

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 E

Model Agreement on rights to use individual studies For registration pursuant to REACH Reg.

Frankfurt, June 2007

¹ www.redeker.de.

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 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 provisions. 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 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. 9.1 of this Model Agreement.

Agreement on rights to use individual studies For registration pursuant to REACH Reg.

between

1. A Inc.

– A –

and

2. B Ltd.

– B –

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I. Preamble

“A” and “B” are manufacturers, importers and/or “only representatives” of the substance ... [*designation of the substance with its chemical name, inclusive of CAS- and EINECS-number*] [*optional: of substances of the substance group ... [designation of the substance group with its chemical name]*] according to its detailed specification in **Annex 1** – hereinafter: “the substance” – with registered head offices in the European Union. Before conclusion of this Agreement, both parties conferred with each other on the questions concerning the substance identity [*optional: within a “non-disclosure and non-use agreement”*].

The substance has phase-in status according to REACH Reg. According to REACH Reg., “A” and “B” must register this substance within the registration deadlines applicable to them. They pre-registered each substance according to Article 28 REACH Reg. and are participants of the preliminary SIEF of this substance.

“A” disposes inter alia of the rights on the study XY for the end point Z for the registration of this substance according to REACH Reg. “B” obtained from “A” [*optional: within the framework of a “non-disclosure and non-use agreement”*] the summary [*optional: robust summary*] of study XY [*optional: the full study report*] for information and examination.

Furthermore, “A” and “B” evaluated this study according to acknowledged standards. Based on this evaluation, they agreed upon a fair, transparent and non-discriminatory cost-sharing according to Article 27 par. 3 and 6 and Article 30 par. 1 REACH Reg.

Taking the above into consideration, “A” and “B” agree as follows:

II. Agreement

1. Definitions

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.

In addition, the definitions in Article 3 REACH Reg. apply.

2. Provision of the study

“A” provides to “B” a copy of the study summary [*optional: robust study summary*] of study XY [*optional: as well as the full study report*].

3. Right to use

“A” grants “B” the limited and non-transferable right to use the study summary [*optional: robust study summary*] of study XY and the permission to refer to the full study report owned by “A” for the purpose of registration of the substance according to REACH Reg.

[*optional: The right to use also applies to “B’s” Affiliates.*]

[*optional: “B” is entitled to base its registration of substances of the substance group ... [designation of the substance group with its chemical name] produced/imported by him [optional: his Affiliates] on the study XY if and to the extent the preconditions of the “substance group and read-across approach” according to Annex XI section 1.5 REACH Reg. have been met. “B” will inform “A” without delay about its intent to such reference on the core data.*]

“A” issues “B” the “letter of access” in **Annex 2** for the rights to use. “B” is entitled to present this “letter of access” to the agency upon registration of the substance.

“B” agrees to use the data provided to him exclusively for the agreed-upon purpose and to abstain from any other use – whether commercial or non-commercial. This applies to the use by Affiliates accordingly.

[*optional: clause on contractual penalty.*]

4. Cost-sharing

For the rights according to paras. 2. and 3., “B” pays “A” an amount of ... € (including VAT, if applicable). This payment is due on

[*optional: For the use of this study for registration within the framework of the “substance group and read-across approach” according to Annex XI section 1.5 REACH Reg., “B” agrees to pay “A” a share of costs in the amount of ... € (including VAT, if applicable). The payment is due within one month after “B” informed “A” about its intent to refer to the study.*]

5. Exclusion of warranty

“A” does not give a warranty for the accuracy and correctness of the study XY or for the acknowledgment of this study by the Agency during the dossier evaluation (according to Title VI REACH Reg.) or for the transferability of the results to the substances produced and/or imported by “B”, unless “A” caused the defect deliberately or with gross negligence.

6. Confidentiality

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. “B’s” Affiliates are not “third parties” within the meaning of this provision. Confidentiality shall also be maintained for information commonly regarded as trade 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.

[*optional*: At submission of his registration “B” will file an application according to Article 10(a)(xi) and Article 119 par. 2(c) REACH Reg. concerning the summaries [*optional*: robust summaries] of study XY. “A” will assist “B” as far as necessary, especially by giving the necessary reasons for the application.]

“B” accounts for the observance of the above regulations by its Affiliates.

[*optional*: clause on contractual penalty.]

7. Competition law compliance

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 comply with Articles 81 and 82 EC Treaty, Article 25 par. 2 REACH Reg. and the Code of Conduct attached in **Annex 3**.

8. Perpetuation of the Agreement

The mutual rights and duties from this Agreement remain unaffected if circumstances occur which cause “A” or “B” to retire from the SIEF or which lead to discontinuation of the obligation to register.

9. Final provisions

The Agreement is subject to the laws of ... [*insert name of the country*] without giving effect to any rules on conflict of laws.

Jurisdiction to resolve disputes of the consortium members shall be given to the Court of ... [*insert town of the court*].

[*optional: Arbitration clause*]

This Agreement is concluded for an indefinite time. Unless otherwise provided for, the rights and obligations agreed cease by performance.

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

etc.

Annex 1: Substance Specification

Annex 2: Letter of Access

Annex 3: Code of Conduct

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 6th World Surfactants Congress GmbH)
Claudia Aubel-Pump (VCI)
Dr. Anja von Hahn (BASF)
Dr. Dieter Fink (VCI)
Dr. Jürgen Fluck (BASF)
RA Frank Froeschle (Bayer)
Dr. Claus-Dierk Hager (Sasol)
Marc Alexander Rudnik (Clariant)
Dr. Stefan Scholl (Cognis)
Dr. Markus Schrader (Degussa)
Dr. Michael Top (Kao)

From the Law Firm of REDEKER SELLNER DAHS & WIDMAIER

Please contact:

Dr. Horst von Holleben, Attorney-at-Law
Kurfürstendamm 218
D-10719 Berlin
Phone: +49 / 30 / 88 56 65-0
Fax: +49 / 30 / 88 56 65-99
E-mail: holleben@redeker.de

Hartmut Scheidmann, Attorney-at-Law
Kurfürstendamm 218
D-10719 Berlin
Phone: +49 / 30 / 88 56 65-0
Fax: +49 / 30 / 88 56 65-99
E-mail: scheidmann@redeker.de

Dr. Andreas Rosenfeld, Attorney-at-Law
Avenue de Cortenbergh 60
B-1000 Brussels
Phone: +32 / 2 / 73 80 92-0
Fax: +32 / 2 / 73 80 92-9
E-mail: rosenfeld@redeker.de