registration period starts on 01.06.2008) and SIEF obligations arise. However, this Model Agreement is also suitable for negotiations after pre-registration.

**Kommentar [8]:** The obligation to joint registration does not apply to non-identical substances belonging to the same substance group. Thus, the contractual integration of members of the same substance (group) into the consortium-group exceeds current legal obligations. However, this might be expedient in order to use the read-across options according to Annex XI par. 3 REACH Reg.

rights directly or indirectly owned. [*alternative*: The corporations listed in **Annex 3** are to be considered as Affiliates of Regular Members].

- (4) *Steering Committee*: decision making body of the Consortium which consists of a representative of each Regular Member. **Annex 5** contains a list of the Representatives [optional: and deputies].
- (5) *Lead Company*: the Regular Member who is responsible, with the assistance of the Project Manager, to prepare and submit the Registration Dossier to the European Chemicals Agency (ECHA) on behalf of the Consortium pursuant to Article 11.1 REACH, hereby acting within the decisions of the Steering Committee.
- (6) *Project Manager*: natural or legal person responsible for daily management of the Consortium within the scope of his/her competences provided by the Lead Company, hereby acting within the decisions of the Steering Committee.
- (7) *Only Representative*: any natural or legal person as defined in Art. 8 REACH.
- (8) *Core Data*: the following data to be submitted jointly by the Consortium pursuant to Article 11.1 subparagraph 2 REACH:
  - classification and labelling of the substance pursuant to Annex VI Section 4 REACH;
  - Study summaries derived from the application of Annexes VII to XI REACH;
  - robust Study summaries derived from the application of Annexes VII to XI, if so required under Annex I REACH;
  - testing proposals where required by the application of Annexes IX and X REACH.
- (9) *Studies*: reports in written or electronic form on investigations, tests or other examinations (including those on vertebrate animals), which relate to intrinsic substance properties or to the exposure assessment and risk characterisation in the chemical safety report and as such are of relevance for registration pursuant to Article 10 REACH; these also include summaries and robust Study summaries of the reports.

**Kommentar [9]:**

Alternatively, in order to improve transparency of this point and to ease calculation of the cost-shares, affiliates can be listed in an annex to the Agreement when the consortium is formed. Later, changes of the regular members' corporate structure can be considered through amendment of the annex by decision of the steering committee. The extent (including an extension) of a regular member's circle of affiliates will be considered within its cost-share according to Annex 9.

**Kommentar [10]:** The term "core data" is not a term derived from REACH Reg. In the Agreement, the term is used for the data indicated in the definition.

- (10) *Information*: Studies according to Section II.1 (12) of this Agreement and other test data and information made available to the Consortium by a Member under this Agreement as well as under a Preliminary Agreement or generated/determined by the Consortium for the purpose of this Agreement.
- (11) *Registration Dossier*: dossier containing Core Data [optional: the chemical safety report and the guidance on safe use of the Substance] to be submitted to the European Chemical Agency (ECHA).
- (12) *Substance*: the substance(s) as defined in the Preamble.
- (13) *SIEF*: Substance Information Exchange Forum as defined in Art. 29 REACH.

To the extent not otherwise defined herein, the definitions in Article 3 REACH shall apply to this Agreement.

## 2. Purpose of the Consortium

- (1) The Members undertake to cooperate in order to comply with the requirements of REACH. In particular, they undertake to pursue jointly the following objectives:
- Development of Core Data for the Substance as specified in Section III of this Agreement [fulfilling the highest tonnage band requirements applicable to at least one of the Regular Members].
  - [optional: Preparation of the chemical safety report and the guidance on safe use of the Substance as specified in Section 4 of this Agreement.]
  - Filing the Registration Dossier by the Lead Company, also on behalf of the Affiliates of the Regular Members who will be notified by the Regular Members to the Steering Committee according to Section II.4 (3) of this Agreement.
  - Exercising the rights to Studies in accordance with Section II.4 of this Agreement.
- (2) The Registration Dossier shall be submitted to the European Chemicals Agency (ECHA) at the latest one month before the end of the registration deadline applicable to the Member with the highest tonnage band.

**Kommentar [11]:** According to Annex VI REACH Reg., Annexes VII to XI REACH Reg. stipulate the following 4-step procedure for the development of core data:  
 1) Gather and share existing information.  
 2) Consider information needs.  
 3) Identify information gaps.  
 4) Generate new data/propose testing strategy.

**Kommentar [12]:** According to the volume concept of the REACH Reg., the scope of the core data is oriented towards tonnage bands per manufacturer/importer (Article 12). If a consortium includes manufacturers/importers with differing tonnage bands, the set of core data to be filed by the consortium is oriented towards the highest tonnage band represented in the consortium. Differentiation within the cost regulation remains possible.

**Kommentar [13]:** The chemical safety report and guidance on the safe use of the substance may – yet, need not be – jointly handed in (Article 11 par. 1 REACH Reg.).

**Kommentar [14]:** The abstract definition of affiliates according to Section II. par. 1.3 is insufficient for the joint submission of the core data since Annex VI par. 1.2 REACH Reg. requires their designation by name. The obligations arising from Articles 11 and 19 REACH Reg. are met if the affiliates of the regular members manufacturing/importing the same substance (and thus belonging to the same SIEF) are integrated into the registration. The nomination of the affiliates to be integrated only takes place shortly before registration, as the corporate structure of the regular members may change until registration by the lead company. No separate nomination of the affiliates ... [1]

**Kommentar [15]:** Submission of the Registration Dossier with the agreement of all Members of the Consortium does not mean in any case that Members with lower tonnage bands and later deadlines submit their registration prior to the deadline relevant for them (which is allowed in accordance with Art. 23 (4)). They can submit their individual information as specified in Art. 11 (1) subparagraph 3 at a later ... [2]

- (3) [optional: The cooperation also applies to the evaluation phase for dossier evaluation pursuant to Title VI, Chapter 1 REACH].
- (4) Each Member remains responsible on its own to comply with REACH, inter alia to submit individually the Information specified in Art. 11 (1), subparagraph 3 [optional: and 4] REACH as well as to fulfil communication requirements in the “downstream” supply chain (Titles IV and V REACH).
- (5) The Members recognize that any activities carried out under this Agreement have to be carried out in full compliance with applicable competition laws, in particular Articles 81 and 82 EC Treaty. The Members explicitly agree to observe the Code of Conduct attached as **Annex 4** to the Agreement.

**Kommentar [16]:** This extension is recommended. According to practical experience, the joint realisation of costly vertebrate studies (according to Annexes IX and X) is the underlying reasoning for the formation of a consortium. These studies can only be realised after registration has taken place and after ECHA has determined additional testing requirements.

**Kommentar [17]:** A consortium assumes only part of the rights and obligations of the members; this is hereby clarified.

**Kommentar [18]:** Pursuant to Article 10(a) REACH Reg, these are:

- . the identity of the manufacturer or the importer pursuant to Annex VI section 1 REACH Reg.
- . the identity of the substance pursuant to Annex VI section 2 REACH Reg.
- . information on the manufacture and use(s) of the substance as specified in Annex VI section 3 REACH Reg.; this information shall represent all of the registrant’s identified use(s).
- . concerning substances registered in quantities between 1 and 10 tons per year, information on exposure according to Annex VI section 6.
- information on quality assurance concerning the aforementioned information.

### 3. Confidentiality

- (1) The Members undertake
- a) to treat all Information as confidential and not disclose it to third parties, unless legal disclosure requirements apply;
  - b) only to use the Information for the purpose of this Agreement and, in particular, not to exploit it commercially;
  - c) not to make the Information, directly or indirectly, the subject of any patent application or other intellectual property right; and
  - d) make the Information available only to Members of the Steering Committee and those employees (including personnel of their Affiliates, as well as experts, other externs and trustees) who need to have access to such Information for the purpose of this Agreement and who are contractually or otherwise obliged to keep it confidential.
- (2) The obligations according to Section II.3 (1) of this Agreement shall not apply to Information of which the receiving Member can prove, that such Information
- a) was known to it on a non-confidential basis prior to receipt thereof;
  - b) was publicly known prior to receipt thereof;

**Kommentar [19]:** Pursuant to Article 25 par. 2 sentence 2 REACH Reg., registrants must refrain from exchanging information concerning their market behaviour, production capacities, production or sales volumes, import volumes or market shares.

**Kommentar [20]:** For example, Article 22 par. 1(e) REACH Reg. stipulates an obligation to inform ECHA on any new knowledge of risks. According to US TOSCA there is an obligation to report to EPA on any new knowledge of risks, also.

- c) became publicly known after receipt thereof without breach of this Agreement;
- d) was disclosed to it by a third party which to the best of its knowledge was authorised to make such disclosure; or
- e) was developed independently by it.

Specific Information shall not become exempt from the obligations according to Section II.3 (1) of this Agreement merely because it is embraced by general information within any of the exceptions according to Section II.3 (2) a) – e) above.

- (3) Affiliates as well as experts, other externs and trustees of one or all Member(s) are not regarded as third parties for the purpose of Section II.3 of this Agreement. The Members are responsible for the compliance with Section II.3. (1) – (2) of their Affiliates and experts, other externs and trustees.

#### 4. Rights to Information

- (1) Studies made available in accordance with Section III.1 *[optional: and in accordance with Section IV.2 (1)]* of this Agreement are owned by the Member who presented such Studies. However, the other Members shall have for an indefinite period of time the non-transferable and non-terminable right to use the summaries or robust Study summaries of such Studies for registration *[optional: and for authorisation]* of the Substance *[optional: of the substances of a substance group listed in Annex 1]* pursuant to REACH, and to refer to the full Study reports, provided that such Members share the cost of the Studies in accordance with the cost-key in Section V.1 (3) of this Agreement. Upon this payment these other Members shall obtain a copy of the Study summary as well as the robust Study summary.
- (2) The Members shall have joint ownership to Studies generated by the Consortium pursuant to Section III.2 *[optional: and pursuant to Section IV.2 (2)]* of this Agreement, provided that the individual Members share the costs of the Studies in accordance with the cost-key in Section V.1 (3) of this Agreement and thus shall have for an indefinite period of time a non-transferable and non-terminable right to use the Studies. They shall obtain a copy of the full Study report. The right of

**Kommentar [21]:** Herewith the protection clause in Article 10(a) REACH Reg. is allowed for.

**Kommentar [22]:** This clause allows for the cost-key (in this Model Agreement Annex 9), which in general only establishes payment obligations for studies needed within the same tonnage bands.

