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## 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

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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”.

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# **Model Agreements**

## **for consortia and other forms of data sharing according to REACH**

### **I. Adaptation of the Cesio proposals of December 2005 to the final version of the REACH Regulation December 2006 and newer findings**

#### **1. The Cesio proposals of December 2005**

In December 2005 the 6<sup>th</sup> World Surfactants Congress GmbH<sup>3</sup> presented the following results to the public within the framework of a project:

- Study “Legal framework conditions of consortia formation pursuant to REACH”;
- Model agreement on the preliminary phase (preliminary agreement) for the formation of a consortium pursuant to REACH;
- Model agreement for the formation of a consortium pursuant to REACH requirements.

The study and model agreements were compiled by the law firm Redeker Sellner Dahs & Widmaier in close cooperation with a Project Committee of experts from industry and associations. The results of the project were published in English on the website of the 6<sup>th</sup> World Surfactants Congress GmbH under [www.cesio2004.de](http://www.cesio2004.de). Some 1000 copies of the German version were printed and widely distributed by the VCI, among others.

These documents, hereinafter simply referred to as the Cesio proposals, have received great attention in the professional circles. They reflect the status of the REACH consultations as at the end of 2005.

#### **2. Order for the adaptation of the Cesio proposals to the final version of REACH and to newer findings**

The Cesio proposals are to be available to concerned parties in a version updated to the latest status of legislation and knowledge. For this reason, after the REACH Regulation<sup>4</sup> was

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<sup>3</sup> Subsidiary of TEGEWA and organiser of the 6<sup>th</sup> World Surfactants Congress in 2004 in Berlin.

<sup>4</sup> The REACH Regulation (hereinafter referred to as REACH Reg.) was published in No. 1907/2006 in the Official Journal of the EU No. L 396, 30.12.2006. It enters into force on 01.06.2007 and is then immediately

adopted, the 6<sup>th</sup> World Surfactants Congress GmbH, with the support of VCI, initiated in January 2007 another project within the framework of which the law firm Redeker Sellner Dahs & Widmaier are commissioned to undertake the adaptation of the Cesio proposals to the final version of the REACH Regulation. In so doing, the findings gained through initial experience with the Cesio proposals over the course of the past year were also taken up and processed.

A Project Group of experts from industry and associations controls and guides the project. The composition of the Project Group is documented in the attachment labelled “Members of the Project Group and Contact Persons of the relevant Law Firm”.

The results of the adaptation will be published.

### **3. Connection with RIP 3.4 (data sharing)**

Besides the basic legal framework now available with the text of the Regulation, the *Technical Guidance Documents* (TGDs), which are prepared within the *REACH Implementation Projects* (RIPs), are of particular importance for the implementation of REACH. One of these RIPs – under No. RIP 3.4 – treats the topic of data sharing, and thus has particular significance for the project of an adaptation of the Cesio proposals.

The Commission commissioned a consortium<sup>5</sup> to compile a *Technical Guidance Document on Data Sharing (RIP 3.4)* in November 2006. The *Guidance Document* is intended to analyse technical and legal obstacles of data sharing, reveal paths toward solutions, compile a *Cost Sharing Guidance Document*, analyse the legal conditions of the SIEF, and develop a *Guidance Document on Consortium Formation*. A *Stakeholder Expert Group* (SEG) guides the process,<sup>6</sup> which is to be completed by mid 2007. Thereafter consultations with the Member States will follow, such that the publication of this *Technical Guidance Document* can be expected in the second half of 2007.

Despite this schedule and the linkage of RIP 3.4 with the adaptation of the Cesio proposals, the Project Group has decided not to delay the adaptation of the Cesio proposals. On the one hand, there are no plans within the framework of the RIP 3.4 to compile model agreements for

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applicable law within the Community. Where the text cites Articles without specifying the Law, this refers to the REACH Reg.

<sup>5</sup> Consortium under the guidance and oversight of the law firm MBR&M and with the participation of Cefic, Eurometaux, AISE and FECC.

<sup>6</sup> Current status: *Final draft guidance document RIP 3.4 (Review 02 May, 2007)*. Hereinafter, this status of RIP 3.4 will be taken into account; another point of view is held here to some degree. The respective status of the negotiations on RIP 3.4, and later on also the final version, are/will be published under <http://ecb.jrc.it/REACH>.

a consortium or other scenarios. Moreover, many reports from the field show that the companies are already commencing with the preparation of consortia or other cooperative programmes. For this reason, updated contract models – based on the Cesio proposals of December 2005 – are to be made available already at this stage.

## **II. Legal framework conditions for contracts on data sharing according to REACH**

### **1. Legal data sharing according to REACH**

The REACH Reg. does not leave the sharing of test data up to the free will of the manufacturers and importers subject to registration obligations. Rather REACH Reg. presents a detailed set of rules on data sharing in order to avoid duplication of studies – especially those involving tests on vertebrate animals – and to minimise the costs of registration for industry and authorities. With this goal

- the REACH Reg. mandates joint use (and cost sharing) of existing test data<sup>7</sup> in the case of substances already registered when a non-phase-in substance<sup>8</sup> or a non-pre-registered phase-in substance<sup>9</sup> is to be registered (Articles 26 and 27);
- for every pre-registered phase-in substance, the REACH Reg. legislates the creation of a Substance Information Exchange Forum (SIEF) with rules governing the exchange of available test data and the generation of missing test data<sup>10</sup> whilst sharing costs in the SIEF (Articles 29 through 30);
- for the manufacturers and importers of the same substance who are subject to registration obligations, the REACH Reg. mandates joint submission of certain “core data”<sup>11</sup> through a “lead registrant” (Articles 11 and 19);
- the REACH Reg. limits the protection of registered test data to 12 years (Article 25(3)) and

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<sup>7</sup> Study summaries and robust study summaries of the information derived from the application of Annexes VII – XI.

<sup>8</sup> Substance that does not fall under the definition in Article 3 No. 20.

<sup>9</sup> Substance that falls under the definition in Article 3 No. 20.

<sup>10</sup> Study summaries and robust study summaries of the information derived from the application of Annexes VII – XI.

<sup>11</sup> “Core data” is not a REACH Reg. term. The term has established itself, however, for the following registration information which must be submitted jointly in accordance with Article 11(1)(2): Study summaries and robust study summaries, classification and labelling, proposals for testing, and quality assurance information for the data.

- at dossier evaluation the Agency will organise the joint conduct of new vertebrate animal studies required according to Annex IX and X by all manufacturers and importers of the same substance (Article 40(3)(e) and Article 53) .

This set of rules of the REACH Reg. on data sharing is summarised briefly<sup>12</sup> in

### **Appendix A I**

A comprehensive presentation of this set of rules is being compiled within the framework of RIP 3.4.

It should be mentioned in conclusion at this point that this set of rules is hardly enforceable in and of itself. Supplementary contractually binding regulations are required among the actors. The *Technical Guidance Document* being created under RIP 3.4 can interpret the legal provisions of the REACH Reg. and offer practical assistance. It cannot change the REACH Reg., however, and is, like all RIPs, not legally binding. For this reason, RIP 3.4 cannot substitute for contractual arrangements.

With this in mind, the model agreements developed as Cesio proposals of December 2005 for a preliminary agreement and a consortium agreement will hereby be adapted to the REACH Reg. that has now been adopted and to the newer findings that have become available in the meantime.

