

## **Results of the project:**

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

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

## **→→ Appendix A I:**

### **Data sharing according to REACH as a framework for contractual forms of data sharing**

Frankfurt, June 2007

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<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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## I. Overview

Avoiding the duplication of studies is a major focus of the lawmakers drafting the REACH Reg.<sup>3</sup> This relates not only to studies involving tests on vertebrate animals, but also to all test data from the application of Annexes VII to IX to be submitted with the registration (Annexes VII and VIII) or as test proposals (Annexes IX and X). In order to implement these objectives, the REACH Reg. establishes a detailed set of rules with the following elements:

- creation of a forum for the exchange of substance information (*Substance Information Exchange Forum* – SIEF) for each pre-registered phase-in substance, with rules for the exchange of available studies and for the generation of missing studies, along with the associated cost sharing (see II. below);
- joint submission of core data<sup>4</sup> through the lead registrant according to Articles 11 and 19 (see III. below);
- joint use of available test data in the case of substances already registered according to Articles 26 and 27 with cost sharing while limiting the protection of registered data to 12 years (see IV. below);
- joint conduct of the required new studies involving tests on vertebrate animals according to Annex IX and X on the basis of the test proposals in the registration dossier in the phase of dossier evaluation according to Title VI REACH Reg. (see V. below).

The presentation and interpretation of this set of rules of the REACH Reg. is – with the exception of the evaluation of test proposals according to Title VI REACH Reg. – the object of the planned *Technical Guidance Document on Data Sharing* (RIP 3.4).<sup>5</sup> With this in mind, the following presentation is merely a cursory one examining the legal basis for model agreements on data sharing compiled in this project. It goes without saying that these model

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<sup>3</sup> Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), (REACH Regulation), OJ No L 396, 30.12.2006, p. 1 – hereinafter referred to as: “REACH Reg.”; citations of articles of law that do not specify the law refer to the REACH Reg.

<sup>4</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.

<sup>5</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 interpretation is offered here in certain cases. 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>.

contracts should not contradict the set of legal rules governing data sharing in the REACH Reg.

## **II. Substance Information Exchange Forum – SIEF**

### **1. Establishment of the SIEF**

As opposed to contractual cooperation in data sharing (e. g. within the framework of a consortium), the SIEF is established by force of law as a result of the pre-registration of a phase-in substance. For each pre-registered phase-in substance, a SIEF is formed as a virtual forum. Primarily, SIEF participants are the manufacturers or importers that have pre-registered this substance. They are considered potential registrants, and according to Article 29(2) the provisions governing the exchange of information according to Article 10(a)(vi) and (vii)<sup>6</sup> and the classification and labelling of the substance are mainly addressed to these SIEF participants. The SIEF also includes downstream users and third parties who have transmitted information to the Agency on the same phase-in substance in accordance with Article 28, or whose information on the same phase-in substance is held by the Agency in accordance with Article 15 as substances in plant protection and biocidal products that are regarded as being registered in the areas of crop protection products and biocides. Finally, SIEF includes registrants who have submitted a registration dossier for this phase-in substance prior to the end of the transitional period that applies to them.

In accordance with Article 28(4) the Agency publishes a list of pre-registered substances. This list includes, among other things, the name of the substances, but not the name of the party who pre-registered or provided the information on this substance. The preparatory papers for RIP 3.4 show, however, that the names, as a minimum, of the manufacturers or importers who have pre-registered will be notified to the other manufacturers or importers of the same substance through REACH IT.<sup>7</sup>

There is no standard point in time for the establishment of the respective SIEF with the rights and obligations arising from Articles 29 and 30. The expiration of the pre-registration deadline on 01.12.2008 initially allows for the establishment of a *pre*-SIEF that as a rule initially only triggers communication on the substance identity among the participants of the

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<sup>6</sup> Study summaries and robust study summaries of the information derived from the application of Annexes VII to XI.

<sup>7</sup> This seems reasonable, whereby one is only left to wonder why this does not appear in the REACH Reg. itself.

*pre*-SIEF, but not the rights and obligations according to Articles 29 and 30 (see Point 2 below).<sup>8</sup>

Observations in the field reveal that many of the actors are not waiting for the pre-registration that commences on 01.06.2008 and the establishment of the respective SIEF. Some contractual partnerships are already being started before the REACH Reg. entered into force on 01.06.2007, or in any case before the start of the pre-registration period on 01.06.2008. But it is advisable that such contractual partnerships already take the rights and obligations of SIEF participants into account that will enter into force at a later date.

## **2. Substance identity/group of substances**

### **a) Substance information of pre-registration generally insufficient**

According to Article 29(1), the SIEF will be formed for each pre-registered substance. Participants of the SIEF are explicitly the manufacturers and importers of the same phase-in substance. The information from the pre-registration concerning the substance identity is generally insufficient to determine whether the same substance has been pre-registered. It is known in practice, for example, that more than one substance, each with a different identity, can relate to one and the same CAS or EINECS number. For this reason in the preparation for RIP 3.4 there has been some discussion about using the information from the pre-registration (name of the substance with EINECS or CAS number, if available, etc.) initially only for the purposes of a *pre*-SIEF. The *formation* of the SIEF arises only after the actors verify the *sameness of the substance*.<sup>9</sup>

The REACH Reg. provides no indication, however, as to how this verification should be carried out. According to REACH Reg., the Agency has no function here, particularly since it does not have the complete information on substance identity based on the pre-registration.<sup>10</sup> For this reason, the SIEF participants themselves are responsible for the verification of the *sameness of the substance*.<sup>11</sup> But the information on substance identity very often involves confidential business information. This applies

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<sup>8</sup> *Final draft guidance document RIP 3.4 (Review 02 May, 2007).*

<sup>9</sup> *Final draft guidance document RIP 3.4 (Review 02 May, 2007).* Here reference is made to the *Guidance document* to RIP 3.10 as the “standard” for the determination of the substance identity. Some point of contention remain in this connection, however.