**Kommentar [23]:** This clause corresponds to the regulation on studies not produced in a SIEF (in Article 30 par. 2 REACH Reg.).

third parties to use such Studies within or even outside the scope of REACH may only be granted by the Steering Committee for a period of twelve (12) years after the first registration of the Substance.

- (3) Affiliates of a Regular Member shall have for an indefinite period of time a non-transferable, royalty-free and non-terminable right to use those Studies covered by para. (1) for registration pursuant to REACH, provided that their respective Regular Member shares the costs in accordance with the cost-key in Section V.1 (3) of this Agreement. Under the same condition, Affiliates of a Regular Member shall have for an indefinite period of time a non-transferable, royalty-free and non-terminable right to use those Studies covered by para. (2). In order to benefit from joint submission the Regular Member has to notify the names and addresses of its Affiliates to the Steering Committee in writing and at least thirty (30) days before submission of the Registration Dossier, in order to enable the Lead Company to include the names and addresses in the Registration Dossier as required in Annex VI Section 1.2 REACH. If no such notification is made, the Affiliates have a royalty free right to refer to the jointly submitted Registration Dossier, especially the Studies indicated in para. (1) and (2), for REACH purposes. A “letter of access” *[optional: in accordance with the model in Annex 9]* for REACH purposes shall be issued by the Project Manager upon request. Upon request, the Project Manager shall also issue a "letter of access" or other necessary documents for the use of the Studies indicated in para. 2 by Affiliates for other purposes.

**Kommentar [24]:** This clause makes sense since all members of the consortium contributed to the financing of the study. The necessary flexibility will be attained through the majority decisions of the steering committee.

**Kommentar [25]:** According to Article 25 par. 3 REACH Reg., the protection ceases to exist 12 years after registration has taken place in accordance with REACH Reg.

**Kommentar [26]:** The abstract definition of “affiliates” according to Section II. par. 1.3 is insufficient for the joint submission of the core data since Annex VI par. 1.2 REACH Reg. requires their designation by name. The obligations arising from Articles 11 and 19 REACH Reg. are met if the affiliates of the regular members manufacturing/importing the same substance (and thus belonging to the same SIEF) are integrated into the registration. The nomination of the affiliates to be integrated takes place only shortly before registration, since the corporate structure of the regular members may change until such registration by the lead company. No separate nomination of the affiliates for the joint registration is necessary if the affiliates are designated via a listing in Annex 3 according to the alternative in Section II. par. 1.3 of this Agreement. Then, only the listed affiliates are to be integrated. In case the nomination is not effected or in case affiliates of the regular members (manufacturing/importing the same substance) join after submission of the registration by the lead company, the right (likewise) granted to refer to ... [3]

**Kommentar [27]:** This clause emphasises (in particular for international consortia) that the consortium has no legal personality.

**Kommentar [28]:** The steering committee may establish its own rules of procedure, which need not be governed by the Agreement. The steering committee may establish sub-committees (e.g. a technical committee) or working groups. This also need not be specifically governed by the Agreement. As a rule, the lack of suitable experts limits the setting up of fixed working groups in particular ... [4]

## 5. Organisation

- (1) This Agreement or the cooperation contemplated herein shall neither constitute or be deemed to constitute a legal entity between the Members nor make a Member the agent or representative of another Member unless expressly stated otherwise.
- (2) The Steering Committee shall have all powers necessary to ensure that the purpose of the Agreement is achieved. The tasks of the Steering Committee may include, inter alia:
- Decisions on funding, scope and matters of policy;
  - Decisions on a working and finance plan and management of financial resources of the Consortium, including budgeting, funding collection and accountancy;

- Decisions to carry out testing;
- 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 ECHA;
- [*optional*: Approval of the chemical safety report and the guidance on safe use of the Substance;]
- Coordination and supervision of activities of the Project Manager and the Lead Company;
- Consent to the nomination and replacement of the Project Manager upon proposal of the Lead Company;
- Decision regarding access of new Regular or Associate Members or regarding provision of other rights to third parties;
- Decision on the exclusion of a Member;
- Ensuring competition law compliance.

Upon unanimous decision, the Steering Committee is entitled to modify **Annexes 1 to 10** of the Agreement. Para. (6) remains unaffected.

- (3) The Lead Company shall be responsible to prepare and submit the Registration Dossier to ECHA. To achieve this task it makes use of the assistance of the Project Manager and requests decisions by the Steering Committee according to para. (2). Furthermore, the Lead Company shall represent the other Members in the SIEF. The Members may issue a written proxy. They may make use of the options laid down in Article 4 REACH in order to prevent disclosure of their identity in the SIEF. The Lead Company [*optional*: Project Manager] is responsible for observance and assertion of the rights and obligations of the Members pursuant to this Agreement and to the Steering Committee's decisions in the SIEF.

The Lead Company is listed in **Annex 5**.

- (4) The Project Manager shall be responsible for daily management of the Consortium within the competences provided by the Lead Company and for implementation of the decisions of the Steering Committee. The Project Manager is nominated and can be replaced by the Lead Company, subject to the consent of the Steering Committee.
- (5) Each Regular Member is entitled to one vote in the Steering Committee. Unless otherwise provided for in this Agreement, the Steering Committee shall decide by simple majority of its members. If a majority of the Members were absent during the vote, such decision(s) shall be taken by a majority of the Members present at the following meeting, (but only) if notice of this procedure was announced in the agenda for the following meeting. Associate Members may participate in the meetings of the Steering Committee as guests without voting rights.
- (6) A Regular Member is allowed to withdraw its representative from the Steering Committee in writing. A withdrawal shall be effective only if another representative is appointed at the same time. **Annex 5** shall be adapted accordingly.
- (7) A Member shall be excluded from voting in the event of a conflict of interest as well as in matters which do not affect such Member (e. g. voting on tests not required for registration of the Member in question).
- (8) The Steering Committee may use the services of experts or other competent third parties for advice and consultation of the project management. A third party shall maintain confidentiality concerning all information made available to them through Members for that purpose. A respective obligation must be imposed upon the third party.
- (9) When required for compliance with relevant competition laws, the Steering Committee shall decide on appointing an independent third party as trustee for the development and processing of Information for registration purposes. In such event, the trustee shall inform the Steering Committee in aggregated form concerning the information obtained, thereby observing confidentiality. The Members shall conclude a confidentiality agreement with the trustee prior to its assignment.
- (10) The working language of the Consortium shall be .....

**Kommentar [29]:** Another voting allocation can be agreed upon; e. g. they could be oriented towards the tonnage bands pursuant to Article 11 par. 1 REACH Reg. Allocation on the basis of revenue or market share is also possible but is critical from the viewpoint of competition law; the determination would have to be done through a trustee.

**Kommentar [30]:** Pursuant to Article 25 par. 2 sentence 2 REACH Reg., information on production volumes is excluded from direct exchange among the participants. However, such information might need to be channelled through a neutral third party – the trustee – since production volumes relevant to exposures need to be disclosed in the chemical safety report.

**Kommentar [31]:** International consortiums will generally prefer the English language.

## 6. Working and Finance Plan

The Steering Committee shall prepare a working and finance plan concerning the planned activities until the submission of the Registration Dossier will have taken place, in particular concerning development of information stated in Section III [*optional*: and in Section IV] of this Agreement.

### III.

#### Development of Core Data

##### 1. Provision of Existing Information on Core Data

- (1) As of the effective date of the Agreement, the Members are obliged to provide the Steering Committee [*optional*: the Project Manager] with Studies indicated in Annex 6, as well as other relevant information on Core Data concerning the Substance.
- (2) The Steering Committee shall determine the financial value of the Studies made available for registration in accordance with para. (1) on the basis of the valuation rules in Annex 7 [*optional*: For the Studies listed in Annex ...[additional Annex to this Agreement] the financial evaluations listed therein shall apply and shall be the basis of the refund of expenses according to Section V.1 (2) a) of this Agreement [*alternative*: For the Studies listed in Annex .....[additional Annex to this Agreement], no determination of their financial value and no refund of expenses according to Section V.1 (2) a) of this Agreement shall take place].]

##### 2. Determination of New Test Data

When required under Annexes VII to XI REACH, the Steering Committee shall define the endpoints on which Studies are not yet available, taking into account the rules on "Waiving" in Annex XI REACH. The Steering Committee shall initiate completion of data according to Annexes VII to VIII REACH in compliance with the legal requirements of REACH on data sharing. The Steering Committee shall decide on testing proposals pursuant to Annexes IX and X REACH. In accordance with Article 10(a)(ix), such testing proposals shall be submitted together with the Registration Dossier. [*optional*: To the extent the testing proposals entail that the Agency or the EC Commission assign additional testing requirements to the Members,

**Kommentar [32]:** It is likely that information about available studies on core data is already exchanged during the pre-phase of consortium formation. It is recommended that the results of this stock-taking be included in an Annex to the Agreement (here Annex 6). Likewise, the existing published studies have probably also been determined during the pre-phase and could therefore also be included in the Annex. This may concern the risk assessments in particular, worked out in HERA or ICCA HPV. However, th ... [5]

**Kommentar [33]:** A supplementary agreement may stipulate that studies which are at the disposal of (on hand to) affiliated companies of consortium members must also be made generally available.