## **2. Consideration of European competition law**

The legal or contractual data sharing according to REACH is generally carried out among competitors that manufacture or import the same substance. For this reason, the prohibition of all agreements between undertakings, decisions by 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 must be observed in all phases of the data sharing. Under no circumstances may the cooperation required of competitors for the data sharing be used as a platform for agreements that are restrictive of competition. The prohibition (horizontal or vertical) of agreed or coordinated restrictions to competition also limits the exchange of confidential and market-related information, or can also necessitate the involvement of a neutral third party, through which the information is then channelled and conditioned in anonymised form. Competition law can

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<sup>12</sup> A comprehensive presentation includes the study “Legal conditions for the formation of consortia according to REACH”, which was submitted within the framework of the Cesio proposals of December 2005 based on the status of REACH at that time.

also make it necessary for the parties to leave the contractual partnership open to other competitors that do not (yet) belong to the partnership.

The implications of competition law relative to consortia is summarised briefly<sup>13</sup> in

## **Appendix A II**

These results are taken into consideration in the following model agreements.

### **III. The contract models for consortia and other forms of data sharing according to REACH (Appendices B – G)**

#### ***Preliminary remarks:***

*The model agreements have been developed on the basis of practical and legal experience of the law firm and of the Project Group. The models cannot cover all constellations and problems occurring in reality, and for this reason they may not be used as a standardised form. In each concrete case, a separate check must be performed to determine whether the regulations of the models are suitable in terms of factual and legal aspects, and which other regulations are required and applicable, if any.*

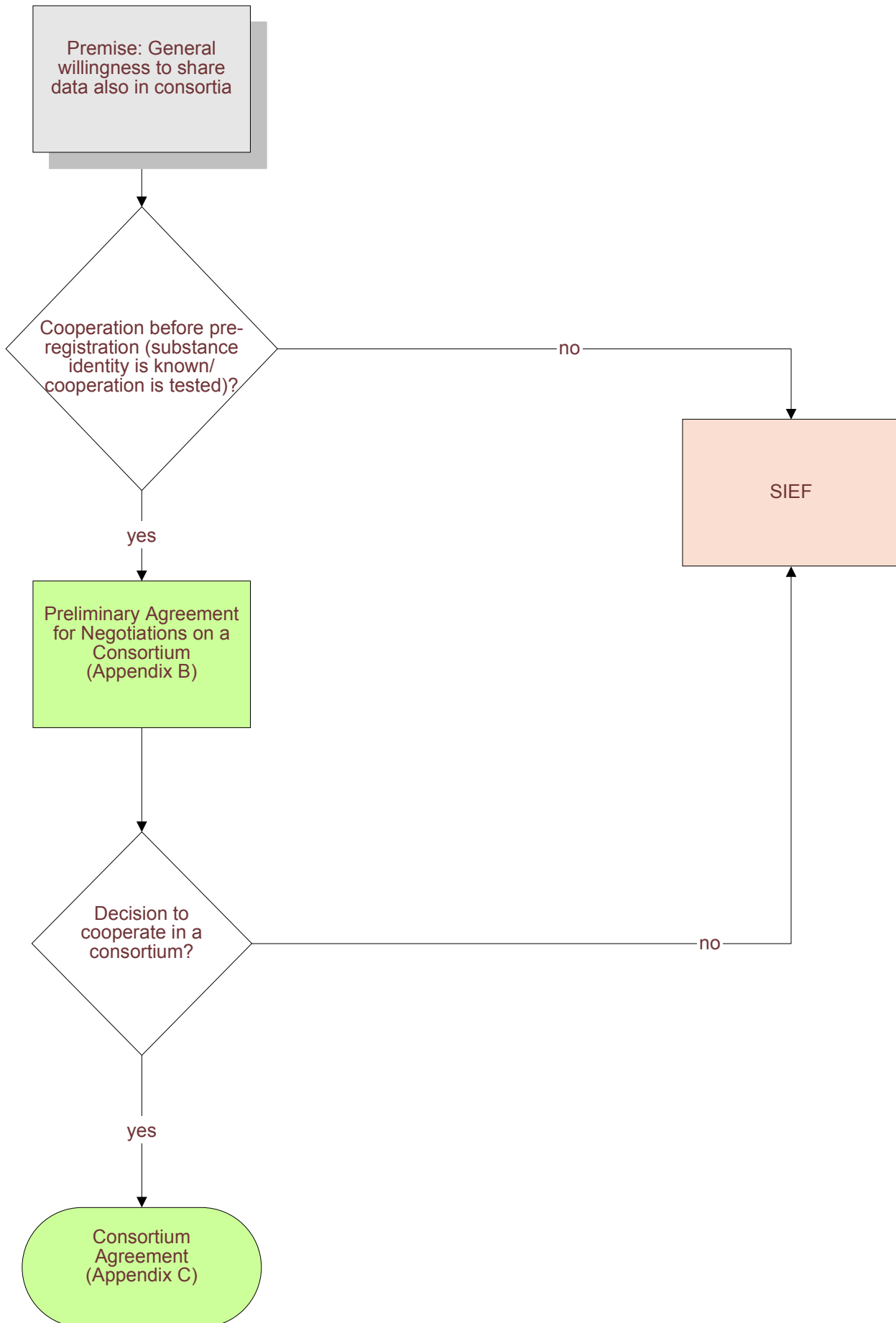
*The model agreements contain factual explanations (Commentary [I] etc.) which, where necessary for understanding, relate the individual contract passages to the REACH Regulation and competition law.*

