

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 G

Model Agreement on granting a right to refer to registered data

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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 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 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 II. par. 9.1 of this Model Agreement.

Agreement on granting a right to refer to registered data

between

1. A Inc.

– A –

and

2. B Ltd.

– B –

Kommentar [1]: "A Inc." may also conclude this agreement with other companies. However, since there will be no contractual relations between "B Ltd." and these other companies, this model agreement only concerns the relationship between "A Inc." and "B Ltd.".

Contents

I. Preamble	3
II. Agreement	4
1. Definitions	4
2. Provision of submitted data	4
3. Right to use	4
4. Cost-sharing	5
5. Exclusion of warranty	5
6. Confidentiality	5
7. Perpetuation of the Agreement	6
8. Competition law compliance	6
9. Final provisions	6
Members of the Project Group and Contact Persons of the relevant Law Firm	8
Annex 1: Substance Specification by “A”	
Annex 2: Letter of Access	
Annex 3: Code of Conduct	

I. Preamble

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

“A” possesses the rights on the study XY for the end point Z [optional: of the Core Data (definition hereinafter at Section II. par. 1)]. He/she registered the substance using this study [optional: these Core Data] on ... [insert date] with the Agency and obtained the registration number ... for this registration.

“B” wishes to register the same substance as a non-phase-in substance [optional: as a phase-in substance not pre-registered] [optional: as pre-registered phase-in substance].

“B” obtained from “A” [optional: within the framework of a “non-disclosure and non-use agreement”] a copy of the study summary [optional: robust study summary] of study XY for end point Z submitted to the Agency [optional: a copy of the full study report of study XY] [optional: a copy of the Core Data submitted to the Agency] for information and examination.

Furthermore, “A” and “B” evaluated the study XY [optional: the Core Data] 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:

Kommentar [2]: If applicable: according to the model in Appendix D.

Kommentar [3]: This sentence is not needed if there is reference (according to Art. 27 REACH RG) to studies on non-phase-in-substances or on phase-in-substances which have not yet been registered. In such case, no SIEF will be set up, and no other reason for contractual conference on the substance identity will exist. Rather, the Agency will officially assess the substance identity on the basis of the information submitted by the prospective registrant (Art. 26 par. 1 (b) REACH RG) and on the information already available to the Agency. Thus, the participants can act on the assumption that substance identity is established by the Agency *ex officio*. Nevertheless, the potential as well as the previous registrants may confer with each other on the substance identity in advance, voluntarily and outside of the data-sharing-procedure (according to Arts. 26 and 27 REACH RG).

Kommentar [4]: Articles 26 and 27 REACH Reg. are applicable.

Kommentar [5]: Articles 26 and 27 REACH Reg. are applicable.

Kommentar [6]: This option may be relevant if the registration deadline valid for “A” is shorter than the registration deadline valid for “B” and if “A” has registered before receiving “B’s” request. Such a situation is not governed by Articles 26 and 27 but rather by Article 30 REACH Reg.

Kommentar [7]: If applicable: according to the model in Appendix D.

Kommentar [8]: Also for non phase-in substances, it is recommended to exchange the study summary or the full-study report in advance – notwithstanding the fact that the Agency assesses the substance identity and the applicability of the study. Knowledge of the study is a useful prerequisite for an agreement on the sharing of costs.

Kommentar [9]: At present, the agreement on costs may be concluded according to the rules set out in Annexes 7 (i. e. the rules on the valuation of studies) and 9 (cost key) to the Model Consortium Agreement. According to Article 27 par. 3 and Article 30 par. 1 REACH Reg., the costs must be shared in a fair/just, transparent and non-discriminatory manner. The ... [1]

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 %, via direct or indirect ownership.

Kommentar [10]: 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.

Core Data: the data to be submitted jointly by the consortium in all cases pursuant to Article 11 par. 1.2 REACH Reg. The Core Data include:

Kommentar [11]: 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.

- classification and labelling of the substance pursuant to Annex VI section 4 REACH-Reg.;
- summaries of information derived from the application of Annexes VII to XI REACH-Reg.;
- robust study summaries derived from the application of Annexes VII to XI, if so required under Annex I REACH-Reg.;
- testing proposals where required by the application of Annexes IX and X REACH-Reg.;

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

2. Provision of submitted data

“A” shall provide “B” with a copy of the submitted study summary [*optional*: robust study summary] of the study XY [*optional*: as well as the full study report] [*optional*: of the submitted Core Data of the substance].