**Kommentar [34]:** It is recommended that the valuation rules be defined in the negotiations prior to conclusion of the consortium agreement and then attached to the Agreement as an Annex (in the Model Agreement Annex 7) in order to avoid disputes during the course of the consortium work. In Annex 7 of the Model Agreement, an e ... [6]

**Kommentar [35]:** Experiences in former consortia have shown that studies to end points available at low costs (representing the major part of the studies required pursuant to Annexes VII and VIII) are submitted several times or are submitted complementarily by the regular members in about equal shares. Thus, in practice, th ... [7]

**Kommentar [36]:** The term "waiving" determines the well-founded derogation from testing requirements specified in Annexes VII to X. The term is well established among experts and is therefore used in this Model Agreement. Experience with Regulation 793/93 (on existing substances) has shown that "waiving" is a focus-point ... [8]

**Kommentar [37]:** After the provisions on data sharing (Title III REACH Reg.) have entered into force on 1. June 2008 and after the respective SIEFs have been formed (1 December 2008), it will have to be considered that prior to testings (according to Annexes VII and VIII REACH Reg.) a preliminary query in the SIEF is necessary. If the consortium does not inc ... [9]

the Steering Committee shall act as follows: It shall coordinate any comments on draft decisions of the Agency or the Commission or legal remedies against the decisions of the Agency or the Commission and shall initiate the necessary tests. ]

**Kommentar [38]:** The option displayed here also takes into consideration that Section II. par. 2.3 of this Agreement designates the integration of the dossier evaluation according to Title VI REACH Reg. as an option. However, the integration is recommended. ECHA decides, during dossier evaluation, in accordance with Title VI REACH Reg. whether tests shall be carried out according to Annexes IX and X REACH Reg. This decision will be directed to single members of the consortium, not to the consortium as a whole. However, it is recommended that an agreement be made on how the members' rights during the dossier-evaluation-procedure (e. g. the right to comment, or to appeal against decisions of ECHA) shall be attended to and to agree on whether the necessary test(s) (due to additional sentential testing requirements) shall be jointly performed. The cost key a ... [10]

### 3. Rights and obligations of the Members in a SIEF

Inter partes, the rights and obligations of the Members (according to III.1 and III.2 above) replace the rights and obligations on the sharing of data involving tests in Article 30 REACH.

### 4. Request for non-disclosure of information

When compiling the Registration Dossier, the Steering Committee determines the information which shall be subject to a request for nondisclosure on the Agency's website according to Article 119 para. 2 REACH.

**Kommentar [39]:** Such request can be made according to Article 10(a)(xi) REACH Reg.; moreover, any such request should be made if the consortium's subject matter is an isolated intermediate – and this is so notwithstanding the fact that Articles 17 and 18 REACH Reg. do not stipulate a right to such request. This was obviously a drafting mistake.

## [optional: IV.

### Preparation of a Chemical Safety Report]

#### 1. Uses

Uses of the Substance to be assessed in the chemical safety report are listed in **Annex 8**.

**Kommentar [40]:** The disclosure of uses is required only if the cooperation extends to the chemical safety report and to the guidance on safe use of the substance. In the event that this is the case, it is recommended to include the uses to be reported in the consortium's chemical safety report in an Annex to the Agreement (here Annex 8).

#### 2. Development and Provision of Information Concerning Chemical Safety Assessment

(1) In order to cover the uses specified in **Annex 8** in the chemical safety report, the Members shall provide the Steering Committee all relevant Studies on uses, in particular with respect to exposure. The Steering Committee shall determine if and to what extent these Studies shall be refunded.

(2) The Steering Committee shall initiate completion of data necessary for the preparation of the chemical safety report.

**Kommentar [41]:** Generally, the project manager will be commissioned by the steering committee to provide the missing exposure data in the communication with downstream users. The provision of exposure data is a central function in the development of chemical safety assessments. REACH Reg. governs (on a legal basis, for the first time) the upstream communication process between downstream users and substance suppliers. However, downstream users may be reluctant to pass on customer know-how.

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

The Lead Company, with the assistance of the Project Manager, is responsible for drafting the chemical safety report and the guidance on safe use of the Substance to be approved by the Steering Committee.

## V.

### Financial Rights and Obligations

#### 1. Consortium Expenses

- (1) The Consortium expenses include:
  - a) Expenses to be refunded to the Members in accordance with the valuation rules pursuant to Section III.1 (2) *[optional: and, if applicable, the expenses determined according to Section IV.2 (1)]* of this Agreement as reimbursement for existing Studies made available by them.
  - b) Expenses for new Studies decided upon by the Steering Committee.
  - c) Current expenses incurred by the Consortium; in particular: remuneration for project management, expenses for a trustee or expenses for a professional expert.
- (2) Expenses incurred by Members when complying with their obligations under Section III *[optional: and under Section IV]* of this Agreement shall not be considered as Consortium expenses.
- (3) The Consortium expenses stated under (1) c) shall be allocated to all Members equally. The expenses stated under (1) a) and b) shall be allocated to Regular Members in accordance with the cost-key specified under Annex 9.

**Kommentar [42]:** In individual cases, cost allocation will be the focus of negotiations in the pre-phase. The following wording(s) are to be understood as recommendations only.

**Kommentar [43]:** It should be noted that Annexes IX to X REACH Reg. only require testing proposals that will be examined by the authorities in Evaluation pursuant Title VI. Additional testing requirements may result only after completion of this Evaluation, which might take a number of years. For practical reasons, the consortium will then commission the test orders following a resolution by the steering committee. This has consequences for the duration of the consortium and the provision of respective financing.

**Kommentar [44]:** The exclusion of expense compensation to members is based on the assumption that, as a rule, all members make the same contributions. If this is not the case, an expense compensation could be agreed upon (at the outset, or upon request of the steering committee) if the contribution made by a given member is above the contributions of the other members. The exclusion of expense compensation shall not favour late members but, rather, shall ease the ongoing work of the consortium.

**Kommentar [45]:** Seite: 15  
Practical experience indicates that the key applied for expense allocation relating to existing and new test data is one of the significant issues to be negotiated during the pre-phase prior to formation of the consortium; a number of points are to be considered. It is recommended that the cost-key be included in the Annex to the Agreement (in the model Annex 9). In Annex 9 of the model, an example of such a cost-key is presented. The cost key in the model Annex 9 takes the different tonnage bands of the members into consideration.

#### 2. Expense Allocation, Settlement Date, Advance Payments

- (1) The Steering Committee shall allocate the expenses incurred by the Consortium up to the end of a calendar year by ... *[Date, e. g. 31 March]* of the respective following year.
- (2) Advance payments can be defined through a resolution of the Steering Committee.

## VI. Membership

### 1. Admission of New Regular Members

- (1) By unanimous decision of the Steering Committee, the Consortium may admit new Regular Members to the extent that these Members are subject to registration requirements concerning the Substance.
- (2) A newly admitted Member shall issue a written declaration accepting the terms and conditions set out in this Agreement. Pursuant to the cost-key specified under **Annex 9** of this Agreement, the new Member shall pay a share of the expenses incurred by the Consortium to date pursuant to Section V.1 (2) a) and b) of this Agreement in the form of a pro-rated refund to the other Members. Moreover, in order to compensate for performances of the Members to date, for expenses incurred thus far by the Consortium in accordance with Section V.1 (2) c) of this Agreement, the new Member shall pay an additional “advantage compensation” to the existing Members up to the amount of the aforementioned reimbursement. The Steering Committee shall define the amount of this additional payment in accordance with **Annex 9**, thereby taking the current stage of the Consortium’s work at the time of admittance into account. Upon payment of the amounts indicated in sentences 1 and 2, the new Member has the unlimited rights and obligations of a Regular Member.
- (3) A registrant who is not accepted by the Steering Committee as a Regular Member according to para. (1) above may be offered a written agreement by the Steering Committee permitting Core Data developed by the Consortium to be submitted also on behalf of the respective registrant in accordance with Articles 11 and 19 REACH. In return, costs for submission of the data must be refunded by the respective registrant in accordance with **Annex 9**.
- (4) If the Consortium in such case as described in para. (3) already went through registration, a registrant might be offered by written agreement the right to refer via a “letter of access” [optional: via the Model Agreement in **Annex 10**] to all or part of the Consortium’s Core Data for the purpose of registration against refund of cost in accordance with **Annex 9**.

**Kommentar [46]:** The cost key in the model Annex 9 takes the different tonnage bands of the members into consideration. Thus, a new member only needs to refund a share of costs for studies needed within its tonnage band.

**Kommentar [47]:** This compensation may double the payment which the applicant is required to pay pursuant to par. 2.1. The additional payment is intended to cover the ongoing work of the consortium thus far (e. g. personnel expenses). Section V. par. 1.3 stipulates that those costs which do not need to be shared shall not favour late members. Further, the additional payment shall settle past expenses of the consortium for a project (Section V. par. 1.2 (c) of the Agreement). The amount of this additional payment is dependent upon the consortium’s work progress at the time of the admittance. The decision is met by the steering committee. Thereby, any discrimination of the new member against a registrant (subparagraphs 3 and 4) who is not accepted by the steering committee must be avoided.

**Kommentar [48]:** This provision (of the agreement) shall take into consideration the legal obligation to jointly submit core data according to Articles 11 and 19 REACH Reg. However, Articles 11 and 19 REACH Reg. require substance identity, i.e. within a substance group identity of the substance with the substances listed in Annex 1 of this Agreement is required. Here the potential registrant will eventually have to adequately prove that his/her substance is identical to the substances listed in Annex 1 of this Agreement. Articles 11 and 19 do not ... [11]

**Kommentar [49]:** After registration by the consortium the legal obligations to joint submission of core data according to Articles 11 and 19 REACH Reg. cease to exist. However, the steering committees may be empowered to issue a letter of access in this case. So the objectives of Art. 11 and 19 REACH Reg. are fulfilled. Cartel law may require access to core data in order to avoid discriminations, also. The cost regulation will be effected by agreement as specified in Annex 9 of this Agreement. A mod ... [12]

- (5) Rights and obligations vis-à-vis third parties according to Articles 26, 27 and 30 REACH remain unaffected.

## 2. [optional: Admission of Associate Members]

The Steering Committee may admit [optional: additional] downstream users as Associate Members, if they are able to contribute information for the purpose of this Agreement.