<sup>10</sup> With regard to data sharing on substances that are already registered, this is another matter. There subsequent registrants must present the full substance identity to the Agency.

<sup>11</sup> In the *Final draft* to RIP 3.4 (*Review 02 May, 2007*), a *facilitator* is recommended from among the SIEF participants to coordinate the SIEF participants as a group. It remains to be seen whether this proposal goes through or whether other mechanisms will be identified.

in particular for process-dependent impurities and for additives necessary to preserve the stability of the substance. According to Article 29(3), SIEF participants must react to requests for information from other participants. But this cannot imply an obligation to pass on confidential business information.

This shows that the operation of the SIEF relies on the *goodwill* of the actors who are prepared, on the basis of on a *non-disclosure and non use-agreement*, to exchange the information necessary for the determination of the substance identity – directly, or possibly through a neutral third party. The fact that this exchange of information also has, under certain circumstances, implications in terms of competition law be noted in passing here (details in Appendix A II of this project).

With this in mind, a model for a “Preliminary agreement on communication in the SIEF” (Appendix D) has also been developed within the frame of this project. The model offers well-meaning actors a basis for the exchange of information on substance identity. This approach can serve not only to clarify the question of whether the actors belong to the “right” SIEF. It can also shed light on the further questions of whether and to what extent the nature of impurities and the degree of purity permit a transfer of the results of available studies to the substances represented in the SIEF in regard to the respective endpoints.<sup>12</sup>

## **b) Group of substances**

According to Article 28(1)(d), the potential registrants shall transmit not only the name of the manufactured or imported substances, but also the name of substances (including EINECS and CAS number) where the available information is relevant for the application of Annex XI(1.3) and (1.5). In its publication according to Article 28(4), the Agency also publishes the name of these substances. The grouping of substances and read-across approach according to Annex IX.(1.5) is of particular interest here. Where this concept can be applied, tests can also be used for substances which are not identical.

Thus the lawmakers clearly want to use pre-registration also for the application of the grouping of substances and read-across approach. On the other hand, the SIEF is formed for “the same phase-in substance” only. This means that the legal rights and obligations

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<sup>12</sup> Article 13(5) underscores the fact that the degree of purity and nature of impurities play a decisive role in the transferability of studies. With a *letter of access* of the study owner, Article 13(5) makes the right to refer to study summaries that are already registered dependent on the substance identity taking purity and nature of impurities into account.

of the data sharing only apply within the respective SIEF. There is no legal obligation to share data between different SIEFs.<sup>13</sup>

This extends the range of contractual regulation of cooperation to incorporate the grouping of substances and read-across approach as well. The “Preliminary agreement on communication in the SIEF” (the model already mentioned as Appendix D) incorporates this extended field of cooperation as an option. Note, however, that this cooperation is not a legal obligation.

### **3. The exchange of available studies in the SIEF**

#### **a) Scope of obligation to share available studies**

The scope of the obligation to exchange available studies on the properties of substances according to Annexes VII to XI is specified in Article 30(1) sentences 1 to 3.<sup>14</sup> It states that the obligation of a SIEF participant to clarify whether an applicable study is available through inquiry within the SIEF is contingent on the precondition: “Before testing is carried out in order to meet the information requirements for the purposes of registration, ...”. This precondition restricts the obligation to exchange available studies. Only the tests according to Annexes VII and VIII must be carried out for the purposes of registration. For the information according to Annexes IX and X, only test proposals are submitted with the registration. The conduct of this testing becomes part of the evaluation only after the Agency issues the relevant requirements. Article 30(1) thus generates obligations to exchange available studies only in relation to studies according to Annexes VII and VIII.<sup>15</sup>

In addition, the different registration deadlines are important as well.<sup>16</sup> The standardised deadline for pre-registration according to Article 28 (independent of the respective tonnage band) does make all manufacturers/importers “of the same phase-in substance” participants in the SIEF. But those who need register only upon expiration of the last

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<sup>13</sup> The *Final draft to RIP 3.4 (Review 02 May, 2007)* shares this point of view. In order to facilitate *read-across* however, it is recommended to provide access to the website of the applicable SIEF for the manufacturers/importers of *read-across* substances via REACH IT.

<sup>14</sup> The *Final draft to RIP 3.4 (Review 02 May, 2007)* describes the application of Article 30 REACH Reg. as the “*individual route*” to be applied only in exceptional cases. As a rule, the “*collective route*” is preferred, which defines the entire process of registration as the common task of all SIEF participants. It should be mentioned here that the *collective route* described can only be realised within the framework of a voluntary consortium. There is no legal obligation in this case. The only legal obligation relates to the requirements in Article 30 (and Articles 11 and 19), which are described in the present analysis.

<sup>15</sup> The *Final draft to RIP 3.4 (Review 02 May, 2007)* does not deal with the aspect adequately.

<sup>16</sup> The *Final draft to RIP 3.4 (Review 02 May, 2007)* fails to treat this aspect, too.

transitional period (eleven years) will see no reason to request studies already within the first registration deadline period (three and one-half years after the Regulation enters into force). Carrying out tests at that point in time is completely out of the question for them. In contrast to the Commission's proposal and later drafts, Article 30(1) in the final version contains no deadline for the requesting of studies. This means that obligations to inquire about available studies in the SIEF according to Article 30(1) depend on the respective registration deadline.<sup>17</sup> The inverse interpretation does not apply, however. Those who receive a request for available studies prior to expiration of their registration deadline must respond in a timely manner under the procedure described under c) below and issue the available studies.

Thus the scope of Article 30(1) sentences 1 to 3 is relatively narrow.