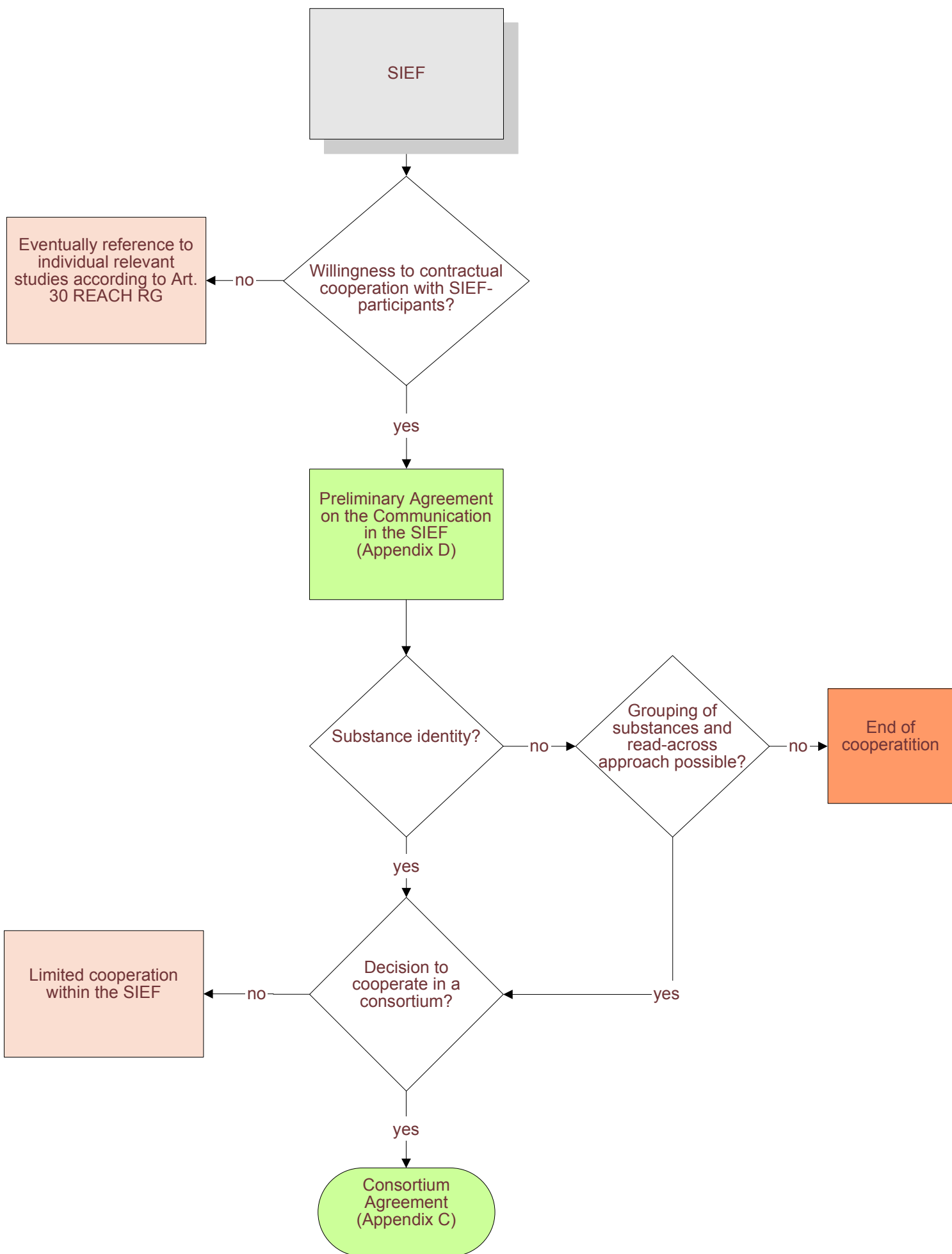
*The following **flowcharts** provide an overview of the scenarios on which the contract models B – G are based.*

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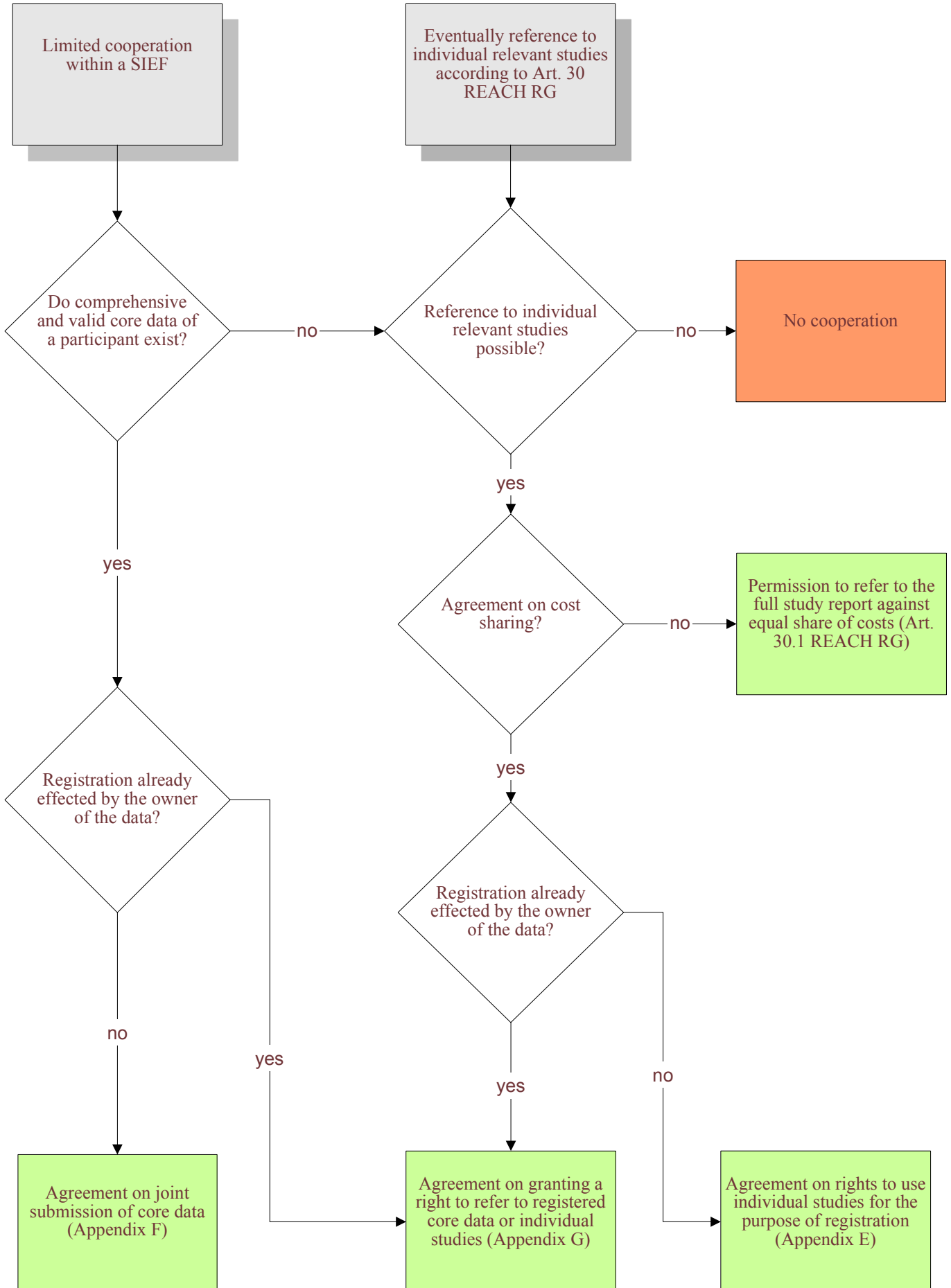
<sup>13</sup> A comprehensive presentation is included in the study “Legal conditions for the formation of consortia according to REACH”, which was submitted within the framework of the Cesio proposals of December 2005. RIP 3.4 will also include an annex to *EC Competition Law*.

Scenario 1 - Comprehensive cooperation from the outset





Scenario 3 - Limited cooperation within a SIEF - legally required data sharing



## **1. Model Agreement on the Preliminary Phase (Preliminary Agreement) for Negotiations on the Formation of a Consortium pursuant to REACH Requirements (Appendix B)**

### **a) Possible scenarios for the use of the model**

The REACH Reg. enters into force on 01.06.2007. The regulations governing pre-registration and data sharing (Title III) and for joint submission (Articles 11 and 19) enter into force on 01.06.2008. The deadline for pre-registration runs through 01.12.2008. By 31.12.2008, the Agency will then publish the list of the pre-registered substances. From 01.12.2008 the so-called pre-SIEF will be established; there is no standard point in time<sup>14</sup> for the creation of the actual SIEF with the rights and obligations arising from Articles 29 and 30.

The observations in the field reveal that many of the companies affected are not waiting for these deadlines, but rather already wish to establish agreements on data sharing now – i. e. even before REACH Reg. enters into force.

