

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 & WIDMAIER¹
with the collaboration of the members of the project group² formed for this project

→→ Appendix D

Model Preliminary Agreement on the Communication in the SIEF

Frankfurt, June 2007

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² 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 Preliminary Agreement, which is a supplement to the 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 provision. Thereby, other conceivable (more) detailed provisions were omitted. Consequently, the Model Preliminary 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.

This Model Preliminary Agreement is based upon 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 II par. 8.3 of this Model Preliminary Agreement.

Preliminary Agreement on the Communication in the SIEF

between

Manufacturer 1, 2 etc.

Importer 1, 2 etc.

[optional: and

Only Representative]

– jointly: the “parties” –

Kommentar [1]: An “Only Representative” pursuant to Article 8 REACH Reg. can be appointed by a manufacturer who is domiciled outside the European Community. This manufacturer will then have the same obligations as an importer and will as such be able to participate in a consortium.

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I. Preamble

1. The parties are manufacturers, importers and/or “only representatives” of the substance ... [*designation of the substance with its substance name, inclusive of CAS- and EINECS-number*] with registered head offices in the European Union. The substance has phase-in status according to REACH Reg.

Kommentar [2]: Here, only the information according to Article 28 par. 1(a) REACH Reg. must be indicated. This information will be published by the Agency.

Under the provision of the REACH Reg., the parties are under an obligation to register the substance within the prescribed deadlines. Each of the parties will [*optional: have*] pre-register [*optional: pre-registered*] the substance according to Article 28 REACH Reg. [*optional: They already submitted a complete registration dossier.*] [*optional: The information of the parties on the substance ... is held by the Agency in accordance with Article 15 REACH Reg. as already recognized documents on substances for the exclusive use in plant protection and biocidal products.*]

2. The parties wish to clarify whether

- substances produced and/or imported by them are the “same phase-in-substances” within the meaning of Annex VI par. 2 REACH Reg. and whether they are therefore under an obligation to share data as members of a SIEF according to Articles 29 and 30 REACH Reg. and to thus jointly submit Core Data according to Articles 11 and 19 REACH Reg.,

Kommentar [3]: According to the Final Draft Guidance Document RIP 3.4 (Review 02 May, 2007) the pre-SIEF arises through pre-registration. The obligations in a SIEF according to Articles 29 and 30 only arise after substance identity has been established. This is subject matter of the agreement to this model.

- [*optional: – in case no substance identity has been established – the preconditions of the “grouping of substances and read-across approach” according to Annex XI section 1.5 are met*].

Kommentar [4]: The term “core data” is not a term derived from REACH Reg. However, it is commonly used for the following data: study summaries and robust study summaries in accordance with Article 10(a)(iv) and (vii) REACH Reg., classification and labelling, testing proposals as well as notes on quality assurance of information.

3. In case clarification according to subparagraph 2 resulted in substance identity [*optional: or showed that the preconditions of the “grouping of substances and read-across approach” according to Annex XI section 1.5 are met*], the parties wish to clarify next

Kommentar [5]: This option enables the parties to abstain from testing via *read-across*, thus avoiding vertebrate studies and saving costs. There is no legal obligation for this form of data sharing.

- whether they form a consortium *or*
- whether they agree on a simplified form of data sharing.

Kommentar [6]: Here, the Model Agreement in Appendix C is recommended.

Kommentar [7]: Here, the Model Agreements in Appendixes E, F or G are recommended.

II. Agreement

1. Definitions

- (1) *Affiliate*: a corporation which controls, is controlled by or is under common control of a regular member, with “control” meaning a combined voting stock of at least 50 %, whether via direct or indirect ownership.
- (2) *Core data*: data which must in any case be jointly submitted by the members of the consortium according to Article 11 par. 1.2 REACH Reg. Such data are:
- classification and labelling of a substance as specified in Annex VI section 4 REACH Reg.;
 - summaries of the information generated through application of Annexes VII to XI if required under Annex I;
 - robust study summaries of information generated through application of Annexes VII to XI if required according to Annex I;
 - testing proposals if required for application of Annexes IX and X.

Kommentar [8]: According to this definition, a minority share cannot lead to the rights and duties of an “affiliate”. Corporations holding minority shares of a regular member can only be integrated into a consortium through membership.

Kommentar [9]: The term “core data” is not a term derived from REACH Reg. In this Agreement, the term is used for the data indicated in the definition.