## 3. Withdrawal

- (1) A Member withdraws from the Consortium by termination or through exclusion from the Consortium.
- (2) Termination is permissible in writing at the end of a calendar year with a notice period of ... [number, e.g. 6] months if due to circumstances involving the Member, the Member is no longer subject to the registration requirements requirements or in the event that other serious reasons arise which make continued membership in the Consortium unreasonable. A Member may terminate his membership without cause upon written notice with a notice period of ... [number, e.g. 2] years.
- (3) The Steering Committee is entitled to exclude a Member by unanimous decision with immediate effect in the event of material breach of the Agreement.
- (4) In the event of termination according to para. (2) or exclusion according to para. (3), payment obligations which have arisen up until that point in time must be met. The rights (related to information according to Section II.4 of this Agreement) which have been acquired up until the point in time of withdrawal shall persist, provided that the Member meets all related payment obligations. Obligations specified in Section II.3 of this Agreement persist for a period of twelve (12) years following the Member's initial registration of the Substance. Other Members' rights of use as specified in Section II.4 of this Agreement respecting the Studies made available by the Member who has withdrawn continue to exist.
- (5) Payments already made by the withdrawing Member will not be refunded.

**Kommentar [50]:** Non-phase-in substances and phase-in substances which have not been pre-registered are regulated by Articles 26 and 27 REACH Reg. Here, the potential registrant submits the substance identity to the Agency. Article 30 REACH Reg. applies if the potential registrant pre-registered a phase-in substance. This also applies if the owner of a study has already registered – e. g. due to a shorter delay for registration. Here, the potential registrant might have to prove in an adequate manner that his substance is identical to the substance defined in Annex 1 of this Agreement. The legal obligations only extend to studies on intrinsic substance properties according to Article 10(a)(vi) and (vii) REACH Reg. – thus, e. g., not to exposure assessments. Within substance groups, the identity of the substance with the substances listed in Annex 1 of the Agreement must be proven. However, the consortium may also grant access to the data if there is no substance identity. But there is no legal obligation to do so. The costs are settled in accordance with the guidelines on cost sharing laid down in Article 27 par. 3 and Article 30 par. 1.2 REACH Reg.

**Kommentar [51]:** A period of six months, for example, would/could be adequate, giving the members of the consortium sufficient time to adjust to the new situation.

**Kommentar [52]:** In our view, such "serious reasons" are no reasons which allow to opt out under Article 11 par. 3 REACH Reg. The members can and must reflect the opt-out options according to Article 11 par. 3 REACH Reg. before concluding the consortium agreement.

**Kommentar [53]:** In this case the infringing member is excluded from voting (see section II. par. 5. (7)).

**Kommentar [54]:** According to practical experience, sometimes it may be difficult to get acceptance for such a clause. However, such clause may be essential for the maintenance of the consortium.

#### 4. Transfer of Membership

- (1) A Regular Member shall be entitled to transfer its membership, including all rights and obligations, to a new Member subject to registration requirements respecting the Substance. Such a transfer requires the unanimous consent of the Steering Committee.
- (2) The consent requirement pursuant to para. (1) does not apply to the transfer of membership to an Affiliate in the event of restructuring within a group of companies.
- (3) The transfer of individual rights and obligations arising from membership is excluded; this also applies to financial claims.

**Kommentar [55]:** In the event of a member firm merging, as a rule, all rights and obligations (including membership in the consortium) are transferred to the new legal entity by act of law (e. g. in German law). Therefore, this case does not require regulation in the Agreement at this point.

**Kommentar [56]:** The purpose of this regulation is to exclude such cases where external parties enter into undesired legal-membership relations with the consortium; in particular, the assignment of remuneration or compensation claims is excluded.

**Kommentar [57]:** Liability is based on the national law stipulated in Section VIII. 2 (1) of this Agreement. A more detailed specification is not possible given the large number of liability cases. Among the members of the consortium, this liability regulation applies e.g. to studies submitted pursuant to Section III. par. 1.1 of the Model Agreement. According to the proposed regulation, members are liable vis-à-vis other members for gross negligence or wilful misconduct in the development of the study which could lead to income ... [13]

#### 5. Liability of Members

- (1) Members, including the Lead Company, shall only be liable in case of gross negligence and wilful misconduct. They shall not be liable for non-typical or unforeseeable damage nor for consequential damage and lost profits. The limitation of liability as set out in sentence 2 of this para. does not apply in case of claims for death, personal injury or wilful misconduct. No warranty for acceptance of the Study by ECHA at the dossier evaluation (according to Title VI REACH) is given.
- (2) In accordance with the general rules, each Member shall be liable vis-à-vis third parties within the scope of his/her responsibility. The Members shall support any Member against whom a claim for liability has been made by a third party in defending against such claims to the extent possible and reasonable.

**Kommentar [58]:** Liability is based on national law. However, it cannot be stipulated in this Agreement which national law will be applicable. The applicability of the relevant national law in case of liability vis-à-vis third parties follows the rules of conflict of laws (private international law). Liability vis-à-vis third parties might become an issue if ... [14]

**Kommentar [59]:** Occasionally there are reservations against imposing contract penalties. However, the contract penalties primarily serve the protection of all those involved rather than serving the purpose of sanctions. The advantage of contract penalties is as follows: The burden of proof for a specific damage or for the causation ... [15]

#### 6. [optional: Contractual Penalties]

- (1) [optional: (2)] If a member violates the obligation to observe the rights of other members pursuant to section II par. 4.1 to 3 of the Agreement, such member shall pay for each violation a contractual penalty in the amount of .... [insert amount] [optional: in the amount of ... % of the expenses for the development of information that is related to the violation] to the other member whose information is affected. If a member violates the obligation to maintain confidentiality pursuant to section II par. 3.1 to 3 of the Agreement, this member shall pay an appropriate contractual penalty to the other member whose

**Kommentar [60]:** The amount of the contract penalty should be reasonably and appropriately determined with a view to the economic significance of the information exchanged in the individual case; the purpose is to encourage participants to exercise great care and diligence with respect to information. However, the penalty must not be ... [16]

information is affected; the amount shall be defined by the steering committee after due assessment of the **circumstances**. The contractual penalty pursuant to sentence 1 and 2 shall not apply if evidence is provided by the member that such violation was **not caused by fault** (including minor negligence) on his/her part. In the event of liability pursuant to section VI par. 5.1 of the Agreement, the affected member is entitled to claim damages from the member who is in violation of his contractual obligations, in addition to the contractual penalty according to sentence 1 and 2.

- (2) If a member otherwise negligently violates obligations related to material cooperation arising in this Agreement, this member shall pay an appropriate contractual penalty to the other members of the consortium – notwithstanding liability pursuant to section VI par. 5.1 of the Agreement. The amount shall be defined by the steering committee after due **assessment of the circumstances**.]

**Kommentar [61]:** The contractual penalty shall be reasonably related to the dimension of the contractual breach. Breach of confidentiality includes a wide variety of possibilities (e. g. wilful disclosure of comprehensive confidential information or disclosure of single confidential information by minor negligence). Therefore, a general flat amount cannot be specified.

**Kommentar [62]:** In reversing the burden of proof in respect to fault, the consequence will be that all those involved will comply with the provisions on confidentiality to the greatest possible extent. Another option would be to abandon fault as a/the prerequisite.

**Kommentar [63]:** The penalty shall be reasonably related to the dimension of the contractual breach. Therefore, a more detailed regulation concerning the amount of the penalty is not possible at this point.

## VII.

### Duration and Dissolution of the Consortium

#### 1. Duration

The Consortium shall exist for an indefinite period of time.

#### 2. Dissolution of the Consortium

The Consortium may be dissolved by unanimous decision of the Members. A respective resolution shall be taken if the purpose as defined under Section II.2 of this Agreement has been fulfilled to its full extent.

#### 3. Winding up of the Consortium

- (1) In the event of dissolution of the Consortium, there shall be a winding up of said Consortium. Subject to para. (2) and (3) all rights and obligations of Members among each other and in relation to third parties resulting from this Agreement shall be settled.

**Kommentar [64]:** Here, one must take into consideration that the SIEF formed for the particular substance (according to Annex 1 of the Agreement) must be able to resume work until 1 June 2018. An earlier dissolution would serve no purpose. Furthermore, it may be advisable to await the performance of tests pursuant to Annexes IX and X REACH Reg. The Agency does not decide on the tests before dossier evaluation. Therefore, it is recommended to follow the option proposed in Section II. par. 2.3 of the Agreement (to integrate the dossier evaluation phase into the definition of the purpose of the consortium).

- (2) Section II.4 of this Agreement shall survive the dissolution of the Consortium with the following modification: Section II.4 (2), third sentence, shall be performed by a trustee who shall act instead of the Steering Committee. The trustee shall distribute any compensation equally among the Members owning the respective Study.
- (3) With regard to Studies, the obligations specified in Section II.3 of this Agreement shall survive for a period of twelve (12) years following the initial submission to ECHA of that Study by a Member. With regard to all other Information, the obligation specified in Section 2.3 of this Agreement shall survive for a period of ... [ for example: three (3)] years after dissolution.

**Kommentar [65]:** The continued validity of the confidentiality obligation over time is appropriate and suitable in order to protect information exchanged during the cooperation period. The 12-year period is oriented towards the 12-year limit specified in Article 25 par. 3 REACH Reg. After the 12 year period has lapsed, the agency may provide the test data (vertebrate animals data) free of charge.

## VIII. Final Provisions

### 1. Exclusivity of and Amendments to the Agreement

- (1) The legal relationships of Members with respect to this Consortium shall be governed exclusively by this Agreement. Any other arrangements do not exist or are ineffective.
- (2) Amendments to this Agreement must be in written form to be effective.

### 2. Applicable Law and Place of Jurisdiction [*optional*: Arbitration]

- (1) This Agreement is subject to the laws of .....[insert country] without giving effect to any rules on conflict of laws.
- (2) [*optional*: In case of a dispute arising out of this Agreement, the parties to the dispute shall first attempt (in good faith) to reach an amicable settlement. Should such amicable settlement fail, the dispute shall be definitely decided in accordance with the rules of conciliation and arbitration of the International Chamber of Commerce in Paris. The award shall be binding on the parties. The arbitral tribunal consists of three arbitrators: each party designates one arbitrator; these two arbitrators then designate the third arbitrator, who acts as chairperson; the chairperson shall have a university degree in law. The cost of arbitration shall be paid by the Members involved on equal terms; any out-of-court costs shall be

**Kommentar [66]:** In international consortia, this question may be a crucial issue in negotiations. It may be expedient to agree on the law applicable in the country of the lead company's registered office.