In this phase prior to the establishment of a SIEF there is still no mandatory cooperation between manufacturers/importers of the same substance. The pre-registration has yet to be completed, and there is still no SIEF. Thus the actors are not gaining knowledge of possible cooperation partners through the implementation of the REACH Reg.<sup>15</sup>, but rather they obtain it in other contexts, e. g. from general knowledge of the market or from joint work in an association. Practical experience shows that – often at the initiative of a few manufacturers – the formation of consortia is already under discussion now.

In this phase of the negotiations on such a consortium, it must become clear to all founding consortium partners whether the participation in the consortium makes sense for them or not. They must be able to estimate the financial cost of an own registration and the possible savings that registration in the consortium would bring, whereby the legal requirements of registration (Title II REACH Reg.) and for pre-registration and data sharing (Title III REACH Reg.) have to be taken into consideration after they enter into force on 01.06.2008. Alternatives to the formation of a consortium corresponding to the models developed in this project (Appendices E – G) have to be weighed.

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<sup>14</sup> For further details, please refer to Appendix A I under Section II.1.

<sup>15</sup> The scenario for the use of the model thus differs significantly from the scenario for the use of the model of a preliminary agreement for the communication in the SIEF (Appendix D). By law, those involved in the SIEF obtain knowledge from other manufacturers/importers based on the pre-registration.

In order for these negotiations to be held in a protected environment, it is recommended to assure the protection of confidential information in a preliminary agreement while making certain that the requirements of EU competition law, which also apply in their entirety for the “preliminary phase”, are observed at the same time.

**b) Structure of the model**

The model of the preliminary agreement, which corresponds in large part to the one from the Cesio proposals, obliges the contract partners to provide the other partners with the information needed to decide on the formation of the consortium – possibly according to the model of the consortium agreement with its Annexes 1 – 10 in Appendix C. This can also include confidential business information, e. g. information on the specification of substances – information that delimits the membership of the consortium.<sup>16</sup> The model of the preliminary agreement opens up the option to pass this confidential information along to a neutral expert, who evaluates the information and recapitulates it to the contract partners in an anonymised form. The preliminary agreement obliges the contract partners not to disclose such information to third parties, and not to use it for purposes other than those of the preliminary agreement (*non-disclosure and non-use agreement*). For this reason, Annex 2 of the preliminary agreement restricts the group of informed employees.

**c) Compliance of the model with the REACH Reg.**

The preliminary agreement is designed for the period before the regulations governing pre-registration and registration, and those governing SIEF, enter into force (01.06.2008 and 01.12.2008, respectively). Compliance with the REACH Reg. is also ensured for the period thereafter, however, as the preliminary agreement includes an opening clause for the participation of additional manufacturers/importers of the same substance (Section II.2.2 of the model).

**d) Compliance of the model with competition law**

The preliminary agreement is generally concluded between competitors. For this reason, the competition law prohibition of certain agreements 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 must also

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<sup>16</sup> Annex 1 of the model consortium agreement.

be observed here. Under no circumstances may the cooperation required of competitors for the data sharing be used as a platform for agreements that are restrictive of competition. An annex to the model preliminary agreement includes a *code of conduct* with a list of *do's and don'ts* of competition law. This list can provide only general indications for the daily work of the contract parties, however. The exchange of confidential information (e. g. on the specification of substances or on the uses) is not prohibited by competition law *per se*, especially in view of the fact that the data sharing required by the lawmakers cannot work without such exchange. It becomes problematic only when it involves business secrets *of relevance to the market*, the exchange of which reduces or eliminates the degree of uncertainty relative to the market development in question, thereby possibly having the effect of restricting competition between the companies. As a general rule, therefore, the exchange of purely scientific or technical data is not an issue in terms of competition law (cf. also Article 25(2) REACH Reg.). In cases of doubt, a neutral third party should be called in to avoid risks involving competition law.

Competition law can also make it necessary for the parties to leave the contractual partnership open to other competitors that do not (yet) belong to the partnership. It is also for this reason that the model contains an opening clause in Section II.2.2.

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

### **a) Possible scenarios for the use of the model**

The REACH Reg. does not include the term consortium in the version that has now been adopted.<sup>17</sup> Within the SIEF it requires in particular the sharing of available test data, and the joint generation of missing test data, according to Annexes VII and VIII<sup>18</sup> with rules for cost sharing. Moreover, in Articles 11 and 19 it prescribes the joint submission of core data<sup>19</sup> through a lead registrant with the agreement of the other registrants. The Regulation lets the actors decide on the form in which they organise their cooperation, however. The self-organisation is carried out on the basis of civil law, i. e. by contract. In particular, a contractually organised consortium should be

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<sup>17</sup> The Commission draft of 29.10.2003 still made explicit mention of – voluntary! – consortia.

<sup>18</sup> For the registration, only the missing tests must be carried out according to Annexes VII and VIII. For missing tests according to Annexes IX and X, proposals for testing are submitted with the registration.

<sup>19</sup> See footnote 11 above.

considered here. This is the object of the model outlined below. Simplified forms of contractual cooperation are discussed under Points 4 – 6.

By way of clarification, note that the SIEF according to Article 29 is not a consortium in the sense of the term used here. The SIEF is a form of legislative relationship only for the exchange and the sharing of data for the purposes of registration<sup>20</sup>. The consortium, by contrast, is a contractual cooperation that extends further. The consortium fulfils the requirements of the SIEF *inter partes* but goes further at the same time by fulfilling the requirements of Articles 11 and 19 for the joint submission of core data and – still further – by also being able to take over the steps of the evaluation (Title VI REACH Reg.) and of the Chemical Safety Report. Members of the SIEF are all manufacturers/importers of the same phase-in substance who have pre-registered (and other participants). By contrast, the consortium can comprise a subset of the SIEF participants. It can also be formed for a group of substances belonging individually to different SIEFs, however.

A consortium according to the model presented here in

### Appendix C

should be considered above all when the actors wish to organise the joint conduct of missing studies of vertebrate animals. Specifically, only the tests according to Annexes VII and VIII must be carried out for the registration. For the required tests according to Annexes IX and X, only proposals for testing are submitted, which can then become test requirements of the Agency in the evaluation (Article 40(3)(e), Article 53). In particular, the compilation of these proposals for testing requires more extensive cooperation, however, given that the options of waiving according to Annex XI – i. e. omitting additional testing on vertebrate animals – have to be investigated prior to the formulation of the proposals for testing. This and the preparation of possible or even probable test requirements of the Agency in the evaluation will repeatedly prompt the actors to form a consortium already in the phase of the registration.

A consortium according to the model in Appendix C should also be considered when the joint compilation of a Chemical Safety Report according to Article 14 REACH Reg. is desired; Articles 11 and 19 render its joint submission discretionary. This generally requires an intensive, contractually organised cooperation, as it involves the joint

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<sup>20</sup> In this respect, the *collective route* presented as the standard form of the SIEF in the *Final draft guidance document RIP 3.4 (Review 02 May, 2007)* is perhaps desirable. It is not legally binding, however. For further details, please refer to Appendix A I under Section II.3.a.

assessment of risks associated with the uses of the substances to be registered and with the exposures in connection with them. The model in Appendix C can serve this purpose as well. Based on the practical experience of the members of the Project Group, particular weight should be accorded to joint submission of a uniform set of data for the respective substance to the authorities; individual registration by each manufacturer/importer is likely to result in inconsistent statements in the dossier, which could lead to complicated requests for additional information by the authorities. A further disadvantage of individual registration is that inconsistent information could be passed along to the downstream users in the safety data sheets as a result.