2. Exchange of information

- (1) The parties shall provide each other with the information necessary for examination and determination of the substance identity according to Annex VI section 2 REACH Reg. [*optional*: The parties shall provide to the Institute ..., as competent neutral trustee, the information necessary for examination and determination of the substance identity according to Annex VI section 2 REACH Reg. In this case, the trustee must establish whether and to what extent the substances produced and/or imported by the parties are identical. He/she shall inform the parties of the result without disclosure of the information received. The result is binding on the parties.]
- (2) [*optional*: The parties shall provide each other with the information necessary for examination of the “grouping of substances and read-across approach” according to Annex XI section 1.5 REACH Reg.] [*optional*: The parties shall provide to the institute ..., as competent neutral trustee, the information necessary for examination of the “grouping of substances and read-across approach” according

to Annex XI section 1.5 REACH-RG. In this case, the trustee must establish whether and to what extent the preconditions of the “grouping of substances and read-across approach” (as specified in Annex XI section 1.5 REACH Reg.) have been met. He/she shall inform the parties of the result without disclosure of the information he/she received. The result is binding on the parties.]

- (3) To the extent that the examination according to Section II. par. 2.1 of this Agreement shows that the same substance is manufactured and/or imported [optional: To the extent that the examination according to Section II. par. 2.2 of this Agreement shows that the preconditions for the “grouping of substances and read-across approach” pursuant to Annex XI section 1.5 REACH Reg. have been met] the parties shall provide each other [the Institute ... as competent neutral trustee] with all information required for the decision as to whether

- the formation of a consortium [optional: according to the Model Agreement published on the website ...] or
 - a simplified form of contractual data sharing [optional: according to the model ... published on the website]
- is to be undertaken.

Kommentar [10]: Insert here the website this model is published on.

Kommentar [11]: Here, the model agreement in Appendix C is recommended.

Kommentar [12]: Here, one of the model agreements E, F or G is recommended. Depending on the planning stage, one or several model agreements may be inserted here as the objectives of the examination.

Kommentar [13]: Insert here the website this model is published on.

- (4) A party shall leave the cooperation if the examination according to Section II. par. 2 shows that the substances produced and/or imported by said party are not identical to the substance produced and/or imported by the other parties [optional: or that the preconditions for the “grouping of substances and read-across approach” according to Annex XI section 1.5 REACH Reg. have not been met]. Paragraph 7.2 of this Agreement applies to this case.

Kommentar [14]: These members are in the wrong SIEF if substance identity is missing. This should be reported to ECHA so that those members can then be assigned to the proper SIEF.

- (5) In general, members are willing to integrate other manufacturers and/or importers of the same substance ... [optional: of substances which might be relevant for the grouping of substances and read-across approach according to Annex XI section 1.5 REACH Reg.] into the cooperation pursuant to this Agreement.

Kommentar [15]: This opening clause suggests itself for two reasons. First, REACH Reg. requires the cooperation of all members of a SIEF to the extent their substances are identical; cooperation within the substance group, is not demanded but certainly desired. Second, cartels law might prohibit the exclusion of other members of the SIEF.

3. Competition law compliance

- (1) The parties are aware that activities under this Agreement could represent a matter to which Articles 81 and 82 EC Treaty apply. The parties explicitly agree to

observe Articles 81 and 82 EC Treaty, Article 25 par. 2 REACH Reg. and the Code of Conduct attached in Annex 1.

- (2) It shall be examined on an individual-case basis whether a trustee appointed by the parties has to carry out the exchange and the evaluation of information or data, if those information or data are relevant to competition (law).

4. Confidentiality, Rights to Information

- (1) The parties shall maintain confidentiality vis-à-vis third parties concerning all information made available to them in the context of the cooperation and marked as “confidential” unless REACH Reg. or other laws contain an obligation to disclose the respective information. Affiliates, external experts, other competent externs and trustees (as specified in par. 5.4 and 5.5 below) are not “third parties” within the meaning of this provision. Confidentiality shall also be maintained for information commonly regarded as business secrets. The aforementioned obligations do not apply to information which has been demonstrably available to the public before receipt by the respective party or which became public through no fault of the recipient.
- (2) The parties agree to disseminate information to persons other than the staff specified under par. 5.3 only to the extent absolutely necessary for setting up the cooperation. This provision also applies to the staff of the parties’ Affiliates. The parties account for observance of the regulations in subparagraphs 1 and 2 by their Affiliates.
- (3) The rights of the parties to the information made available by them shall remain unaffected. The remaining parties are under an obligation to use the information exclusively within the scope of the present Preliminary Agreement. Particularly they must not use the information commercially.
- (4) In the event of non-compliance with the duties according to subparagraphs 1 to 3, the parties are entitled to exclude the breaching party from any further cooperation. The obligation to render compensation for damages in accordance with the legal provisions shall remain unaffected. [optional: In the event of non-compliance with the obligations specified under subparagraphs 1 to 3, the party shall pay a contractual penalty in the amount of ... €[insert amount] [optional: in the amount of ... % of the expenses incurred for information relating to the breach] to the other parties whose information is affected. The contractual penalty

Kommentar [16]: Pursuant to Article 25 par. 2.2 REACH Reg., registrants shall refrain from exchanging information concerning their market behaviour, in particular concerning production capacities, production or sales volumes, import volumes or market shares.