Kommentar [12]: “B” obtained the study summaries or the study- or Core Data prior to the conclusion of the agreement “for information and examination”. This does not guarantee that the documents are permanently at his disposal. It may also be that the documents have only temporarily been left to “B” before conclusion of the Agreement. This is the reason why section II par. 2 of this model stipulates a contractual title to possession of the relevant documents. This clause is only of declaratory nature and may be omitted if “B” received the documents without any restrictions.

3. Right to use

“A” shall grant “B” the limited and non-transferable right to use the study summary [*optional*: robust study summary] of study XY [*optional*: the whole set of the Core Data] submitted by “A” and the permission to refer to the full study report of the study XY [*optional*: to the underlying studies of the Core Data] for the purpose of registration of the substance by “B” pursuant to REACH Reg.

Kommentar [13]: Article 10(a)(vi) REACH Reg.

Kommentar [14]: Article 10(a)(vii) REACH Reg.

Kommentar [15]: Hereby, the protection clause in Article 10(a) last sentence REACH Reg. is considered.

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

[*optional*: “B” is entitled to base his/her registrations of substances of the substance group ... [*designation of the substance group with its chemical name*] produced and/or imported by him/her [*optional*: his Affiliates] on the study XY [*optional*: to a part or all of the Core Data] if and to the extent the preconditions of the “substance group and read-across approach” (pursuant to Annex XI section 1.5 REACH Reg.) have been met. “B” shall inform “A” without delay about his/her intent to such reference.]

Kommentar [16]: Insert here the precise definition of the substance.

“A” shall issue “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.

Kommentar [17]: This obligation to inform shall enable “A” to claim an additional cost refund according to par. 4.2 of this Agreement.

Kommentar [18]: The model “letter of access” in Annex 10 of the Model Consortium Agreement may be used analogously.

Kommentar [19]: The model “letter of access” in Annex 10 of the Model Consortium Agreement may be used analogously.

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

[*optional*: clause on contractual penalties]

Kommentar [20]: The constellation presumed in this model is that “A” already registered. Thus, at registration, “B” does not need to submit himself/herself the study summaries according to Article 10(a)(vi) and/or (vii) provided to him/her by “A”. The “letter of access” is relevant for the proof to have permission to refer to the full study report(s) pursuant to Article 10(a) last sentence as well as pursuant to Article 13 par. 5 REACH Reg.

4. Cost-sharing

For the rights to use the study XY [*optional*: the Core Data], pursuant to par. 3 of this Agreement “B” shall pay “A” an amount of ... € (including VAT, if applicable). This payment is due on

Kommentar [21]: A contractual penalty may be appropriate for the protection against violations of the rights to use. The clause may be framed similar to Section VI par. 6.1 of the Model Consortium Agreement.

[*optional*: For the right to refer to the study [*optional*: the Core Data] for registrations within the framework of the “substance group and read-across approach” pursuant to Annex XI section 1.5 REACH Reg., “B” shall pay “A” a share of costs in the amount of ... € (including VAT, if applicable). The payment is due within one month after “B” has informed “A” about his/her 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 [*optional*: the Core Data] or for the acknowledgment 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 business secrets. The aforementioned obligations do not apply to information which can be demonstrated as having been available to the public before receipt by the respective party or which became public through no fault of the recipient.

[optional: At registration, “B” shall file an application for non-disclosure pursuant to Article 10(a)(xi) REACH Reg. with respect to information which may be kept secret according to Article 119 par. 2 REACH Reg. “A” shall assist “B” as far as necessary, especially by giving the necessary reasons for the application.]

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

[optional: clause on contractual penalty.]

7. Perpetuation of the Agreement

The mutual rights and obligations from this Agreement remain unaffected if circumstances occur which lead to discontinuation of “A’s” or “B’s” obligation to register.

8. Competition law compliance

The parties are aware that activities under this Agreement could represent a matter to which the application of 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.

9. Final provisions

The law applicable in ... [insert name of the state] applies without giving effect to any rules on conflict of laws.

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

[optional: Arbitration clause]

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

Kommentar [22]: 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 [23]: E.g. US TOSCA stipulates the obligation to inform EPA on new knowledge of risks (...reporting).