#### **b) Classification and labelling**

The goal of every SIEF is also to establish agreement on the classification and labelling of the substance where differences exist among the potential registrants (Article 29(2)(b)). But there are no instruments in Articles 29 and 30 to achieve this goal of the SIEF. Achieving agreement on classification and labelling only takes on an obligatory character within the framework of the joint submission of data by multiple registrants according to Article 11 (see III. of this analysis). Failure to reach an agreement on classification and labelling within the SIEF, however, remains of no consequence according to the rules of the SIEF.

#### **c) Procedure in the exchange of available studies in the SIEF**

According to Article 30(1) the registrant must clarify whether an applicable study is available within his SIEF before carrying out a test according to Annexes VII and VIII for registration. The registrant must request available studies involving tests on vertebrate animals; he is free to request studies not involving tests on vertebrate animals.

The study owner shall provide proof of cost of the study within one month after the request. The REACH Reg. does not say how this cost is to be calculated. So in practice the question will arise as to whether the costs in terms of Article 30(1) subparagraph 2

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<sup>17</sup> The *Final draft* to RIP 3.4 (*Review 02 May, 2007*) does not analyse this aspect. According to Article 23(4), those subject to registration obligations can voluntarily register at any time prior to the expiration of their deadline. Article 30 then applies to them earlier, of course.

are to include only the laboratory costs incurred by the institute that carried out the test, or whether they are to be based on the current replacement value taking other cost factors into account. The REACH Reg. merely states that the costs should be determined “in a fair, transparent and non-discriminatory way”. The official interpretation of this formula is expected in the planned – legally non-binding – “Cost Sharing Guidance”. This guidance is not yet available, however.<sup>18</sup> If the actors fail to reach an agreement – with or without the cost sharing guidance – then Article 30(1) subparagraph 2 stipulates that the cost “shall be shared equally”.<sup>19</sup> The costs will be “shared equally” only for studies that the registrant needs according to his tonnage band.

Within two weeks after receipt of payment, the owner shall give permission to refer to the full study report for the purpose of registration (Article 30(1) subparagraph 2). This provision requires interpretation. According to the intention and purpose of data sharing, the recipient must be put in a position to fulfil his obligations according to Article 10(a)(vi) and (vii) relative to the endpoint treated in the study (study summaries and robust study summaries relative to that endpoint). For this reason, the study owner will have to provide either the study summary (resp. the robust study summary) or the study itself so the recipient can write the summary himself if necessary.<sup>20</sup> In legal terms, this can only involve a restricted and non-transferable right to use. Preferably, the actors will reach a contractual agreement on this. Within the framework of this project, a model of such an agreement is provided for this purpose as Appendix E.

#### **d) Sanctions for failure to fulfil obligations to exchange available studies in the SIEF**

The sanctions for failure to fulfil obligations to exchange available studies in the SIEF are regulated in Article 30(3). The first point to consider here is that the sanctions regulated in Article 30(3) do not cover the case where the actors – the study owner and

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<sup>18</sup> Annex 4 (*cost sharing*) of the *Final draft* to RIP 3.4 (*Review 02 May, 2007*) calls for such a guidance document and declares the current replacement value of the study as the criterion. The guidance is largely based on practical experience with voluntary consortia (e. g. in the HERA project) as set down in Annex 7 of the model of a consortium contract already in the Cesio proposals of December 2005 and now included once again in the model in Appendix C of this project.

<sup>19</sup> This formulation resolves the possible conflict only when it is clear which factors determine the “cost” in terms of Article 30(1). For this reason, the wording “shared equally” will likewise be difficult at best to implement without the aforementioned cost sharing guidance.

<sup>20</sup> According to Article 13(5), if the substance is already registered, then reference to the study summaries of the previous registrant suffices to fulfil the obligations according to Article 10(a)(vi) and (vii) provided the permission for this has been given by the previous registrant and the substance identity has been established. This would be a legally acceptable alternative to transmittal of the study report or the study summary. It remains to be seen whether this can be applied in practice.

the requesting registrant – fail to agree on a cost sharing arrangement. As discussed under c) above, the cost shall be “shared equally” in this case. The lawmakers treat this question as one that must be clarified exclusively by the actors. The Agency is not involved in the event of a failure to agree.

The sanctions in Article 30(3) relate to the case where the study owner refuses to provide proof of the cost of his study or refuses to provide the study itself to the other participants. If this involves studies on vertebrate animals, then the study owner who refuses shall not be able to proceed with registration until he provides the information to the other participant(s). The other participant(s) shall proceed with registration without fulfilling the applicable information requirement. The study will only be repeated if the owner persistently refuses and the Agency decides that the test should be repeated. If this relates to test data involving tests on vertebrate animals, then the refusal of the study owner to provide proof of cost or to issue the study will force the requesting SIEF participant to repeat the study. In both cases – studies involving and not involving tests on vertebrate animals – the owner of the study who refuses to provide proof of the cost or to provide the study will be penalised (probably by fines, as a rule) (Article 30(6)). But there are still no national regulations governing penalties or fines which clearly link the threat to specific offences.

The REACH Reg. thus creates a “threat of coercion” for the case where the study owner refuses to provide proof of the cost or to provide the study. It remains to be seen whether this threat of coercion can be implemented in the event of a dispute. The sanctions are hardly to be applied if the substance identity is a matter of dispute between the study owner and the party requesting the study. In that case, it is only certain that both parties are in the same *pre*-SIEF as a result of their pre-registration. But as discussed under a) above, the question as to whether both parties are in the “right” SIEF can only be clarified based only on the voluntary clarification of the substance identity – possibly based on a *non-disclosure and non-use agreement* according to Appendix D of this project. According to REACH Reg., the Agency has no right to intervene in the clarification of the substance identity in this case. Thus the sanctions according to Article 30(3) and (6) might be irrelevant if the question of substance identity is not satisfactorily clarified between the actors.