If the actors desire neither contractual organisation of the joint conduct of studies of vertebrate animals according to Annex VIII and, in particular, according to Annexes IX and X, nor joint submission of the Chemical Safety Report, the benefits of a consortium will not necessarily justify the cost. In this case simplified forms of cooperation may be appropriate (cf. in this connection Appendices E – G).

#### **b) Structure of the model**

The model contract includes the Annexes 1 – 10, which are to be filled with content over the course of contract negotiations on the formation of the consortium, or confirmed if they are already completely formulated in terms of content.

Furthermore, the model contract is designed as a basic contract with recommendations for the standard case, and includes modules with recommendations for special scenarios presented as options marked in square brackets. This also applies to some degree for Annexes 1 – 10. **Example:** Submission of the **Chemical Safety Report** according to Article 14 REACH Reg. within the framework of the joint submission according to Articles 11 and 19 is possible but not required. The consortium can limit itself to the compilation of the intrinsic properties of a substance. In this latter case, no detailed presentation of the uses of the substance according to Annex 8 of the model contract is required. For this reason, Annex 8 is – like Section IV of the model contract (Compilation of the Chemical Safety Report) – printed in square brackets in the model.

#### **c) Compliance of the model with the REACH Reg.**

For the members of the consortium who are subject to registration obligations, the fulfilment of the legal obligations relative to data sharing according to REACH Reg. is ensured *inter partes*: they provide each other with access to available studies (Article

30(1)), they carry out missing studies jointly (Article 30(2)), and they submit to the Agency at least the core data through the lead company (Articles 11 and 19).

What needs to be regulated in the contract is the third-party relationship to other manufacturers/importers of the *same* substance, as the manufacturers/importers of the *same* phase-in substance in the SIEF are obliged to data sharing and to joint submission of core data (Articles 11 and 19). Whether the *same* substance is involved cannot be determined from the information of the pre-registration. Such determination also necessitates the exchange of further information (e. g. concerning impurities) – some of which is confidential. Details relative to this situation are provided elsewhere (cf. Appendix A I under Section II.2.a).<sup>21</sup> In the course of this *substance identity check*, it can become apparent that some manufacturers/importers are not assigned to the correct SIEF.

Therefore the *third-party relationship* to other existing manufacturers/importers of the *same* substance, for example, must also be regulated in the consortium agreement. This need not necessarily take the form of integrating manufacturers/importers that do not belong to the consortium into the consortium as *late* members; there may be good reasons not to do so, e.g. in the case of joint compilation of the Chemical Safety Report in the consortium.<sup>22</sup> But the consortium must request missing studies needed for the registration<sup>23</sup> from other members of the SIEF (Article 30(1)). Conversely, the consortium must provide other members of the SIEF with studies that they lack for registration (Article 30(1)). If studies required for the registration (according to Annex VII and VIII) are completely lacking in the SIEF, the consortium must organise the joint conduct of the missing study (Article 30(2)). This can take the form, for example, of the consortium or the lead company offering to conduct the study on behalf of *all* manufacturers/importers who are subject to registration obligations.

The obligations of the consortium can also include the organisation of joint submission of core data in terms of Articles 11 and 19(1) also with the other manufacturers/importers who do not belong to the consortium, e. g. in a way that the lead company of the consortium also offers the joint submission of the core data (not the Chemical Safety Report) to other manufacturers/importers of the same substance who are subject to

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<sup>21</sup> If the consortium treats a group of substances, there is no legal obligation from the SIEF or from Articles 11 and 19, as the substances belonging to the group are not identical.

<sup>22</sup> In this case the exchange of information on uses and exposures at customers is required. This can be a very delicate matter and requires cooperation based on a certain level of trust, which cannot be expected of every competitor. For this reason, the model contract calls for unanimity in the steering committee for the admission of a new member.

<sup>23</sup> This refers only to the studies in Annexes VII and VIII.

registration obligations. Even with an established substance identity, however, it is not realistic to record all manufacturers and importers who are subject to registration obligations in the joint submission of core data. The different registration deadlines already make this clear. A company that is not required to register until 11 years after the regulation enters into force cannot be forced to register just 3 ½ years after entry into force, nor even to cooperate, simply because a registrant with a production volume of more than 1,000 t/year must register already by that point in time.<sup>24</sup>

In addition the consortium agreement must make provision for the case where, after registration has been completed, manufacturers/importers of the *same* substance wish to register that substance. In this case there are obligations to share study summaries and robust study summaries, which are already available. Details regulated in Articles 26 and 27 REACH Reg. are taken into consideration in the model of the consortium agreement.

In connection with the provision of available studies to third parties that do not belong to the consortium, in the SIEF or in the case of a substance that has already been registered, it should be noted that according to Article 27(3) and (6) in combination with Article 77(2)(g) the Agency should issue a guidance document on cost sharing that should follow the principles of “fair, transparent and non-discriminatory”. This guidance document will not be binding, but it will be of major significance in any disputes with the Agency or the ECJ.<sup>25</sup> For this reason, in the consortium agreement it is reasonable to bring the cost allocation regulation for the provision of studies to third parties by means of a *letter of access* into harmony with the planned guidance document of the Agency. Plans call for an Annex 4 on *cost sharing* in the draft of the *Final Guidance RIP 3.4*,<sup>26</sup> which will give an indication of how the future guidance document on cost sharing of the Agency will look. It is important that the rules submitted with the Cesio proposals from December 2005 on the valuation assessment of studies and on the cost allocation formula<sup>27</sup> had been more or less adopted within annex 4 of the *Final draft guidance document RIP 3.4 (Review 02 May, 2007)*; deviations in the details are still under discussion. This essentially guarantees that the assessment rules within a

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<sup>24</sup> Apparently another point of view is held in the *Final draft guidance document RIP 3.4 (Review 02 May, 2007)*. For further details, please refer to Appendix A I under Section III.2.b.

<sup>25</sup> This applies above all in the case where, in the absence of agreement among those involved, the Agency grants a right of reference to studies already submitted (Article 27(6)(1)). Or when the study owner must assert cost reimbursement claims vis-à-vis third parties before national courts (Article 27(6) sentence 4 and Article 30(3) sentence 5).

<sup>26</sup> *Final draft guidance document RIP 3.4 (Review 02 May, 2007)*.

<sup>27</sup> Annexes 7 and 9 to the model contract submitted at that time.

consortium coincide with the assessment rules vis-à-vis third parties who are not contractually bound.

With this in mind, the model contract now submitted once again includes the Annexes 7 (Valuation rules) and 9 (Cost allocation formula) as well as the passage – applicable only directly inter partes – stipulating that third parties who can demand a letter of access for studies of the consortium will be treated according to these cost allocation principles. The cost allocation regulation is to be differentiated in the case of admission of a *late member* into the consortium, as the consortium generally performs much more for the members than prescribed by law in the REACH Reg.