Kommentar [17]: Code of Conduct according to Annex 4 of the Model Consortium Agreement.

Kommentar [18]: The risk of a violation of cartel law is avoided or significantly alleviated if the exchange according to section II par. 2.1 and 2.2 is anyhow carried out by a trustee for the protection of the parties. Thus, the clause under par. 3.2 is only relevant if the parties exchange their information directly among each other.

Kommentar [19]: In particular, it must be considered that pursuant to Article 119 par. 1(e) REACH Reg. the results of toxicological and ecotoxicological studies must be published. Under Article 119 par. 2, study summaries will also be published if non-disclosure has not been requested. Furthermore, e.g. Article 22 par. 1(e) REACH Reg. lays down the obligation to submit new knowledge of the risks of the substance to the agency.

Kommentar [20]: E.g. US TOSCA stipulates the obligation to inform EPA on new knowledge of risks (...reporting).

Kommentar [21]: The members might have a reason to keep the cooperation as such secret. In such event, a suitable provision must be added here.

Kommentar [22]: The ECJ commonly regards “business secrets” in need of being protected any and all operational or business information meeting the following criteria: The information is only known to a closed group of persons; the holder wishes to keep the ... [1]

Kommentar [23]: This restriction seems appropriate in order to ensure the greatest possible degree of confidentiality.

Kommentar [24]: Occasionally, there are reservations against agreeing upon contract penalties. However, the contract penalties serve the protection of all those involved rather than sef ... [2]

Kommentar [25]: The amount of the contract penalty agreed upon should meet the following criteria: In the specific case it should be commensurate to the economic value of the exchanged infor ... [3]

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.**]

Kommentar [26]: By reversal of the burden of proof in respect to fault, as a consequence, all those involved will be encouraged to the greatest possible diligence in respect of their obligation to maintain confidentiality. Another option would be to impose here liability regardless of fault.

5. Organisation

- (1) This Agreement or the cooperation contemplated herein shall not constitute or be deemed to constitute a legal entity between the parties nor make a member agent or representative of another member. The parties shall not act jointly in external legal relations.
- (2) **Coordination of the cooperation** shall be undertaken by ... [*designation of the party*].
- (3) The parties shall assign **staff for the cooperation**. The names of the staff shall be listed in **Annex 2**.
- (4) The parties may include external experts called in by the staff designated under subparagraph 3. Such experts shall be made subject to the obligations under par. 4.1.
- (5) Subparagraph 4 equally applies to any trustee commissioned according to par. 3.2 for the purpose of ensuring compliance with competition law.
- (6) [*optional: The **working language** is*]

Kommentar [27]: It seems appropriate to also determine a coordinator in the preliminary phase, who "holds the reins" and probably assumes the function of the lead company in the event that a consortium is formed. This task can also be assigned to a consultant or to the secretariat of a product-specific association.

Kommentar [28]: This restriction concerning staff involved seems appropriate in order to ensure the greatest degree of confidentiality.

Kommentar [29]: International consortia will probably prefer the English language.

6. Expenses

- (1) Each party shall cover its own expenses for the cooperation unless otherwise expressly agreed upon among the parties on an individual basis. The parties carry the costs incurred by the trustee ... [*in equal shares/according to another cost key inserted here.*]
- (2) [*optional: ... [name of the party referred to in par. 5.2] shall obtain a refund of expenses incurred for coordination activities from the other parties upon presenting verification of such expenses.*]

7. Duration of the Preliminary Agreement

- (1) The Preliminary Agreement is of unlimited duration. It shall end upon the conclusion of a cooperation agreement between all or some of the parties or upon final agreement to not set up a cooperation.

- (2) If the cooperation agreement is not concluded or if a party does not become a member of said cooperation, the obligations specified in par. 4 of the present Preliminary Agreement shall continue to apply for a period of 12 years following initial registration of the substance by any party.
- (3) A party can withdraw from the Preliminary Agreement through a unilateral declaration to the other parties. In this case, subparagraph 2 shall apply to the departing party accordingly.