**e) The granting of a right to refer by the Agency**

In certain cases, Article 30(3) sentence 4 and 5 empowers the Agency to grant to a third party the right to refer to test data that have already been registered. This is to be the

case with phase-in substances if the study owner refuses to issue the study to the third party – for details on sanctions imposed to the study owner, refer to d) above – and then the Agency determines that another registrant – i. e. presumably not the refusing study owner – has registered the missing study summary. It is particularly strange that in the case of Article 30(3) sentence 4 and 5 the granting of the right to refer by the Agency is not preceded by a negotiation procedure e. g. on cost sharing between the “other registrant” and the third party who needs the study. Instead, the right to refer will be granted *ex officio* without a request of the third party and without a hearing of the “other registrant”. The question of whether this provisions meets the requirements of the fundamental rights protected by Community law will not be examined further here.<sup>21</sup>

According to Article 30(3) sentence 4, the Agency grants the third party permission to refer to the registered data of the “other registrant” without imposing an obligation on that third party to pay any costs. Only when the owner of the data provides the full study report to the third party shall the study owner be entitled to claim payment from the beneficiary – which he must assert before the national courts, however. If the beneficiary does not need the study for the purposes of registration, then he can register at no cost.<sup>22</sup> It appears extremely doubtful that such a free-of-charge right of reference will retain its validity from the standpoint of the principle of equal treatment<sup>23</sup> that applies on the EU level. Possibly this question may require clarification by the European Court of Justice (ECJ).

#### 4. Procedures in the SIEF when studies are not available

If a relevant study involving tests is not available within the SIEF, then only one study will be carried out by a participant acting on behalf of the other participants. Article 30(2) obliges the participants of a SIEF to undertake all reasonable steps to achieve agreement within a deadline set by the Agency, as to who is to carry out the test on behalf of the other participants and to submit a study summary or robust study summary to the Agency. If no agreement is reached, then the Agency will designate which registrant or downstream user is to carry out the test.

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<sup>21</sup> In this context *the right to a hearing* is also one of the fundamental rights protected by Community law according to the case law of the ECJ (ECJ, 23.10.1974 Case 17/74, ECR 1974 - 1063, par. 15).

<sup>22</sup> According to Article 27(6), there is no free-of-charge right of reference with non phase-in substances and with phase-in substances that have not been pre-registered. This clause was inserted into Article 27(6) “at the last minute” during the review of the legislation. A clause of this kind is missing from Article 30(3) sentence 4 and 5, however.

<sup>23</sup> Prevailing opinion, cf. among other references ECJ, Judgement of 7 July 1993, Case-No. C-217/91, EC Reports 1993, p. I – 3923, par. 37 – *Kingdom of Spain/Commission*; ECJ, Judgement of 13 December 1994, Case-No. C-306/93, EC Reports 1994, p. I – 5555, par. 30 – *SMW Winzersekt*).

The requirements in Article 30(2) are also tied to the prerequisite of the substance identity among the actors. The fact that the substance of the actors belongs to a group of substances does not suffice to meet the requirements in Article 30(2). Moreover, Article 30(2) applies only in the case of tests according to Annexes VII and VIII, as only those tests have to be carried out for the registration; for necessary studies involving tests on vertebrate animals according to Annexes IX and X, only test proposals are submitted in the registration. Decisions concerning those proposals are then taken within the framework of dossier evaluation. SIEF participants are obliged to exchange information according to Article 10(a)(vi) and (vii) only “for the purposes of registration” (Article 29(2)(a)).

The procedure prescribed in Article 30(2) necessitates an intensive interaction of the parties, which basically involves the entire registration procedure and can hardly be accomplished without contractual regulations that must also take into account, in particular, questions of competition law, among other things. The decision must also be taken here, for example, as to whether a test is required at all according to the provisions of Annex XI REACH Reg. Basically, such interaction is conceivable from a practical point of view only within the framework of a contract that regulates all rights and obligations of the actors. Within the framework of this project, models for such a contractual regulation are provided in the Appendices C (Consortium agreement) and F (Agreement on joint submission of core data according to Articles 11 and 19).

## **5. Duration of the SIEF**

“Each SIEF shall be operational until 1 June 2018”. This is stated in Article 29(3) sentence 2. The deadline is oriented to the course of the last registration period for substances in a quantity of from 1 to 100 tonnes per year (Article 23(3)). Operational means that up to that point in time the obligation to exchange available studies and the obligation to generate new studies for purposes of registration will remain in force.

Contractual agreements established for the implementation of the legal obligations (e. g. consortia) must also be oriented to this deadline.

## **6. Opt-out options**

The SIEF provisions in Articles 29 and 30 include no right of SIEF participants to *opt out*.<sup>24</sup> Thus anyone who, by force of law, is a participant of the SIEF cannot leave that SIEF by

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<sup>24</sup> The parliamentary resolution of 17.11.2006 still contains such an option relative to test data without testing of vertebrate animals. But the latest review of the legislation did not provide for this.

giving notice of termination or other such declaration. Even where the SIEF participant stops production or explicitly dispenses with registration, it remains unclear whether this leads to the withdrawal from the SIEF. In any case, a registrant who, in accordance with Article 11(3), has opted against joint submission of the core data and registered separately, remains a SIEF participant with all rights and obligations.

Notwithstanding this, the respective SIEF always applies only for “the same substance”. Section II.2 of this analysis examines in greater detail the problem of unclear definition of substance identity through the pre-registration data. These data only lead to the *pre*-SIEF. If, after pre-registration, it is determined – e. g. within the framework of a *non-disclosure and non-use agreement* according to the model in Appendix D – that the actors do not manufacture or import “the same substance” (e. g. as a result of different impurities), then it is clear that the actors do not belong to the same SIEF. Based on the current status of the work for RIP 3.4, it has yet to be clarified how the respective assignments to the “right” SIEF are to be made. One will have to wait for the final version of RIP 3.4.