#### **d) Compliance of the model with competition law**

According to competition law, the free choice of founding members of a consortium can be restricted. This can be assumed when the exclusion of other manufacturers or importers *of the same substance* from the SIEF has the effect of restricting competition, i. e. it can have a considerable impact on the ability of those affected to access the market or to remain in the market (for further details, please refer to Appendix A II under Section III.3). So if the substance specification of the consortium (Annex 1 of the model contract) is formulated more narrowly than that of the SIEF (e. g. with respect to the degree of purity and the nature of impurities), then this can lead to the exclusion of manufacturers/importers that use another manufacturing process. This can be justified factually (especially in case of impacts on the *risk assessment*), but it can also have a discriminatory character and thus raise concerns in terms of competition law. Each such case must be examined separately.

If the substance specification of the consortium (Annex 1 of the model contract) records a substance category (according to Annex XI(1.5) REACH Reg.), then the exclusion of manufacturers/importers of the substances that belong to the category must be checked especially in terms of competition law, as considerable savings can be incurred<sup>28</sup> under certain circumstances through *read-across* etc.

In the case of applications for *late membership* in the consortium, it is altogether possible that admitting other manufacturers or importers into the consortium at a later date will be in the interests of the current members. But this need not necessarily be the case. For this reason, the model of the consortium agreement calls for unanimity of the

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<sup>28</sup> In legal terms, this form of data sharing is certainly desirable according to the REACH Reg., but it is not mandatory.

steering committee in the question of *late membership*. This can lead to a rejection of late members, for which there may be factual grounds. A factual justification exists when the applicant is not prepared to disclose its substance identity or when, in the case of disclosure, it turns out that there is no sameness with the substance specification in Annex 1 of the model contract. There also ought to be no objection then from the standpoint of competition law to a rejection of the late membership.

In order to minimise residual risks involving competition law or problems with the regulations on data sharing in the REACH Reg. in the case of rejection of a late member by the steering committee, the model contract authorises the steering committee to extend submission of the core data according to Articles 11 and 19 REACH Reg. to the “rejected party” in exchange for cost reimbursement. Alternatively – if registration has already been completed by the consortium – the consortium would offer to sell a *letter of access* relative to all core data (i. e. not only data on vertebrate animals) to the “rejected party” (also in exchange for cost reimbursement). This is not connected with any right of use relative to the Chemical Safety Report. The Chemical Safety Report works with market-relevant data and is not part of the information that falls under the requirements on data sharing in the SIEF or according to Articles 11 and 19 REACH Reg.

The exchange of information that is necessary for the cooperation (e. g. the exchange of confidential business information) can also be problematic in terms of competition law. It is not prohibited *per se*, particularly since the REACH Reg. legally mandates this cooperation. For this reason, the involvement of a neutral third party for the exchange of confidential information is only necessary when it involves business secrets *of relevance to the market*, the exchange of which reduces or eliminates the degree of uncertainty relative to the market development in question, thereby possibly having the effect of restricting competition between the companies. As a general rule, the exchange of purely scientific or technical data is not an issue in terms of competition law (cf. Article 25(2) REACH Reg.). In cases of doubt, to avoid risks involving competition law, legal advice should be sought or a neutral third party should be called in from the outset.

An annex to the model contract includes a *code of conduct* with a list of *do's and don'ts* of competition law. This list can provide only general indications for the daily work of consortia, however.

### 3. Model Preliminary Agreement on the Communication in the SIEF (Appendix D)

#### a) Possible scenarios

The REACH regulation provides only very limited instruments for the organisation of the SIEF. In accordance with Article 28(4) the Agency is publishing the list of pre-registered substances on their website until 01.01.2009, along with those substances for which the available information could substitute for testing of the pre-registered substances under application of Annex XI(1.3)<sup>29</sup> and (1.5).<sup>30</sup> This list contains only the names of the substances, including the EINECS and CAS number, if available, and other identification codes as well as the initial deadline envisioned for registration. In addition, for each pre-registering party REACH IT will identify who else has pre-registered relative to each substance.<sup>31</sup> It is possible that only the name and address of a third party representative according to Article 4 REACH Reg. will appear there when the manufacturer or importer wishes to remain anonymous.

As a general rule, this information is not sufficient to realise the objectives of the SIEF as defined in Article 29(2) and the joint submission prescribed in Articles 11 and 19. The request for and provision of available studies in the SIEF (Article 30(1)) is legally mandated only for identical substances (according to Annex VI(2)). This clearly follows from Article 29(1), according to which the SIEF is formed for “the same phase-in substance”.<sup>32</sup> The same applies for the joint generation of new studies within the framework of the SIEF (Article 30(2)) and for the joint submission of the core data according to Articles 11 and 19. But the information on substance identity can involve confidential business information. This applies in particular for process-dependent impurities<sup>33</sup> and for additives necessary to preserve the stability of the substance. Among other things, Article 29(3) does oblige the SIEF participants to react to requests for information from other participants. But Article 29(3) cannot be interpreted to require the provision of confidential business information as well.

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<sup>29</sup> Quantitative or qualitative structure-activity relationship ((Q)SAR).

<sup>30</sup> Grouping of substances and read-across approach.

<sup>31</sup> For further details, please refer to Appendix A I section II.1.

<sup>32</sup> In the absence of the substance identity, the use of available studies can nonetheless be reasonable if the prerequisites in Annex XI(1.5) (Grouping of substances and read across approach) are met. The obligations according to Article 30 do not apply here, however. But within the framework of contractual cooperation (e. g. in consortia) this option can be used.

<sup>33</sup> It clearly follows from, among others, Article 13(5) that the degree of purity and the nature of impurities play a decisive role for the substance identity. This should be borne in mind during the controversial discussion of the term substance identity according to RIP 3.10.

With this in mind, the necessary process of clarification relative to substance identity among SIEF participants will only come to fruition in case of doubt when the SIEF participants protect their interests by means of a *non-disclosure and non-use agreement*. The model of the preliminary agreement submitted on communication in the SIEF included in

### Appendix D

serves this purpose.

The initial aim of the preliminary agreement is only to safeguard confidentiality for the necessary clarification process within or outside of the SIEF relative to the substance identity. But the agreement should preferably be extended to include the question of whether available studies within or outside of the SIEF can – despite the lack of substance identity – substitute for tests through application of the grouping of substances and read across approach according to Annex XI(1.5).<sup>34</sup>

If the clarification process shows that neither substance identity nor prerequisites for the grouping of substances and read-across approach exist, then further cooperation becomes superfluous. At this point there is also no legal obligation to share data or to submit core data jointly, as these obligations, as remarked at the outset, only apply where there is substance identity.

If the clarification process shows that either the substance identity or the prerequisites for the grouping of substances and read-across approach exist, then the partners of the preliminary agreement will want to discuss in a further step<sup>35</sup> the possible form of the cooperation. In particular, they will want to discuss the establishment of a consortium according to the model in Appendix C. These discussions and negotiations, too, must take place in a protected environment. The result of these negotiations can be the establishment of a consortium<sup>36</sup> or another form of cooperation. But the result can also

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<sup>34</sup> The application of the grouping of substances and read across approach according to Annex XI(1.5) does not involve one and the same SIEF, but rather a collaboration among multiple SIEFs. There is no legal obligation to share data here. In contractual terms, however, cooperation is possible and legally desirable in this case.