Kommentar [30]: The continuation of the confidentiality obligation over time is suitable and appropriate in order to exclude unauthorized use of information in the event of the consortium failing, or premature withdrawal of participants. The 12-year period is oriented towards the 12-year period stated in Article 25 par. 3 REACH Reg., stipulating that the agency may issue test data (vertebrate animal data) after a 12-year period free of charge.

8. Final Provisions

- (1) The legal relationships between the parties relative to the cooperation in the preliminary phase shall be governed exclusively by the present Preliminary Agreement; no other arrangements are in existence.
- (2) Any changes or amendments to the Preliminary Agreement must be in writing to be effective.
- (3) The Agreement is subject to the laws of [insert name of the country] without giving effect to any rules on conflict of laws.
- (4) [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 Members. The arbitral tribunal consists of three arbitrators: each party to the dispute 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 costs of arbitration shall be paid by the Members involved on equal terms; any out-of-court costs shall be borne by the party having incurred said costs. [optional: The arbitration tribunal shall decide on the regulation of the cost of arbitration including out-of-court costs incurred by the parties in accordance to the outcome of arbitration.] The language of the proceedings shall be ... [insert language in accordance to Section II par. 5.6]. The venue of arbitration shall be ... [insert the venue in accordance to Section II par. 8.5].]
- (5) Place of jurisdiction for any disputes among the parties is ... [name of place].

Kommentar [31]: In international agreements it might turn out to be difficult to agree on the applicable law since every party knows the law of the country of its origin best. The law applicable in the country of the "coordinator's" (see par. 5.2) registered office may suggest itself.

Kommentar [32]: 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.

Kommentar [33]: An arbitration agreement is advisable particularly in the event of an international consortium. This is why reference is made to the ICC Rules of Arbitration. If most members are German, other arbitration institutions might also be suitable such as Deutsche Institution für Schiedsgerichtsbarkeit e.V. (DIS) or Schiedsordnung der IHK Frankfurt/Main.

Kommentar [34]: An alternative for the allocation of cost would be to agree on an allocation with or without consideration of the outcome of the procedure.

Kommentar [35]: In international consortia, the jurisdictional venue may be a crucial issue in negotiations. In the event of dispute, it may be expedient to agree on the Court competent for the "Coordinator's" (see par. 5.2) registered office as the competent jurisdictional venue. In any event, there should be consistency with the applicable law (see Commentary [31]). This provision is only of very limited relevance, if the optional arbitration clause is agreed upon. It may then only concern legal action taken before national courts against the decision of the arbitration tribunal.

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

etc.

Annex 1: Code of Conduct

Annex 2: Appointed Staff Members

Kommentar [36]: Code of Conduct according to Annex 2 to the Preliminary Agreement for Negotiations on the Formation of a Consortium.

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

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Seite 6: [1] Kommentar [22]

The ECJ commonly regards “business secrets” in need of being protected any and all operational or business information meeting the following criteria: The information is only known to a closed group of persons; the holder wishes to keep the information secret; the holder has a legitimate interest in non-disclosure of the information (see Fluck, *Transparenz, Schutz von Unternehmensdaten und Zwangskonsortien im geplanten REACH-System*, in: Rengeling (Ed.), “Umgestaltung des Europäischen Chemikalienrechts durch Europäische Chemikalien-Politik”, 2003, p. 123).

Seite 6: [2] Kommentar [24]

Occasionally, there are reservations against agreeing upon contract penalties. However, the contract penalties serve the protection of all those involved rather than serving the purpose of sanctions. The advantage of contract penalties: the burden of proof for a specific damage, 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. It has to be decided on a case-to-case basis, whether an agreement on contract penalties is appropriate in a preliminary agreement.

Seite 6: [3] Kommentar [25]

The amount of the contract penalty agreed upon should meet the following criteria: In the specific case it should be commensurate to the economic value of the exchanged information. Furthermore, it should encourage the parties to treat the information with great diligence – it should however not be out of proportion. As a general rule, misuse of studies should not occur in the preliminary phase, as studies are not yet prepared and not yet placed at the disposal of the parties. Since a benchmark referring to a clear economic value is still missing in the preliminary phase, it will be difficult to fix a blanket amount in the preliminary agreement during the preliminary phase. Thus, here, the optional clause (percentage of the expenses incurred for information relating to the breach) suggests itself. According to practical experience, 50 % would be adequate (however, the party demanding the contract penalty would have to prove the expenses).