### **III. Joint submission of core data according to Articles 11 and 19 REACH Reg.**

#### **1. Overview of the regulations**

Articles 11 (for substances) and 19 (for intermediates) oblige the manufacturers/importers of the same substance to joint submission of the core data<sup>25</sup> within the framework of their registrations. This is to occur through submission of these core data by the “lead registrant” within the framework of his registration with the agreement of the other registrants. Thus each manufacturer/importer subject to registration obligations registers himself; the only difference being that part of the data he must submit according to Article 10 – the core data, in fact – is submitted on behalf of all registrants by the lead registrant.<sup>26</sup> In this regard, certain data (identity of the manufacturer, identity of the substance, information on the manufacture and use of the substance, information on exposure according to Annex VI(6) for substances in quantities of from 1 to 10 tonnes) must be submitted separately by each registrant.

The joint submission by the lead registrant – on behalf of the other registrants – of the Chemical Safety Report and the guidance on the safe use of the substance is possible but not mandatory.

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<sup>25</sup> See footnote 3.

<sup>26</sup> Thus the idea of OSOR (*One Substance One Registration*) has been achieved only partially.

In exceptional cases, Articles 11(3) and 19(2) enable separate submission of the core data (*opt-out*, for further details see section 3 d) below).

Fulfilment of the obligations according to Articles 11 and 19 necessitates an extensive collaboration among the manufacturers/importers of the same substance during the registration process. In particular, this involves assessments of whether and to what extent available studies are adequate and additional studies are required. In this connection, a whole series of legal questions must be considered, the regulation of which the REACH Reg. leaves to the “civil law self-organisation”.<sup>27</sup> This can take the form of a comprehensive consortium agreement (e. g. according to the model in Appendix C of this project). But it can also be handled by having one manufacturer or importer compile the registration dossier in the role of lead registrant, whereby the other manufacturers/importers then associate themselves with that information, more or less without discussion. This, too, requires contractual agreements (cf. the model in Appendix F of this project).

## **2. Specific issues**

### **a) Substance identity/group of substances**

The obligations according to Articles 11 and 19 apply only for the manufacturers/importers of “the same substance”. A registration must be submitted for each individual substance. To the extent that substances belong to a substance group in terms of the grouping of substances and read-across approach according to Annex XI(1.5), this involves different individual substances, each of which must be registered independently. Thus there is no obligation according to Articles 11 and 19 for manufacturers/importers of the substances of a substance group to submit these core data jointly. A contract (in particular, a consortium agreement) can also be used, however, to organise and coordinate the submission of registration data within the framework of formally separate registrations for manufacturers/importers of the substances belonging to a group of substances. Such contracts can make use of the options (possible *waiving* of for individual tests) provided under the grouping of substances and read-across approach in Annex XI(1.5) REACH Reg., which also ultimately result in cost advantages.

Inasmuch as the legal obligations in Articles 11 and 19 are tied to the substance identity (“the same substance”), the joint submission of the core data may involve only those

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<sup>27</sup> cf. Fluck, in a German publication “Schriften zum deutschen und europäischen Umweltrecht”, Vol. 32, p. 127, footnote 17.

members of the SIEF who manufacture or import the same substance. Thus the *pre-SIEF*, which will be established only on the basis of the pre-registration information, does not provide the relevant criteria for the applicability of Articles 11 and 19.

**b) Different registration deadlines**

Article 11(2) clearly states on the one hand that, in the joint submission of the core data, each registrant need only comply for core data that are required within his tonnage band. The different registration deadlines are not mentioned here. On the other hand, no-one can be forced to register earlier than he is prescribed to do so by the regulations. During the deliberations on the REACH Reg., tonnage-dependent registration deadlines were a core element of the protection provisions in favour of the affected economic sector, especially also for SMEs. Article 23, which regulates the registration deadlines, makes no provision for suspending the deadlines relative to the joint submission of the core data according to Articles 11 and 19. Nor do the rules governing the *opt-out* in Article 11(3) include any mention of different registration deadlines. Thus the use of the registration deadlines granted according to Article 23 requires no justification in terms of the *opt-out* according to Article 11(3). Consequently, this means that Articles 11 and 19 essentially ought to obtain relevance for the manufacturers/importers within the same tonnage band.

The deliberations of the *Final draft* of RIP 3.4 (*Review 02 May, 2007*) contradict the interpretation presented here. According to those deliberations, the obligations to submit core data jointly should apply to all manufacturers, importers and only representatives of the same substance from the outset, independent of their tonnage bands.<sup>28</sup> The *Final draft* provides no further justification for this interpretation, however. The registration deadlines granted under Article 23 are not considered. For this reason, the interpretation fails to convince. Accordingly, VCI has strongly objected to the interpretation represented in the *Final draft* of RIP 3.4 (*Review 02 May, 2007*). One must now wait to see whether the review of RIP 3.4 within its adoption procedure involving the member states leads to an adjustment of this interpretation before its final adoption.

A registrant can voluntarily register in advance of his registration deadline, however (Article 23(4)). He can also undertake contractually within a consortium to submit his registration at an earlier point in time together with other manufacturers/importers. This

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<sup>28</sup> Section 9.3.1 of the *Final draft* of RIP 3.4 (*Review 02 May, 2007*)

can be advantageous to him from a market standpoint (e. g. receipt of a registration number at an earlier point in time).