<sup>35</sup> The model of the preliminary agreement (Appendix B) and the model for the communication in the SIEF (Appendix D) meet in this 2nd step. In the preliminary agreement (Appendix B), the question of the substance specification (Annex 1 to the model consortium agreement) forms an essential part of the negotiations toward the establishment of a consortium.

<sup>36</sup> The model of a preliminary agreement in the Cesio proposals had merged this 2nd step with the 1st step of the model of a non-disclosure and non-use agreement submitted here. There the question of the substance specification (Annex 1 to the model consortium agreement) forms an essential part of the negotiations toward the establishment of a consortium. The partners of a non-disclosure and non-use agreement are free to negotiate on the establishment of a consortium from the outset, of course.

be that some partners “bail out” if the prerequisites for opting out according to Article 11(3) are met.

**b) Structure of the model**

First of all, the model includes the non-disclosure and non-use agreement relative to the clarification process for the substance identity of the pre-registered substances and of the substances where the available information is relevant to the application of the Annex XI(1.3) ((Q)SAR) and (1.5) (Grouping of substances and read-across approach). In case of a positive basis for cooperation, the non-disclosure and non-use agreement will be extended in a further module to include the clarification process on the form of cooperation. Here model D largely follows the model of the preliminary agreement in Appendix B, which should guide negotiations on the formation of a consortium.

**c) Compliance of the model with the REACH Reg.**

Compliance of the model with the REACH Reg. does not appear to be problematical, as the 1st step of the agreement serves to ensure the functionality of the SIEF.

**d) Compliance of the model with competition law**

The exchange of confidential business information required for the cooperation can be problematic in terms of competition law. It is not prohibited *per se*, particularly since the REACH Reg. legally mandates this cooperation. Within the SIEF the initial focus is on the determination of the substance identity.<sup>37</sup> But there is also a focus on the question of whether and to what extent available studies for substance A are also suitable for use in determining the substance properties of substance B. As Article 13(5) REACH Reg. shows, this is only the case if substance B is identical with substance A, including the degree of purity and the nature of – manufacturing-dependent – impurities. It is possible that this information is described in public documents. In this case, the transmission of such information is unobjectionable from the point of view of competition law. The situation is different, however, if even the purity in the specific case represents a market-relevant business secret or if the purity suggests a specific market behaviour. This must be investigated in each individual case; legal counsel should be consulted in case of doubt.

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<sup>37</sup> As a matter of principle, RIP 3.10 applies here, whereby the VCI holds different points of view regarding individual questions (e. g. on the so-called “80/20 rule”). If necessary, VCI should be contacted about this.

An annex to the model contract includes a *code of conduct* with a list of *do's and don'ts*. This list can provide only general indications for the daily work of consortia, however.

#### **4. Model Agreement on rights to use individual studies for the registration pursuant to REACH Reg. (Appendix E)**

##### **a) Possible scenarios for the use of the model**

The model can be used when, within a SIEF according to Article 30(1) REACH Reg., a specific study that a participant of the SIEF lacks for its registration is provided by another member of the SIEF in exchange for cost reimbursement. A contractual arrangement is needed here to regulate the scope of the right to use the study, the compensation to be paid, etc. More extensive cooperation within the framework of the joint submission of core data according to Articles 11 and 19 REACH Reg. may be legally required, but must be separated from the mechanisms of Article 30 REACH Reg.

In the case of substances that are already registered, not the model in Appendix E but the model in Appendix G applies for the sharing of available studies by means of a *letter of access*. The latter scenario also includes the case where the study owner has already registered a phase-in substance, and another SIEF participant has pre-registered but has a longer registration deadline.

##### **b) Structure of the model**

The model is contingent on the actors' having exchanged information on the substance identity prior to signing. For this reason, the substance specification can be stipulated in Annex 1 of the model. Although according to the scenario under a) the substance of the study owner has not been registered yet, the model provides for a *letter of access* as Annex 2. Here this *letter of access* should merely cover the requirement in Article 10(a) last sentence REACH Reg., according to which the proof that the registrant has permission to refer to the full study report of the study owner must be provided with the registration.

##### **c) Compliance of the model with the REACH Reg.**

The model serves the purpose of implementing the requirements on data sharing in Article 30. In the case of Article 30, this is contingent on the substance identity, which

the actors may have to clarify beforehand (possibly under application of the model in Appendix D).

According to Article 30(1) sentence 1 the SIEF participant requests “this study” (e. g. the study of vertebrate animals) from the study owner. But after payment has been made, the SIEF participant obtains only the permission to refer to the full study report for the purpose of registration. For this reason, the model grants a non-transferable right to use to the SIEF participant which includes the permission to refer to the full study report. In addition, the model entitles the SIEF participant to receive a copy of the study summaries, and in case of mutual agreement a copy of the study report.

With reference to the question of compensation to be paid for the right to use, the planned “cost sharing guidance” (Article 30(1) subparagraph 2) is not yet available. But the actors can orient themselves here according to the cost allocation for consortia. This cost allocation has been developed in the context of practical collaboration in voluntary consortia, e. g. according to the ICCA/OECD existing chemicals programme, taking valuation rules for studies into consideration. In the opinion of the authors, the cost allocation according to Annex 7 and 9 of the model of a consortium agreement in Appendix C follows the principles of “fair, transparent and non-discriminatory” in terms of Article 27(3) and (6) and Article 30(1). This seems to be confirmed by the ongoing work on the “*Technical Guidance Document on Data Sharing*“ (RIP 3.4) (*Final draft guidance document RIP 3.4 (Review 02 May, 2007)*), an Annex 4 of which presents rules on cost sharing that largely correspond to the Annexes 7 and 9 of this model. Annex 9 of the model for a consortium agreement also includes a compensation rule for the provision of an individual study.<sup>38</sup>

#### **d) Compliance of the model with competition law**

There appear to be no special problems relative to competition law.

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<sup>38</sup> Based on the replacement value of the study determined according to the valuation rules in Annex 7 of the model agreement.

## **5. Model Agreement on joint submission of core data for registration pursuant to Articles 11 and 19 REACH Reg. (Appendix F)**

### **a) Possible scenarios for the use of the model**

An essential feature for a simplified form of data sharing that requires no consortium agreement is that the contract parties restrict their collaboration to the legal minimum. The minimum requirement is met when one of the registrants (of the same substance) has all of the necessary test data for the registration (information according to Article 10(a)(vi) and (vii)) or procures it, and by agreement with the other manufacturers/importers (of the same substance) submits it to the Agency along with the other information required in Articles 11 and 19 (classification and labelling, test proposals for more extensive testing, possibly quality assurance information). In this case, the other actors associate themselves with the data of the lead registrant.

The practical application of this contract model is seen above all in HPVCs. A further application area presents itself where two companies, A and B, have multiple substances that are identical to each other, and share the work of compiling the registration dossiers for these substances without wishing more comprehensive or closer contractual collaboration.

The joint assessment of the risks within the framework of the Chemical Safety Report is not a legal requirement and therefore does not apply in this scenario. Similarly, the preparation for the joint conduct of studies involving tests on vertebrate animals according to Annexes IX and X does not apply in this scenario. These tests are to be conducted on the basis of requirements of the Agency within the framework of dossier evaluation. An organisation of the collaboration is then necessary, however (Article 40(3)(e)) but not mandatory within the phase of registration.