Kommentar [24]: 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-dis- ... [2]

Kommentar [25]: The confidentiality provision is of a rather clarifying nature. It can be assumed that the participants concluded a confidentiality agreement at an earlier point ... [3]

Kommentar [26]: Study summaries will be published if there is no application of non-disclosure (Article 119 par. 2(c) REACH Reg.). If A filed an application according to Art. 10 (a) (xi) ... [4]

Kommentar [27]: In order to ensure confidentiality, an agreement on contractual penalties may be suitable. The clause may be framed similar to Section VI par. 6.1 of the Model Consortium Agreement

Kommentar [28]: Pursuant to Article 25 par. 2 sentence 2 REACH Reg. registrants shall refrain from exchanging information concerning their market behaviour, in particular on production capacities, pro- ... [5]

Kommentar [29]: In international agreements, it may be difficult to agree on the applicable law, as every party knows the law of the country of its origin best. The law applicable in the country(... [6]

Kommentar [30]: In international consortia, the jurisdictional venue may be a crucial issue in negotiations. In the case of dispute, it may be expedient to agree upon the court respo- ... [7]

Kommentar [31]: For a model of an arbitration clause see Section VIII. par. 2.2 of the Model Consortium Agreement.

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

etc.

Annex 1: Substance Specification by “A”

Kommentar [32]: Substance specification according to the model of Annex 1 to the Model Consortium Agreement.

Annex 2: Letter of Access

Kommentar [33]: The model “letter of access” in Annex 10 of the Model Consortium Agreement is to be used analogously.

Annex 3: Code of Conduct

Kommentar [34]: Code of conduct according to Annex 4 of the Model Consortium Agreement.

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Seite 3: [1] Kommentar [9]

At present, the agreement on costs may be concluded according to the rules set out in Annexes 7 (i. e. the rules on the valuation of studies) and 9 (cost key) to the Model Consortium Agreement. According to Article 27 par. 3 and Article 30 par. 1 REACH Reg., the costs must be shared in a fair/just, transparent and non-discriminatory manner. The cost-sharing guidance hopefully to be issued by the Agency (according to Article 77 par. 2 REACH Reg.) might provide a basis. However, this guidance does not yet exist and the Agency is not obliged to issue it. Preparatory work is done within RIP 3.4. However, this work is not yet finished (present state: Final draft guidance document RIP 3.4 review 02 May, 2007). The remarks on cost sharing in the draft RIP 3.4 known to date rely to a great extent on the works on study valuation and cost sharing in the Cesio proposals from December 2005. Annexes 7 and 9 of the Model Consortium Agreement (Appendix C) contain updated versions of these proposals. The drafters of the model agreements are convinced that Annexes 7 and 9 of the Model Consortium Agreement (Appendix C) propose a fair, transparent and non-discriminatory cost-sharing and can thus form the basis of “B’s” obligation to bear costs.

Seite 6: [2] Kommentar [24]

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: [3] Kommentar [25]

The confidentiality provision is of a rather clarifying nature. It can be assumed that the participants concluded a confidentiality agreement at an earlier point – before exchange of information. They should have done so.

Seite 6: [4] Kommentar [26]

Study summaries will be published if there is no application of non-disclosure (Article 119 par. 2(c) REACH Reg.). If A filed an application according to Art. 10 (a) (xi) REACH RG within his/her registration, the Agency will decide on the validity of the justification. If “B” just refers to the study summaries submitted by “A” via “letter of access”, “B” may not need to file himself an application according to Art. 10 (a) (xi).

Seite 6: [5] Kommentar [28]

Pursuant to Article 25 par. 2 sentence 2 REACH Reg. registrants shall refrain from exchanging information concerning their market behaviour, in particular on production capacities, production or sales volumes, import volumes or market shares.

Seite 6: [6] Kommentar [29]

In international agreements, it may be difficult to agree on the applicable law, as every party knows the law of the country of its origin best. The law applicable in the country of “A’s” registered office may suggest itself as a good solution.

Seite 6: [7] Kommentar [30]

In international consortia, the jurisdictional venue may be a crucial issue in negotiations. In the case of dispute, it may be expedient to agree upon the court responsible for “A’s” registered head office as the competent jurisdictional venue. In any case, this should be consistent with the agreed-upon applicable law (see Commentary [29]).