### c) **Lead registrant**

A lead registrant must submit the core data according to Articles 11 and 19 on behalf of all registrants of the same substance. No further details are specified, however, as to who this lead registrant is or how he is selected. The REACH Reg. counts on the self-organisation capacities of the SIEF participants in this regard. Experience will show how well this works. In general, a market leader or possibly a consortium formed outside of the SIEF will prefer to assume the role of the lead registrant. The question of what happens when no lead registrant can be found, or when the actors cannot agree on a lead registrant, remains open. The *opt-out* regulations do not provide for this scenario. Nor do Articles 11 and 19 include any authorisation for the Agency to designate the lead registrant if the actors fail to agree. Article 30(2) provides for such decision-making authority where studies are not available,<sup>29</sup> but this regulation does not apply for Articles 11 and 19. In this respect, there is also no basis on which to penalise.

It is possible, however, that this question will play no major role in practice. Within the framework of the European regulation on existing chemicals 793/93, it was left up to the various manufacturers/importers of an existing chemical to identify a lead company for the coordination. As a rule, this approach was implemented in practice without problems.

### d) **Opt-out**

Articles 11(3) and 19(2) grant a registrant the right to submit core data separately if

- it would be disproportionately costly for him to submit this information jointly<sup>30</sup>  
or
- submitting the information jointly would lead to disclosure of confidential business information, or
- he disagrees with the lead registrant on the selection of information.

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<sup>29</sup> Likewise in § 20(a)(5) of the applicable German Chemical Law.

<sup>30</sup> This might be the case, for example, when the registrant himself possesses the core data. In this case it would be unfair to require him to carry out the complicated agreements with the lead registrant and to participate in the cost of the joint submission.

In this case, the registrant submits a declaration together with his registration dossier, in which he outlines at least one of these reasons. If a manufacturer/importer makes use of these options, the Agency will probably verify his justification for the *opt-out* within the framework dossier evaluation (Article 41(5)(a)).

Details on the *opt-out* will be included in RIP 3.4. It is important to realise that the *opt-out* according to Articles 11(3) and 19(2) does not result in withdrawal from the SIEF. The rights and obligations according to Articles 29 and 30 thus remain fully intact in this case.

The REACH Reg. includes no consequences for the case that the Agency finds the grounds for the *opt-out* to be insufficient. The completeness or validity of the registration is not put into question for this reason. Whether there is an adequate basis for penalties (Article 126) appears questionable<sup>31</sup> – in any case, the penalising authority will have to prove fault.

#### **IV. Joint use of available data in the case of registered substances**

##### **1. Overview**

Articles 26 and 27 are applicable here. They apply for substances that do not have the status of phase-in substances, as well as for substances with the status of a phase-in substance but which have not been pre-registered, whatever the reason. In the latter case, the manufacturer/importer cannot make use of the transitional periods in Article 23. Thus he may not commence with the production or import of this phase-in substance until after he has submitted a registration.

For pre-registered phase-in substances, Articles 26 and 27 do not apply when a participant of the SIEF has already registered and another participant would like to refer to the already registered study summaries for his registration. In this case, the rules of Article 30 apply, as well as the general provision of Article 13(5).

The goal of the rules presented in Articles 26 and 27 is, as with the SIEF regulations, to avoid unnecessary testing, especially testing on animals. For this reason, each potential registrant of the non phase-in substance or of a non pre-registered phase-in substance must submit an

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<sup>31</sup> According to the present information, the Commission is considering the idea of allowing the Member States to set penalties for the case of the *opt-out* with insufficient grounds.

inquiry to the Agency whether a registration has already been undertaken for the same substance. If this is the case, the REACH Reg. differentiates between two cases:

- With study summaries submitted at least 12 years earlier within the framework of a registration according to REACH Reg., the potential registrant can make reference to such studies free of charge.
- If the substance has been registered according to REACH Reg. less than twelve years earlier, then the Agency initiates a communications process between the study owner and the potential registrant. This process leads either to an agreement between the actors or, if no agreement is reached, the Agency shall give the potential registrant permission to refer to the registered study summaries of the study owner. This authorisation is not free of charge, however (for details, see below).

## **2. Specific issues**

With regard to the document RIP 3.4 which will be available shortly, no comprehensive description of the rules for the data sharing in Articles 26 and 27 is to be provided here. It suffices to note the following points:

### **a) Identity/group of substances**

The complex questions of substance identity apply likewise for the rules in Articles 26 and 27, even if they need not be clarified autonomously and directly among the (pre-) registrants. In his inquiry, the potential registrant must present the full identity of his substance according to Annex VI(2) REACH Reg. to the Agency. For its part, the Agency also has the information on the identity of the substance, which has already been registered. For this reason, the Agency can take its own decision as to whether there is substance identity or not. If the Agency determines that there is no substance identity, then it informs the potential registrant of this. If it confirms substance identity, then the communication process described above is initiated with the study owner. In this respect, none of the actors has a right of appeal.

If the substance of the potential registrant belongs to a group of substances to which the substance already registered also belongs, then there is no substance identity, so the obligatory rules on data sharing in Articles 26 and 27 are not applicable. Thus it is left to the actors here to make use of the benefits of the grouping of substances and read-across approach in Annex XI(1.5) through an appropriate agreement.

**b) Procedure**

The procedure for the joint use of available data in the case of registered substances is regulated in Article 27 and applies there only to substances that have been registered less than 12 years earlier; for substances that have been registered more than 12 years earlier, the use of the study summaries is, as described above, subject to no restrictions.