**Kommentar [67]:** An arbitration agreement is advisable in particular in the event of an international consortium. This is why reference has been made to the ICC Rules of Arbitration. Other rules of arbitration such as of the German Institute of Arbitration are of equal worth.

borne by the Member having incurring said costs. [optional: The arbitral tribunal shall decide on the regulation of the cost of arbitration including out-of-court costs incurred by the parties in accordance with the outcome of arbitration] Arbitration shall take place in .....[insert place in accordance to section VIII par. 2.1], the language of the arbitration proceedings shall be ....[insert .language in accordance to Section II. 5 (10)].

**Kommentar [68]:** Cost allocation could be based on allocation independent of the outcome of the proceedings or, alternatively, contingent upon the outcome.

(3) [optional: Jurisdiction to resolve disputes of the Members of the Consortium shall be given to the court of ... [insert town of the court] .

**Kommentar [69]:** This option should be used if no arbitration is agreed on. In international consortia, the jurisdictional venue may be a crucial issue in negotiations. In the event of a dispute, it may be expedient to agree on the court competent for the Lead Company's registered office as the competent jurisdictional venue. In any event, there should be consistency with the applicable law [see para. (1)].

**3. Severability**

- (1) If a provision of this Agreement is found to be unclear or incomplete, an interpretation that best approximates the intent of the Members as expressed in this Agreement shall apply.
- (2) If a provision is invalid, this does not affect the validity of the other provisions. It is deemed to be agreed upon that an admissible provision which best approximates the intent of the Members replaces the invalid provision; accordingly, the Members agree to make a respective written amendment to the Agreement without any delay.

**4. Copies of the Agreement**

This Agreement has been made out in ... copies; each Member shall receive one copy.

Member (Company/Representative)	Place	Date
.....	.....	.....
.....	.....	.....
.....	.....	.....

etc.

**Annexes 1 – 10**

**ATTACHMENT:**

**Members of the Project Group and Contact Persons of the relevant Law Firm**

Dr. Alex Föller (Managing Director TEGEWA) (Chairman)  
Hans-Hermann Nacke (Managing Director VCI) (Chairman)  
Lothar Noll (Managing Director 6<sup>th</sup> World Surfactants Congress GmbH)  
Claudia Aubel-Pump (VCI)  
Dr. Anja von Hahn (BASF)  
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Dr. Jürgen Fluck (BASF)  
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**Annex 1:**  
**Substance Specification**

*(Note:*

*Enter the data necessary for exact identification of the Substance to be registered by the Consortium. Please note that every Member must independently inform the Agency concerning the identity of the Substance to be registered, observing Annex VI Section 2 REACH. There may be need for reconciliation.*

*If a category of substances is the subject of the Consortium, all substances belonging to the category which are manufactured or imported by the Consortium are to be stated here.)*

**Annex 2:**  
**Tonnage Bands of Regular Members (Manufacturers/Importers)**

**(Note:**

*State here the legally defined tonnage bands (1-10 t/a; 10-100 t/a; 100-1000 t/a; >1000 t/a) that are attributable to the individual Members.)*

**[optional: Annex 3<sup>3</sup>:**  
**Affiliates of the Regular Members]**

**(Note:**

*If the alternative option in Section II.(1) sentence 2 of this Agreement shall be exercised, state here the Affiliates (subsidiary, holding company, sister company) of the Regular Members of the Consortium who shall participate in the Regular Members' rights to use according to Section II. par. 4.3 of this Agreement. The Regular Member has to name new Affiliates arising from a change of the corporate structure of the respective Regular Member at a later point in time.))*

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<sup>3</sup> Annex 3 need only be completed if the alternative to the abstract definition of Affiliates according to Section II. par. 1.3 of the Model Agreement is chosen. Annex 3 is inapplicable if the abstract definition of Affiliates according to Section II. par. 1.3 of the Model Agreement is applied.



**Annex 4:  
Code of Conduct**

**I.**

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

**Article 81 EC Treaty**

[Prohibition of agreements and practices distorting competition]

1. The following shall be prohibited and is incompatible with the common market: all agreements between undertakings, decisions of associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:
  - (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
  - (b) limit or control production, markets, technical development, or investment;
  - (c) share markets or sources of supply;
  - (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
  - (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.
2. Any agreements or decisions prohibited pursuant to this article shall be automatically void.
3. The provisions of para. (1) may, however, be declared inapplicable in the case of:
  - any agreement or category of agreements between undertakings,

- any decision or category of decisions by associations of undertakings,
- any concerted practice or category of concerted practices,

which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:

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

### **Article 82 EC Treaty**

[Prohibition of abuse of a dominant position within the common market]

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

Such abuse may, in particular, consist in:

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

## **II.**

The Members shall act in compliance with the following checklist:

DO	DON'T
<b>Application of competition law</b>	
<p>Articles 81 and 82 EC Treaty may be applicable to the foundation and activities of a Consortium.</p>	<p>Do not assume that conflicts with competition law are excluded simply by the fact that the Consortium complies with the provisions of the REACH.</p>
<b>Consultation in Matters of Competition Law</b>	
<p>An in-house legal expert or the company compliance officer or an external legal counsel should be consulted whenever there are uncertainties relating to compliance with competition law.</p> <p>All Consortium meetings/discussions which are not in compliance with the Code of Conduct shall be stopped until a legal expert is involved.</p>	<p>Do not assume that the Code of Conduct deals with all competition law issues exhaustively. Essentially, compliance with Articles 81 and 82 EC Treaty can be determined only on the basis of market impact in each individual case. The Code may therefore be regarded only as a source of general conduct recommendations.</p>
<b>Activities of the Consortium</b>	
<p>Cooperation within the scope of the Consortium should be restricted to the initially defined goals and purposes of the cooperation.</p>	<p>Pursuant to Articles 81 and 82 EC Treaty the following activities are prohibited within the scope of the Consortium:</p> <ul style="list-style-type: none"> <li>- Coming to arrangements on prices, markets and customers (see Article 81 para. 1 (a) to (e) EC Treaty);</li> <li>- Joint boycotting of other companies;</li> <li>- Unjustified unequal treatment of trade partners;</li> <li>- The abusive exploitation of a dominant market position.</li> </ul>
<b>Exchange of Confidential Information</b>	
<p>A trustee may be involved for the exchange of confidential information, if required.</p>	<p>The exchange of confidential information concerning market behaviour is inadmissible, specifically as it relates to</p>

- production capacities,
- production or sales volumes,
- import volumes,
- market shares,
- price policy,
- distribution and marketing terms,
- marketing strategies,
- information regarding supplier relationships.

#### **Documentation on Cooperation**

Minutes of all meetings of the Consortium shall be kept, which detail the subject of the meeting.

The contents of the minutes shall be reviewed by an in-house legal expert or the company compliance officer prior to sending them to all participants of the Consortium.

All meetings which are not in compliance with the Code of Conduct shall be stopped until a legal expert is involved.

**Annex 5:  
Names and Addresses**

**1. Representative [Deputy] of Regular Members in the Steering Committee**

*Company name and postal address ...*

*Name of Representatives [Deputy] .... /telephone, fax, email*

**2. Lead Company**

*Company name and postal address ...*

**3.**

**Annex 6:**  
**Members' Existing Studies on Core Data**

*(Note:*

*State here the Studies which certain Consortium Members wish to make available to the Consortium for purposes of the REACH registration. Clearly identify the Study, including date, author and end point to which the Study relates, etc. Please also record whether a suitable summary and/or robust summary concerning the Study have already been put in place for registration pursuant to Article 9(a)(vi) and (vii) REACH)*

**Annex 7:  
Valuation Rules**

***Note:***

*Please disclose here the rules for the financial valuation of existing Studies (Appendix 6).*

*For example, the following valuation rules, which have been developed in practice, could be cited:*

**1. General**

- a) The REACH registration of a substance requires Studies on physico-chemical, ecotoxicological and toxicological properties, as well as Studies on human and environmental exposure.
- b) In keeping with the Consortium Agreement, each Consortium Member is obliged to contribute all Studies, test data and other Information needed for registration according to REACH and to make such Information available to other Consortium Members, usually against compensation of costs.
- c) The following rules apply for the valuation of the Studies, test data and other Information (i) contributed by Consortium Members to the Consortium or (ii) generated or established by the Consortium, which together with the aforementioned Information are made available to later Members.
- d) The rules also apply if, within the framework of SIEF, the Steering Committee awards third parties with usage rights to Studies, test data and/or other Information contributed to the Consortium by individual Members, or generated or established by the Consortium within the scope of the present Agreement.
- e) The aforementioned reports are initially evaluated with respect to their scientific value for registration pursuant to REACH. In a second step, their financial value is calculated through the use of various mark-ups and deductions.

- f) 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' requirements for a high quality report are satisfied.

## 2. Scientific Evaluation

- a) For reports which are contributed by individual Members the supplier provides the Consortium with 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.
- b) The quality of the reports is determined by the Steering Committee (or by experts commissioned by it) in accordance with the *Klimisch et al*<sup>4</sup> 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.

The chapter on "Categories of reliability" of the aforementioned publication elaborates in detail on the individual categories.

- c) The chapter "Criteria for reliability categories" of the *Klimisch et al* publication contains detailed descriptions concerning the minimum requirements for Studies which were not fully performed or documented in accordance with currently accepted standards and which were thus classified under category (2) "reliable with restrictions".
- d) Allocation to one of 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. An exception is provided for the reports in category (2) "reliable with restrictions", which must be further differentiated for the purpose of the subsequent financial valuation. In this case, in addition to the requirement stated above, supplementary detailed documentation, supported by the greatest level of detail possible, must be prepared. As a rule, it should be noted that the absence of

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<sup>4</sup> Klimisch/Andrae/Tillmann, *A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data*, Regulatory Toxicology and Pharmacology 25 (1997), pp. 1–5.

certain information must not be such that it can significantly affect the recipient's confidence in the correctness of the results and conclusions.