### **b) Structure of the model**

As presented under a), this simplified model depends on the lead registrant providing input with which the other actors associate themselves. Therefore prior to conclusion of the agreement according to this model, the potential users of the data of the lead registrant must receive the necessary knowledge of the substance identity of the substance manufactured/imported by the lead registrant as well as of the data that the lead registrant has available for that substance. In the case of HPVCs, the know-how protection generally plays no major role. For the case that the disclosure of the data by

A to B could affect confidential business information, the introduction of the model contract includes an option stating that the interested parties have received this knowledge based on a *non-disclosure and non-use agreement* – possibly according to the model in Appendix D of this project.

With or without a *non-disclosure and non-use agreement*, the lead registrant discloses its substance identity in its offer, i. e. not merely the information of the pre-registration. This substance identity communicated by the lead registrant is definitive for the further course of the procedure. The other actors verify on their own whether their own substance identity matches that of the lead registrant. If so, they associate themselves with it. When this is not possible from their point of view, they can either ask the lead registrant to extend the range (e. g. relative to impurities) or choose to *opt out* according to Article 11(3), if sensitive data are involved here.

The data presented by the lead registrant (including *waiving* and test proposals) are also accepted. If the lead registrant justifies the *waiving* with exposure-dependent circumstances and the other actors have other exposure conditions, they can either ask the lead registrant to extend the range of the exposures or choose to *opt out* according to Article 11(3), if sensitive data are involved here.

A number of variants are possible. One of the actors might have data that differ at one endpoint, for example. Here this actor can, under certain circumstances, choose to *opt out* for this endpoint according to Article 11(3)(c). Another variant can be the case where the lead registrant too lacks a study required for registration according to Annexes VII and VIII, which the other actors also do not have. In this case, the test must be carried out for the registration. If the lead registrant carries out the missing test with the consent of the other actors, then the regulations of Article 30 (2) apply here – provided no other contractual provisions have been established. Thus the contract parties receive the full study report (not merely a right of reference) for the missing study upon payment of their share to the lead registrant. Regulations governing the organisation of the cooperation are also largely unnecessary here if the other actors accede to the comprehensive management of the lead registrant.

**c) Compliance of the model with the REACH Reg.**

The contract model is based on the assumption that A will be the “lead registrant”, i. e. not only B but also most of the other SIEF participants will associate themselves with the joint submission of the core data by A – in the interest of saving time, for example.

But it is also conceivable that another group of participants of a SIEF will designate a “lead registrant” and this latter submits the registration dossier. In this case, A’s only recourse is to try to gain acceptance of its core data by the SIEF in the joint submission. With this in mind, Section II.4 of the contract model contains a relevant opening clause for the case where the lead role of A cannot be implemented. But the contractual obligation can also be met by A in this scenario, as A can submit its data separately for A and B, and thereby declare and justify for A and B the *opt-out* according to Article 11(3) with reference to the registration of core data by other participants of the SIEF. This requires an agreement with B on how to proceed thereafter, however. The opening clause is particularly important where the contract according to Model F is concluded prior to the pre-registration phase.

**d) Compliance of the model with competition law**

There are no apparent problems in terms of competition law as long as the lead registrant does not exclude any of the participants in the SIEF from its offer of joint registration of the core data. This can involve the exchange of confidential data only with **exposure-dependent** *waiving*. Particular caution should be exercised here, as this can involve market-relevant data. In any case, this simplified form of cooperation should also be based on the *code of conduct* concerning competition law as an annex to the contract.

**6. Model Agreement on granting a right to refer to registered data (Appendix G)**

**a) Possible scenarios for the use of the model**

The model can always be used in the case where a substance has already been registered, so that the Agency has already received the registered data.

This is the case when a non phase-in substance or a non pre-registered phase-in substance is to be registered and the potential registrant wishes to make reference to study summaries registered less than 12 years earlier (cf. Appendix A I under Section IV). Here Articles 26 and 27 give priority to an agreement among the actors over Agency interventions.

But the model also applies for the case where the study owner has already registered a phase-in substance, and the other SIEF participant has pre-registered the same phase-in substance but has a longer registration deadline. It is conceivable that the members of

the SIEF have different registration deadlines. In such cases, joint submission of the core data according to Articles 11 and 19 REACH Reg. cannot work. A party (designated here as B) that is under no obligation to register before 2013 or even 2018 cannot be forced to register already by 2010 simply because a member of the SIEF (designated here as A) must register already by that point in time. Nor can B be forced – already long before expiration of its registration deadline – to verify the registration dossier of A and to submit its declaration of agreement or, failing such agreement, choose to *opt out* according to Article 11(3).<sup>39</sup>

Articles 26 and 27 do not apply to phase-in substances that have already been pre-registered, but rather Article 30 applies if the potential registrant wishes to make reference to study summaries of another SIEF participant that have already been registered. The model can also be used for this scenario.

But the model can also be used where the potential registrant B wishes to make reference – with the permission of A – not only to individual studies and study summaries, but to all of the core data<sup>40</sup> submitted by A. This scenario essentially corresponds to the objectives of a joint submission of the core data according to Articles 11 and 19, but with other means.

## **b) Structure of the model**

In contrast to the scenarios of models E and F, the substance of the owner of the data (designated as A in the example) is already registered. By this means, the Agency has access to the information on the substance identity of A.

In the case of non phase-in substances and non pre-registered phase-in substances, the Agency gets the information on the identity of the substance of B within B's inquiry. The Agency starts the communication process between A and B only in the case of sameness of the substances concerned (Article 26(3)). The definition of the substance identity in Annex 1 is not absolutely necessary here.

In the case of pre-registered phase-in substances, on the other hand, the definition of the substance identity in Annex 1 has a constitutive character. This can take the form of both sides exchanging information on the substance identity (possibly according to model D) before signing the agreement. But it can also take the form of A, as owner of

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<sup>39</sup> Apparently another point of view is held in the *Final draft guidance document RIP 3.4 (Review 02 May, 2007)*. For further details, please refer to Appendix A I under Section III.2.b.

<sup>40</sup> Footnote 11.

the studies or core data, disclosing its substance identity in its offer. This substance identity communicated by A is decisive for the further course of the procedure. The other actors verify on their own whether their own substance identity matches that of A. They do not need to disclose their substance identity to A in this case. It is their responsibility to check whether substance identity is given, and thus whether the data registered by A match or not.

A grants a *letter of access* to its studies. If granting a *letter of access* to all core data (including waiving and test proposals) is wanted, then certain particularities must be taken into account. If the lead registrant justifies the *waiving* with exposure-dependent circumstances, the other actors must check whether their exposure conditions differ. If so, they must submit test data or test proposals that differ accordingly. It is possible that they should then negotiate with A over a differentiated letter of access – possibly with a different financial compensation arrangement.

**c) Compliance of the model with the REACH Reg.**

The model complies with the REACH REG. to the extent that it involves the access to study summaries which are already registered according to Articles 26 and 27 (or Article 30 in the case of pre-registered phase-in-substances). If it involves the access to all core data<sup>41</sup> for pre-registered phase-in substances, then Articles 11 and 19 do not apply (anymore) when registration has already been completed. But the objectives of Articles 11 and 19 are also achieved in this case.

**d) Compliance of the model with competition law**

There are no apparent problems from a competition law point of view as long as A offers the right to refer to all members of the SIEF.

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<sup>41</sup> Footnote 11.

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