The potential registrant is obliged to submit a request to the previous registrant for study summaries involving tests on vertebrate animals. With study summaries not involving tests on vertebrate animals, he is free to do so. If the potential registrant submits a request to the previous registrant for the study summaries, then the actors should make every effort to reach an agreement on the joint use of the study and on the sharing of the costs (Article 27(2)(3)). For cost sharing, reference can be made here to the planned cost sharing guidance.<sup>32</sup> If no agreement is reached, then the Agency grants the potential registrant permission to refer to the required information, provided the potential registrant proves, on request of the Agency, that he has, in exchange for this information, paid the previous registrant a share of cost incurred (Article 27(6)). This is to exclude the possibility of making reference free of charge, which would be to the advantage of so-called *free-riders*. An appeal with suspensive effect can be raised against the decision with which the Agency grants permission (Article 27(7)) – in this context, the previous registrant could also object that the Agency erred in accepting the substance identity.

The permission to refer does not provide the potential registrant with a copy of the full study report. Nor is the study owner obliged to make available the full study report to the potential registrant. If he makes available the full study report, then his claim vis-à-vis the potential registrant for the assumption of costs incurred to be “shared equally” is assertable before the national courts.

**V. Conduct of new studies involving tests on vertebrate animals according to Annexes IX and X REACH Reg. with test proposals of multiple registrants****1. Overview**

Among other things, the study summaries according to Annexes VII to XI REACH Reg. must be submitted with the registration dossier. If studies from which study summaries are derived

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<sup>32</sup> See above under Section II.3.c).

are not available, the corresponding tests must be carried out before submission of the registration dossier. This only applies to tests according to Annexes VII and VIII, however. If studies involving tests on vertebrate animals according to Annexes IX and X are not available, then the registrant submits test proposals, unless these tests can be waived according to the conditions of Annexes IX and X in column 2 (deviations from the standard approach) or of Annex XI (*waiving*).

The decision as to whether the proposed tests must be carried out or not is taken within the framework of dossier evaluation according to Title VI of the REACH Reg. (Articles 40 *et seq.*). Here the registrant will be provided with test requirements corresponding to the proposals or in amended form, or the test proposal will be rejected. The Agency takes the decision in consultation with the competent authorities of the Member States after the applicant has been given the opportunity to comment. If these competent authorities fail to reach an agreement, then the Commission decides. An appeal with suspensive effect can be raised against decisions of the Agency. If the Commission decides, then the only recourse under the preconditions of Article 230(4) EC Treaty is a legal challenge before the ECJ, which does not have suspensive effect, however.

The evaluation according to Title VI of the REACH Reg. will not be examined further here. Instead, reference is made to the comprehensive document *Evaluation Guidance* (RIP 4.1 to 4.2).<sup>33</sup> The following analysis examines only specific questions arising in connection with the submission of test proposals by multiple manufacturers/importers. The objective here, as elsewhere, is to avoid duplication of tests. With this objective, the Agency bundles the test proposals in a way that gives the registrants the opportunity to reach an agreement on who will carry out the test on behalf of all of the other registrants. This must take place within 90 days. If the Agency is not informed of such an agreement within 90 days, then it designates the registrant or downstream user who has to carry out the test on behalf of all of the others (Article 53(1)<sup>34</sup>). This procedure is announced in the draft decision that the actors receive for comment (Article 40(3)(e)).

If a registrant or downstream user carries out a test on behalf of others, the costs for this are to be shared equally by all of them. All of the registrants receive a copy of the full study report. As long as one of the actors has not paid his financial contribution, the other actors can prohibit him from continuing to place the substance on the market. Claims of this type and also all claims for payment must be asserted before the national courts. The actors can decide

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<sup>33</sup> Current Draft under <http://ecb.jrc.it/REACH>.

<sup>34</sup> Thus Article 53(1) corresponds to Article 30(2), which prescribes this procedure already for the registration relative to the tests according to Annexes VII and VIII.

to assert their claims for remuneration before an arbitration board and to accept its arbitration order.

## **2. Specific issues**

### **a) Substance identity/group of substances**

According to Article 40(3)(e), the abovementioned bundling of test proposals for multiple registrants applies only where the test proposals concern “the same substance”<sup>35</sup>. According to the draft of RIP 4.1, this is to be determined according to RIP 3.10. But even when substance identity appears to be established, the hazard profile can be different with regard to impurities, in which case bundling is precluded and the tests must be carried out individually.<sup>36</sup>

If the test proposals are submitted for a group of substances (e. g. within the framework of a consortium formed for the group), then Article 40(3)(e) is not applicable for the group as such, as the different substances of the group are not identical. On the other hand, when submitting the test proposals the consortium makes use of possible synergies according to the grouping of substances and read-across approach in Annex XI(1.5). The Agency verifies this in the dossier evaluation (Annex XI, introduction, last sentence, REACH Reg.). But also in the case where the consortium has not made valid use of the grouping of substances and read-across approach in Annex XI(1.5) in the registration dossier, the Agency will check whether it already has enough information on the substance for the respective endpoint.<sup>37</sup> Above all in test proposals involving tests on vertebrate animals, the Agency will look for ways to avoid such tests, as tests on vertebrate animals for the purposes of this Regulation may only be carried out as a last resort (Article 25(1) sentence 1). If necessary, the Agency will reject the test proposal (Article 40(3)(d)).

### **b) Joint submission of the test proposals**

If, within the framework of a consortium and/or according to Articles 11 and 19, multiple manufacturers or importers of the same substance have submitted test proposals according to Annexes IX and X together with the core data, then one will also be able to assume that they have also proposed for the respective endpoint of “the same

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<sup>35</sup> Article 40(3)(e) does not explicitly state that they also have to concern the same endpoint, but this is obvious.

<sup>36</sup> Draft of RIP 4.1 to 4.2 under Section 2.3.1.