- e) 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.
- f) If the documents (IUCLID data record and/or robust summary) submitted by a party supplying a report are not in conformity with the *state of the art* or the requirements of the present Valuation Rules, the Steering Committee may demand up to two subsequent improvements.
- g) If serious uncertainties or reasonable cause for doubt continue to exist despite the subsequent improvements, the supplier must provide the experts commissioned for the valuation with the original Study report and (if relevant) the accompanying raw data in an appropriate form. If the supplier does not meet this requirement, the report is classified under category (4) as "not assignable".

### 3. Financial Valuation

- a) 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 detached from the subsequent compensation 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.
- b) The assessment basis for determining 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 the following measures:
  - i) preliminary testing for determining test concentrations
  - ii) Substance testing according to the standard protocol
  - iii) development of suitable analytical methods
  - iv) supplementary analyses
    - (1) Substance characterization
    - (2) stability in test medium

- (3) concentration in test medium
- v) administrative expenses
  - (1) processing and professional support by the commissioning party
  - (2) travel expenses
  - (3) archival of the test Substance and raw data
  - (4) preparation of IUCLID data set and robust summary.

The calculation only includes expenses which are verifiably documented or (if such documentation is not available) which can be justified with sufficient plausibility.

- c) The expenses for preliminary testing and Substance testing according to the standard protocol are calculated as the mathematical average of the prices charged by the following three European testing institutes according to their price lists:
  - i) Testing Institute A [*determined by the Consortium Members*]
  - ii) Testing Institute B [*determined by the Consortium Members*]
  - iii) Testing Institute C [*determined by the Consortium Members*].

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

- d) 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/calculation is determined from the difference presented in the price lists of institutes (or is to be inquired into there).
- e) 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 (excluding GLP). Otherwise, the classification to the respective category is placed in doubt.
- f) 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 (i. e. 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 (fixed sum).

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

- g) The calculation of expenses for Substance analysis, for which no market prices are available, requires from the party supplying the report the following information for each analytical procedure:
  - i) brief description of the procedure or method, including the limit of detection
  - ii) estimated costs for the development or provision <sup>5</sup> of the procedure or method
  - iii) costs per analysis
  - iv) number of analyses performed.

The development and provision costs can also be included in the costs for each analysis.

- h) A fixed surcharge of 15 %<sup>6</sup> of the sum total of experimental costs (Substance testing and analysis) is charged for administrative expenses (processing and professional support by the commissioning party, travel expenses, archival of the test Substance and raw data, preparation of IUCLID data set and robust summary). In the case of significant amounts in excess of the above surcharge, the expenses are to be substantiated and documented individually.
- i) The decision to conduct a Study involves the risk that the Study results could adversely affect or prevent future Substance marketing; hence, the individual

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

<sup>6</sup> The Guidance on data sharing issued by the ECHA in September 2007 establishes a surcharge of 3 to 20 % depending on the value of the Study. The percentage declines if the value of the Study rises. The surcharge laid down in par. 3 (h) of this Annex could therefore also be formulated with the same flexibility (ranging from 2 to 30 %).

Member contributing a report to the Consortium exposed himself/herself to the risk that the investments could result in a Study of minor (or no) benefit. The other Members are not exposed to this risk since they already know the Study result. Therefore, the contributing Member is granted a fixed surcharge of 30 %<sup>7</sup> of experimental costs.

- j) The current value of a given report is comprised of the experimental and administrative expenses, as well as the risk premium specified above.

#### 4. Example: Determination of Scientific and Financial Value of 2 Reports (Current Value)

- a) Preliminary note:

All incoming data used in this example were selected at random and do not necessarily reflect any realistic situations and current costs.

- b) Substance testing

	Report 1	Report 2
Owner	Member A	Member B
Year of testing	2001	1984
Method	OECD Guideline xyz	similar to OECD Guideline xyz
GLP	yes	No
Analysis of test Substance	pharmaceutical grade 99.9 %	unknown, presumably >99 %
Stability	yes	unknown, reliably yes
Concentration monitoring	yes	Yes

<sup>7</sup> In the Guidance on data sharing issued by the ECHA in September 2007 this surcharge ("risk factor") of 10 to 30 % is considered as justified for Studies of higher value according to Annexes IX and X REACH. The surcharge laid down in par. 3 (i) of this Annex could therefore also be formulated with the same flexibility (ranging from 10 to 30 %).

Reliability	(1) reliable without restriction	(2) reliable with restrictions
Comments	Study conducted in accordance with OECD, EC and EPA test guidelines and in accordance with GLP.	Several details of test conditions are not given, e. g. sex, age or body weight of the test animals, housing conditions etc. However, the Study is acceptable since the general conduct of the Study is acceptable and since a detailed description of the observations is provided in the report.

## c) Analyses

Test Substance	standard	standard
Stability	standard	standard
Concentration monitoring		
Method	literature	literature
Development	none	None
Provision		
Working days	10	8
Per diem rate	€ 600	€ 600
Analysis costs	€ 100 per analysis	€ 100 per analysis
Number of analyses	60	50

## d) Determination of the current value of the reports

Type of expense/surcharge/deduction	Report 1		Report 2	
Preliminary test to determine concentration	€		€	
	<del>25,000</del>		<del>25,000</del>	
Test per standard protocol	€		€	
	<del>100,000</del>		<del>100,000</del>	
Without GLP	0		€ -	
			<del>20,000</del>	
Other deficiencies	0		€ -	
			<del>10,000</del>	
Costs of Substance testing		€		€
		<del>125,000</del>		<del>105,000</del>
Development of analytical procedure/method	0		0	
Provision of analytical procedure/method	€ 6,000		€ 4,800	
Analysis of test Substance	€ 1,000		0	
Stability	€ 500		0	
Concentration monitoring (60/50 analyses at € 100)	€ 6,000		€ 5,000	
Analysis costs		€		€ 9,800
		<del>12,500</del>		
Experimental costs		€		€
		<del>148,500</del>		<del>114,800</del>
Administrative costs (15 % of experimental costs)	€		€	
	22,275		17,220	
Risk premium (30 % of experimental costs)	€		€	
	44,550		34,440	
Total surcharges		€		€
		<del>66,825</del>		<del>51,660</del>
Current report value		€		€
		<del>215,225</del>		<del>166,460</del>

**[optional: Annex 8:  
Identified Uses of Regular Members to the Extent Treated in the Chemical Safety  
Report]**

**(Note:**

*State only the “identified uses” (Article 3 No. 25 REACH) subject to treatment in the chemical safety report of the Consortium. For reasons related to competition law, only such uses are to be included in Annex 7 which are described in the technical instruction sheets or other documentation accessible to the professional community. If the Consortium is to include niche applications in the chemical safety report which are not accessible to the professional community, it may be necessary to channel information through a neutral third party (trustee).*

*Annex 7 does not apply if the Consortium submits only the core data.)*

## Annex 9:<sup>8</sup> Cost Allocation Key

### **Note:**

*Please disclose the key for the allocation of Consortium costs among the Members (Regular Members and Associate Members) at this point.*

*It should be noted that according to No. V.1.4 of the Model Agreement, the allocation of current expenses (No. V.1.2 (c)) among all Members (Regular Members and Associate Members) is carried out at equal shares. If this is not desired, this clause of the Agreement would have to be modified.*

*As an example, the costs of existing Studies and new Studies (generated by the Consortium) are calculated on the basis of the following cost allocation key:*

### **1. General**

- a) The cost allocation key serves the fair allocation of costs of Studies, test data and other information required for the REACH registration among the Members.
- b) Cost allocations can be calculated for all reports to end points for which information is required according to Annexes V to VIII REACH [unless the Members agreed according to Section 3.1 (2) of this Agreement in Annex ... not to financially evaluate the Study and not to consider it for cost sharing<sup>9</sup>].
- c) A Member can normally submit only one report per end point for a cost allocation. If the Member has several redundant reports at the same end point, they can be used for securing the key Study. For non-redundant reports, the

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<sup>8</sup> The valuation rules displayed here stem from the practice of cooperation in voluntary consortia according to the ICCA/OECD programme for existing chemical substances and have been developed in light of the valuation rules for Studies (see Annex 7 of this Model Agreement). In the drafters' opinion, the cost regulation in Annexes 7 and 9 of this Model Agreement correspond to the basic principles "fair, transparent and non discriminatory" as stipulated in Articles 27.6 and 30.1 REACH. This is confirmed by the Guidance on Data Sharing issued by the ECHA in September 2007 (based on RI 3.4).

<sup>9</sup> Experiences in former consortia have shown that Studies to end points available at low costs (representing the major part of the Studies required pursuant to Annexes VII and VIII) are submitted several times and are complementary in about equal shares. Thus, in practice, the parties might have an interest not to evaluate such Studies or to evaluate them in a simple way (i. e. somewhat superficially and, thus, not according to the elaborate valuation rules laid down in Annex 7) in order to minimize costs and administrative expenses. Accordingly, for those Studies, another option would be to (pursuant to Section 3.1 (2) of this Agreement) either abstain completely from evaluation and cost sharing or to apply a simple/flat assessed-value after mutual consent (see para. (2) a) of this Annex).

Steering Committee makes the decision whether and to what extent they can be included in the cost allocation.

- d) For Studies which are not required pursuant to Annex VII to X REACH or Studies which relate to issues for which no standard protocol is available, the Steering Committee decides whether or not such Studies are to be included in the Registration Dossier and in cost allocation.

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

- a) The current value of a given report, determined in accordance with the rules of financial valuation of Studies, test data and other information (Annex 6 of this Agreement) [*optional*: the value laid down according to Section 3.1 (2) of this Agreement in Annex ...]<sup>10</sup> serves as the measuring base for cost allocation and compensation.
- b) Since the owners of the reports contributed to the Consortium, other Regular Members should only be granted the right to use the reports for the purpose of Substance registration pursuant to REACH; the other Regular Members are eligible for reduction of ... %<sup>11</sup> relative to the current value of the report. Any usage of the reports for other purposes requires a separate bilateral agreement.

## 3. Cost Allocation among the Consortium Members

- a) The Regular Members share equally the costs of the Studies, test data and other information that they are required to submit to satisfy their registration requirements within their tonnage bands specified in Annex 2 of the present Agreement.<sup>12</sup> [*optional*: By written declaration vis-à-vis the Steering Committee

<sup>10</sup> See footnote above.