<sup>37</sup> Draft of RIP 4.1 to 4.2 under Section 2.1.6.2, according to which this also applies with options for exposure-related *waiving* according to XI (3) REACH Reg.

test” in terms of Article 40(3)(e). With this, the preconditions for a bundling according to Article 40(3)(d)) are established. If the joint submission is based on a consortium agreement, then as a rule an “agreement” has also been reached in terms of Article 40(3)(e) as to who will conduct the test on behalf of all of the registrants – at least among the members of the consortium. As a rule, the question of cost sharing is also clarified in this case. If the test proposals are submitted within the framework of a collaboration that is limited to the legal minimum according to Articles 11 and 19,<sup>38</sup> then this agreement will still have to be reached. If it is not reached, then the Agency will designate one registrant who will carry out the test on behalf of all of them.

### c) **Separate submission of the test proposals**

It is possible that completely separate registrations are submitted or that, with joint submission of core data according to Articles 11 and 19 relative to a specific endpoint, the *opt-out* according to Articles 11(3)(c) or 19(2)(c) has been declared for the test proposed by the lead registrant and another test strategy has been proposed.<sup>39</sup> In these cases, the Agency will check whether the separate registration or the test proposal submitted separately was justified.<sup>40</sup> If it finds that the separate submission was correct, then the test will be carried out separately and individually. If the Agency finds that the separate submission of the test proposals is not correct, then it will apply Article 40(3)(e), harmonise the test strategy, and ask the actors to reach an agreement in terms of Article 40(3)(e). If this fails, then the Agency will designate one actor who will carry out the test on behalf of all of them.<sup>41</sup>

### d) **Test requirements and different tonnage bands**

In the registration process, the scope of the available information and deadlines is oriented toward registration according to tonnage bands. The question is, what is the impact of the different tonnage bands in the dossier evaluation?

As a matter of principle, the conduct of studies involving tests on vertebrate animals according to Annexes IX and X can only be required of the registrants who have

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<sup>38</sup> E.g. according to the model in Appendix F of this project.

<sup>39</sup> The *opt-out* is also a possibility, for example, when the actor is able to provide grounds for an exposure-related *waiving* according to Annex XI(3) REACH Reg. If the *opt-out* is justified, then the Agency must exclude that actor from the decision to bundle according to Article 40(3)(e). According to Article 41, however, this is likely to lead to a *compliance check* of the registration.

<sup>40</sup> RIP 4.1 to 4.2 under Section 2.1.3.2. This is also already checked prior to the *compliance check* according to Article 41 during the dossier evaluation.

<sup>41</sup> As before.

submitted the respective test proposals in their registration. In deciding who will carry out the test on behalf of all actors, the selection must be made from among these actors only. And the obligation to share the costs of the study equally can only affect those who have to carry out such a test according to the tonnage band that applies to them. Article 43 links the deadlines for the verification of test proposals according to tonnage bands to the registration deadlines accordingly (e. g. 2 years after expiration of the registration deadline for substances > 1000 tonnes per year).

The results of such studies according to Annexes IX and X can also apply, however, to the manufacturers of substances in lower tonnage bands. According to Article 42(2), the results can have consequences for the authorisation procedure or for restrictions according to Title VIII REACH Reg. Such consequences can also affect smaller manufacturers. This can be a reason for smaller manufacturers to take part in a consortium voluntarily, in order to influence the test proposals.

**e) Significance of dossier evaluation with regard to contracts on data sharing**

The joint or coordinated conduct of studies according to Annexes IX and X within the framework of the dossier evaluation can be viewed as the continuation of data sharing according to Title III REACH Reg. by other means. With this in mind, contractual consortia will often be formed particularly with regard to the conduct of studies according to Annexes IX and X. The cost sharing arrangement agreed in consortia will also apply for the conduct of such studies in particular. The decision-making structures in consortia are also set up for this.<sup>42</sup> For this reason, consortia do not generally cease to exist upon submission of the registration dossier. They correspond to the overall legal concept of Article 40(3)(e), as they have already anticipated the required agreement in the consortium agreement. Joint decision-making structures are also helpful not least because the process of dossier evaluation requires actors to comment, possibly jointly, on the draft decisions of the Agency (Article 50(1)). The same applies when an appeal is raised against test requirements (Article 50(8)).

If the contractual cooperation is limited to the joint submission of the core data according to Articles 11 and 19, and if test proposals are also submitted in this context (e. g. according to model F presented in this project), then new arrangements may become necessary for the phase of the dossier evaluation, in order to reach the agreement required there in terms of Article 40(3)(e).

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<sup>42</sup> The “agreement” required in Article 53 with regard to the question of who will carry out the test on behalf of all of the registrants is prescribed in the consortium agreement.

In the establishment of the cost allocation formulation, e. g. in consortium agreements, the phase of dossier evaluation should also be considered. In this context, Article 53(2) must be observed, which calls for costs to be “shared equally” as a matter of principle. This determination, too, can only be viewed as a function of the respective tonnage band of the actors. In addition, the actors can reach a contractual agreement on another transparent and non-discriminatory allocation key (e. g. oriented to production/import volume).

The interpretations under c) (separate submission of test proposals) show that the restriction of a consortium to a portion of the members of a SIEF is subject to revision during the dossier evaluation. If the consortium has submitted a certain test proposal with the registration and the Agency finds that another registrant for the same substance and the same endpoint has submitted a test proposal with his registration (with the same test strategy or another one), then the Agency will, according to Article 40(3)(e), urge the consortium<sup>43</sup> and the other registrants to reach an agreement in terms of this regulation or, failing that, it will designate one of the actors to carry out the test on behalf of all of them. The consortium can wait for this result and then, when the time comes, react accordingly. But the consortium can also try, right from its establishment or at a later point in time, to integrate all major players in the consortium – at least those in the same tonnage band. If it succeeds in doing so, there will be no problem with Articles 40(3)(e) or 53(1) and (2).

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<sup>43</sup> From a legal perspective, the members of the consortium participate as individuals – they reach an agreement among themselves, however, and therefore act jointly.

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