<sup>11</sup> In general, a reduction vis-à-vis the determined costs of the Study seems justified, since the rights to use are not conferrable (sec. II par. 4.1 of the Model Agreement) and since the rights vis-à-vis third parties (e.g. in a SIEF) to utilize the Study remain in any case with the owner of the Study. A certain percentage of reduction cannot be recommended since it depends on the circumstances in the individual case. A rather low reduction may be justified if most of the Members of the Consortium are identical to the participants in the SIEF and extensive reference against refund of costs is thus improbable. On the other hand, higher reduction may be justified if the Study is suitable for extensive reference within the context of REACH and for voluminous utilisation outside the context of REACH. Against this background, a reduction of 25 to 50 % might be appropriate in general. However, if the right to use is provided to the Members of the Consortium for world-wide registration, the reduction must be lower.

<sup>12</sup> In Section 7 (Cost sharing) of the Guidance on data sharing issued by ECHA a “volume factor” for the tonnage band > 1000 t/a is seen as justified since it makes a difference whether e. g. 1 100 t/a or 50 000 t/a are produced. Thus, a respective quantity scale may be incorporated here. In such case, tonnage bands are recommended instead of precise declarations of production volumes. The latter would entail problems under cartel law which could afford the engagement of a trustee. This would complicate the work in a Consortium. Moreover, great imbalances between the

Regular Members may share the costs concerning such Studies, test data and other information that they are not or not yet required to submit within their tonnage bands specified in Annex 2 of the present Agreement; in such case, they obtain the usage rights specified under No. II.4. of the present Agreement concerning such Studies, test data and other information.]

- b) If, after conclusion of the Agreement, Regular Members are required to submit appropriate additional information to the Agency in accordance with Article 12 REACH due to a change in the annual quantities manufactured or imported by them, they participate in cost sharing if they use Studies, test data or other information which they have not co-financed before.
- c) The Regular Members share equally the costs of the Studies, test data and other information required for the desired registration according to tonnage bands.
- d) By contribution of a report of category (1) “reliable without restriction”, the prorated share of a full Member is considered as paid for the relevant end point. This applies to all Regular Members who contribute reports of equal value. The cost allocation is carried out by the remaining Regular Members.
- e) If reports from category (1) “reliable without restriction” and (2) “reliable with restrictions” are available at the same end point, the report with the higher value is used as a key Study for cost allocation calculation. The party supplying a report of a lesser value contributes to cost allocation according to the value difference, calculated for the Report according to Annex 6 of the Agreement.
- f) If a report from category (1) “reliable without restriction” is not in existence, but only one or several reports from (2) “reliable with restrictions” are available, the current value of the report with the highest value is used as a key Study for the calculation of the cost allocation.
- g) In the case of Studies, test data and other information which are contributed by Associate Members, the Management Committee decides whether they are needed or desired for the Registration Dossier. In the event of a positive decision, for purposes of cost allocation for that respective end point, the Associate Members are considered as Regular Members . The Associate Member receives the allocated compensation, but does not pay any compensation to other Members and

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regular Members concerning the benefited affiliates can be taken into consideration through an additional “corporate factor”.

does not receive any usage rights to the other reports. Any discrepancies from this procedure are to be agreed upon separately.

#### **4. Compensation**

- a) The total compensation results from the sum total of contributions to be paid by participating Members in consideration of the performance via the submission of reports.
- b) The total amount of the compensation is divided among the owners of the supplied reports according to the value determined for the respective report under Annex 6 of the present Agreement.

#### **5. Entry of a New Full Member (New Member)**

- a) Each new Member upon entry pays a share of the costs according to No. VI.1.3 of the Agreement. The share covers the contribution to costs of Studies, test data and other information as well as “advantage compensation”, which takes into account the initiative, commitment and any other preliminary performance provided by previous Members.
- b) The financial contribution paid by new Members for the Studies, test data and other information is determined in accordance with the same criteria as that of the other Consortium Members. In the cost allocation, the number of shares is raised by 1 for every new Member. [*optional*: If the Members excluded Studies from the evaluation and cost refund according to Section 3.1 (2) of this Agreement, a flat sum of € ... must be added to financial contribution of the new Member unless the new Member disposes of a respective Study.]
- c) If a new Member enters the Consortium following the submission of the Registration Dossier, the Member must pay the prorated share for all Studies, test data and other information contained in the Registration Dossier. A cost allocation is only possible for the reports of the new Member which are subsequently requested by the authorities.
- d) The “advantage compensation” which accounts for the general costs incurred by the Consortium to date is determined by the progress of the Consortium’s activities and is levied for each end point of the Registration Dossier. It amounts to 0 % at the time of conclusion of the Consortium Agreement and rises to 100 %

of the new Member's share for Studies, test data and other information by the time the Registration Dossier is completed. The exact value is determined by the Steering Committee within the scope of the entry negotiations.

- e) The maximum amount of the share of costs for a new Member may not exceed 50 % of the value of the Studies, test data and other information (exclusive use for REACH).
- f) The share of costs paid by new Members is paid out to the former Members as a refund of the prorated costs of the previously smaller Consortium.

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

- a) Third parties subject to registration requirements but who are not (nor will be) Members, e. g. as in the case of rejection of an applicant as full Member, may be (via the Steering Committee) integrated into the joint submission of Core Data and be granted the right (pursuant to Section 4.1 (3) to (5) of this Agreement) to refer to Studies, test data and other information – e. g. waiving argumentations, reasoning of testing proposals – of the Consortium. Concerning data already registered, such rights are granted through issuance of a Letter of Access (model in Annex 9 of this Agreement).
- b) The cost share for the joint submission of core data and for the provision of rights to use will be fixed by the Steering Committee analogously to the regulation in par. 5 of this Annex.<sup>13</sup> Concerning the advantage compensation (par. 5.d of this Annex), 100 % should be calculated since the registrant does not contribute to the work of the Consortium.
- c) The cost settlement obtained for granting rights to use the Studies generated by the Consortium according to Section 3.2 [*optional*: and according to Section 4.2 (2)] of this Agreement is allocated at equal shares to the Members participating in cost allocation. For the rest, the owner of the Studies and information submitted are entitled to a pro-rata share of costs.

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<sup>13</sup> This cost settlement is an approximation on the regulations for a Consortium Member joining after registration. It has to be assumed that it constitutes a just, transparent and non-discriminatory cost settlement (see Articles 27. 3 and 30.1 REACH). Furthermore, it is advantageous vis-à-vis the legally prescribed sharing of costs in equal shares in case no agreement on costs can be reached (Article 30.1 REACH).

## 7. Example of Cost Allocation and Compensation for Reports at End Point XY

The starting figures cited in this example originate from the example in Annex 6 or, like the figures in the aforesaid Annex, were chosen at random and do not necessarily reflect any realistic situations and current costs.

### a) Assumptions for the calculation

Number of Members participating in cost allocation of reports at end point XY	7
Number of contributed reports at end point XY	2

### b) Value of reports in the case of limitation of usage exclusively for REACH

	Report 1		Report 2	
Current value of reports according to Annex 6		€ 215,225		€ 166,460
Deduction for limitation of usage for REACH (30 % of current value) <sup>14</sup>	-€ 64,598		-€ 49,938	
Value of reports in case of limitation of usage exclusively for REACH		€ 150,727		€ 116,522

### c) Cost allocation

Value of key Study (exclusive usage for REACH)	€ 150,727
Share per Member (150,727 / 7)	€ 21,532
Financial contribution of Member A (Owner of Report 1)	€ 0
Financial contribution of Member B (Owner of Report 2) according to the lower value: $21,532 \times (150,727 - 116,522) /$	€ 4,886

<sup>14</sup> The reduction of 30 % is meant as example, see footnote 16.

150,727	
Financial contribution of other Members: $5 \times 21,532$	€ 107,660

## d) Compensation

Total amount of cost allocation ( $107,660 + 4,886$ )	€ 112,546
Share for Member A according to the higher value of Report 1 $112,546 \times 150,727 / (150,727 + 116,522)$	€ 63,475
Share of Member B according to lower value of Report 2 $112,546 \times 116,522 / (150,727 + 116,522)$	€ 49,071

## e) Entry of a new Member (without own Studies, test data and other information)

Share per Member (previously): $150,727 / 7$	€ 21,532
Share per Member (new): $150,727 / (7+1)$	€ 18,841
Benefit premium (e. g. 60 % of the share of a Member (new) for entry one year after the formation of the Consortium)	€ 11,305
Maximum amount for a new Member (50 % of the value of the key Study)	€ 75,364
Share of costs for a new Member: $18,841 + 11,305$	€ 30,146
Refund to previous Members due to the reduced share per Member: $18,841 / 7$	€ 2,692
Refund to previous Members: $11,305 / 7$	€ 1,615

## f) Right to use (Letter of Access)

Share of costs for a Letter of Access: as under h), but 100 % advantage compensation.	37.682 €
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**[optional: Annex 10:  
Letter of Access (Model)]**

*[address of regulatory authority]*

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

Dear Sirs,

The Consortium<sup>15</sup> on the registration of the substance ..... *[insert the short name of the substance to be registered]* under REACH *[insert name of law]* (hereinafter referred to as “the Consortium”) agrees that the data, Studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments specified in detail below owned by Members and submitted by the Consortium in support of the registration under REACH *[insert name of law]* of

Substance ..... *[insert the exact name of the substance to be registered]*

(hereinafter collectively referred to as the “Dossier”), may be referred

by Applicant: *Company XYZ*

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

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

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

1. The right of referral only gives access to the Dossier of the substance for the registration as specified above.

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<sup>15</sup> At the date of issue of this Letter of Access the Members are: ..... *[insert names of the Members]*.

2. The right of referral is solely granted in favour of *Company XYZ* and is not transferable to any other entity or person.
3. *Company XYZ* is not authorised to receive any copies of the Dossier nor is *Company XYZ* authorised to inspect or view the Dossier or any related specific document in whole or in part.<sup>16</sup>
4. This Letter of Access shall under no circumstances be construed as granting *Company XYZ* any property rights whatsoever in the Dossier.
5. Nothing in this letter shall require *The Consortium* to file any additional data.

Signature: Authorized Representative of the Consortium]

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<sup>16</sup> Depending on the contract between the Consortium and *Company XYZ*, the latter may receive the results, summaries and/or robust summaries of Studies directly from the Consortium.

**Seite 6: [1] Kommentar [14]**

The abstract definition of affiliates according to Section II. par. 1.3 is insufficient for the joint submission of the core data since Annex VI par. 1.2 REACH Reg. requires their designation by name. The obligations arising from Articles 11 and 19 REACH Reg. are met if the affiliates of the regular members manufacturing/importing the same substance (and thus belonging to the same SIEF) are integrated into the registration. The nomination of the affiliates to be integrated only takes place shortly before registration, as the corporate structure of the regular members may change until registration by the lead company. No separate nomination of the affiliates for the joint registration is necessary if the affiliates are designated via a listing in Annex 3 according to the alternative in Section II. par. 1.3 of this Agreement. In this way, only the listed affiliates are to be integrated (inclusive of later amendments by the steering committee).

**Seite 6: [2] Kommentar [15]**

Submission of the Registration Dossier with the agreement of all Members of the Consortium does not mean in any case that Members with lower tonnage bands and later deadlines submit their registration prior to the deadline relevant for them (which is allowed in accordance with Art. 23 (4)). They can submit their individual information as specified in Art. 11 (1) subparagraph 3 at a later date and hereby refer to the Registration Dossier already submitted by the Lead Company. If necessary they get a letter of access by the Lead Company.

**Seite 9: [3] Kommentar [26]**

The abstract definition of “affiliates” according to Section II. par. 1.3 is insufficient for the joint submission of the core data since Annex VI par. 1.2 REACH Reg. requires their designation by name. The obligations arising from Articles 11 and 19 REACH Reg. are met if the affiliates of the regular members manufacturing/importing the same substance (and thus belonging to the same SIEF) are integrated into the registration. The nomination of the affiliates to be integrated takes place only shortly before registration, since the corporate structure of the regular members may change until such registration by the lead company. No separate nomination of the affiliates for the joint registration is necessary if the affiliates are designated via a listing in Annex 3 according to the alternative in Section II. par. 1.3 of this Agreement. Then, only the listed affiliates are to be integrated. In case the nomination is not effected or in case affiliates of the regular members (manufacturing/importing the same substance) join after submission of the registration by the lead company, the right (likewise) granted to refer to the studies/core data submitted by the lead company comes into effect.

**Seite 9: [4] Kommentar [28]**

The steering committee may establish its own rules of procedure, which need not be governed by the Agreement. The steering committee may establish sub-committees (e.g. a technical committee) or working groups. This also need not be specifically governed by the Agreement. As a rule, the lack of suitable experts limits the setting up of fixed working groups in particular, since many companies will engage in more than one consortium.

**Seite 12: [5] Kommentar [32]**

It is likely that information about available studies on core data is already exchanged during the pre-phase of consortium formation. It is recommended that the results of this stock-taking be included in an Annex to the Agreement (here Annex 6). Likewise, the existing published studies have probably also been determined during the pre-phase and could therefore also be included in the Annex. This may concern the risk assessments in particular, worked out in HERA or ICCA HPV. However, the members are further required to provide the consortium with all existing and available studies (e. g. subsequently finalised studies). The working plan (Section II par. 6) governs the time schedule and other technical details of data transfer.

**Seite 12: [6] Kommentar [34]**

It is recommended that the valuation rules be defined in the negotiations prior to conclusion of the consortium agreement and then attached to the Agreement as an Annex (in the Model Agreement Annex 7) in order to avoid disputes during the course of the consortium work. In Annex 7 of the Model Agreement, an example for such valuation rules is presented.

**Seite 12: [7] Kommentar [35]**

Experiences in former consortia have shown that studies to end points available at low costs (representing the major part of the studies required pursuant to Annexes VII and VIII) are submitted several times or are submitted complementarily by the regular members in about equal shares. Thus, in practice, the parties might

have an interest not to evaluate such studies or to evaluate them in a simple way (i. e. somewhat superficially and, thus, not according to the elaborate valuation rules laid down in Annex 7) in order to minimize costs and administrative expenses. Accordingly, for those studies, another option would be to list them in a separate annex and to either apply a simple/flat assessed-value after mutual consent or to abstain completely from evaluation and cost sharing. Furthermore, it is possible to agree in exceptional cases that all studies shall be evaluated in a simplified manner or that an evaluation shall be omitted completely. Members of the consortium who did not bring in an “inexpensive study” pay a flat sum fixed by the steering committee for obtaining their rights to use the studies. Pro-rated shares of the flat sum will be distributed to the owner of the “inexpensive studies” (see Annex 9).

#### **Seite 12: [8] Kommentar [36]**

The term “waiving” determines the well-founded derogation from testing requirements specified in Annexes VII to X. The term is well established among experts and is therefore used in this Model Agreement. Experience with Regulation 793/93 (on existing substances) has shown that “waiving” is a focus-point in the development of the registration dossier. “Waiving” has an impacts on the dimension of costs of the registration.

#### **Seite 12: [9] Kommentar [37]**

After the provisions on data sharing (Title III REACH Reg.) have entered into force on 1. June 2008 and after the respective SIEFs have been formed (1 December 2008), it will have to be considered that prior to testings (according to Annexes VII and VIII REACH Reg.) a preliminary query in the SIEF is necessary. If the consortium does not include all members of the SIEF, vertebrate studies available within the SIEF must be acquired. Other studies available in the SIEF can (but do not need to) be acquired. If a study (according to Annexes VII and VIII REACH Reg.) is lacking, an agreement pursuant to Article 30 par. 2 REACH Reg. must be sought: Members of the consortium and manufacturers/importers within the same SIEF who are not members of the consortium must agree on a joint preparation of the study. The consortium may offer (to the other SIEF-participants) to conduct the study independently – or, also, on behalf of the consortium with a share of costs. These obligations do not exist before Title III REACH Reg. enters into force on 1 June 2008.

#### **Seite 13: [10] Kommentar [38]**

The option displayed here also takes into consideration that Section II. par. 2.3 of this Agreement designates the integration of the dossier evaluation according to Title VI REACH Reg. as an option. However, the integration is recommended. ECHA decides, during dossier evaluation, in accordance with Title VI REACH Reg. whether tests shall be carried out according to Annexes IX and X REACH Reg. This decision will be directed to single members of the consortium, not to the consortium as a whole. However, it is recommended that an agreement be made on how the members’ rights during the dossier-evaluation-procedure (e. g. the right to comment, or to appeal against decisions of ECHA) shall be attended to and to agree on whether the necessary test(s) (due to additional sentential testing requirements) shall be jointly performed. The cost key agreed upon also applies to such tests.

#### **Seite 15: [11] Kommentar [48]**

This provision (of the agreement) shall take into consideration the legal obligation to jointly submit core data according to Articles 11 and 19 REACH Reg. However, Articles 11 and 19 REACH Reg. require substance identity, i.e. within a substance group identity of the substance with the substances listed in Annex 1 of this Agreement is required. Here the potential registrant will eventually have to adequately prove that his/her substance is identical to the substances listed in Annex 1 of this Agreement. Articles 11 and 19 do not contain a cost regulation (in contrast to the provisions on data sharing in Articles 27 and 30 REACH Reg.). Thus, this agreement must provide rules for this matter. Annex 9 of this Model Agreement contains recommendation hereunto. A model for such an agreement of the Consortium with a third party is provided in Annex F of the project.

#### **Seite 15: [12] Kommentar [49]**

After registration by the consortium the legal obligations to joint submission of core data according to Articles 11 and 19 REACH Reg. cease to exist. However, the steering committees may be empowered to issue a letter of access in this case. So the objectives of Art. 11 and 19 REACH Reg. are fulfilled. Cartel law may require access to core data in order to avoid discriminations, also. The cost regulation will be effected by agreement as specified in Annex 9 of this Agreement. A model for such an agreement of the Consortium with a third party is provided in Annex G of the project.

**Seite 17: [13] Kommentar [57]**

Liability is based on the national law stipulated in Section VIII. 2 (1) of this Agreement. A more detailed specification is not possible given the large number of liability cases. Among the members of the consortium, this liability regulation applies e.g. to studies submitted pursuant to Section III. par. 1.1 of the Model Agreement. According to the proposed regulation, members are liable vis-à-vis other members for gross negligence or wilful misconduct in the development of the study which could lead to incorrect safety data sheets and thus to liability vis-à-vis actors in the product chain.

**Seite 17: [14] Kommentar [58]**

Liability is based on national law. However, it cannot be stipulated in this Agreement which national law will be applicable. The applicability of the relevant national law in case of liability vis-à-vis third parties follows the rules of conflict of laws (private international law). Liability vis-à-vis third parties might become an issue if the chemical safety reports rely on wrong data since this could entail mistakes in the guidance on safe use of the substance. In a case like this liability of the members among each other for correctness of their studies (Section VI. par. 5.1 of the Model Agreement) could have effect too.

**Seite 17: [15] Kommentar [59]**

Occasionally there are reservations against imposing contract penalties. However, the contract penalties primarily serve the protection of all those involved rather than serving the purpose of sanctions. The advantage of contract penalties is as follows: The burden of proof for a specific damage or for the causation of conduct resulting in the damage etc. ceases to apply, and consequently the participants will be put under pressure to comply with their contractual obligations – in this case to maintain confidentiality and protection of the rights to studies. For this reason, contract penalties are recommended.

**Seite 17: [16] Kommentar [60]**

The amount of the contract penalty should be reasonably and appropriately determined with a view to the economic significance of the information exchanged in the individual case; the purpose is to encourage participants to exercise great care and diligence with respect to information. However, the penalty must not be unreasonably high. An amount of e. g. € 100,000 is considered by the Project Group to be adequate since, generally speaking, 1000 t sold correspond to income of approx. € 50,000 – 100,000. If a calculation model were used rather than a fixed amount, 50 % of the expenses for the development of information that is related to the violation would be appropriate according to practical experience.