



OPERATIONAL IMPLEMENTATION OF THE SUBSTANCES INFORMATION EXCHANGE FORUMS (SIEF) AND CONSORTIA

10 FORMS OF COOPERATION

Potential registrants are free to organise themselves in order to meet (1) their SIEF objectives (data sharing and classification and labelling) and (2) the joint submission of data. Indeed, a SIEF in itself has no prescribed legal form. Also, the REACH Regulation does not organize the way participants to a SIEF must cooperate to meet their obligations, nor does it regulate possible forms of co-operation between them for SIEF or other purposes.

It is often presented that "consortium" must be formed (or consortium agreements signed) to organise data sharing and the joint submission of data. This is not the case.

10.1 Possible forms of cooperation

There are several possible forms of cooperation that companies can chose to organise their cooperation under REACH. The forms of cooperation can go from loose ways of cooperating (e.g. IT tools to communicate between all SIEF members) to more structured and binding models (e.g. consortia created by means of contracts). Other examples of forms of co-operation may be envisaged for example: one manufacturer provides a full data set to the other manufacturers in a SIEF which are invited to "join" this data set via a simple letter of access. Neither the use of a full "consortium agreement" nor the use of another formal, written agreement is legally required by REACH. However, it is advisable that, whatever the form of the cooperation chosen, the parties agree in writing (this can be by means of a contract but also even by email) on the main rules of data sharing and at least on the ownership of the studies jointly developed, and the sharing of costs.

10.2 What is a Consortium?

For the purpose of this guidance document, the term "consortium" will be used to refer to a more organized and formal type of co-operation between parties (implying either a signed agreement or the adoption of operating rules, or reference to an agreed set of general rules). Importantly, SIEF and Consortia are two different concepts and must be clearly differentiated. A SIEF regroups all Pre-Registrants of the same substance (and other Data Holders where relevant) and participation to a SIEF is mandatory for SIEF Participants under REACH. However, a consortium is voluntary and may not necessarily regroup all participants to a particular SIEF, but can regroup only some of them or participants of more than one SIEF.



10.3 How is a Consortium to be created?

REACH actors may decide to create a consortium at any stage of the REACH Process, e.g. before pre-registration, to ease the process of checking the identity and sameness in view of the formation of a SIEF, and afterwards.

When a SIEF has been formed, participants in that SIEF who need to fulfil the obligations of the REACH Regulation would necessarily have to co-operate to reach this aim. They will look for ways to achieve this. The facilitator or any other participant in a SIEF and its related virtual forum may propose to the others a means of working together through 'formal cooperation' and signing a consortium agreement, or by adopting common rules. This proposal and chosen form of co-operation could be made by the SIEF Participants on their own, or by asking for the services and assistance of a Third Party such as a trade association, a sectoral association, a consultant, a law firm or any other service provider.

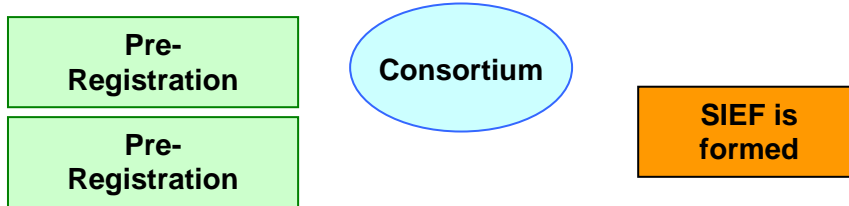
By either signing the consortium agreement, or accepting operating rules by a decision in a meeting, or deciding to refer to a common agreed set of rules (hereinafter only referred to as an agreement), participants in the agreement will de facto 'create the consortium'. There is no need to have any additional formalities. As a consequence, there is no specific requirement that consortia be organized by way of the creation of a separate legal entity having legal personality under the legislation of a Member State.

It should be noted that when a consortium is created by a trade association or a law firm it should not be confused with that body, and must be distinctly identified from it. It may well also be the case that some companies are already organized by having for example either a sectoral group or a consortium preparing the work to be ready for REACH. In this case, they may decide either to continue their co-operation with the same structure, or to create a new parallel structure, or to have any other pattern for co-operating.

In the following examples note that the life of a SIEF may involve one or more pattern of cooperation but these are only to be considered as facilitation. The consortium formation does not bring the SIEF to an end. The SIEF continues to exist through the eleven years specified in the REACH Regulation. Vice versa, a consortium may continue after the SIEF ends.

Example 1:

Companies having pre-registered decide to co-operate by way of a consortium for the discussion on the identity check and the sameness of the substance. Once the SIEF is formed they may decide to pursue their activity with the same consortium (but to be modified e.g. regarding its composition, if needed). Once they sign the consortium agreement, it is created.



Example 2:

The Companies having pre-registered decide to cooperate for the discussion on the identity check and the sameness of the substance But, not immediately by creating a consortium. They first meet and sign a pre-consortium agreement including appropriate confidentiality clauses. Once the SIEF is created, they decide to create a consortium.



10.4 Forms of co-operation in SIEF when using Consortia

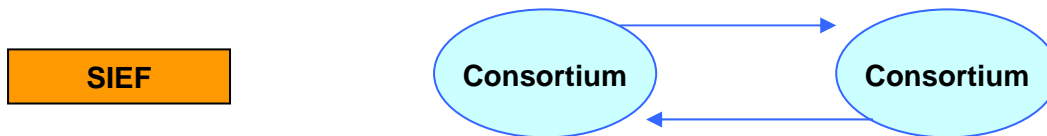
Co-operation by way of consortia to achieve effectiveness of the SIEF, once it is formed may take different forms. You will find a few examples below.

Example 3: Participants in a SIEF decide to form a unique consortium.

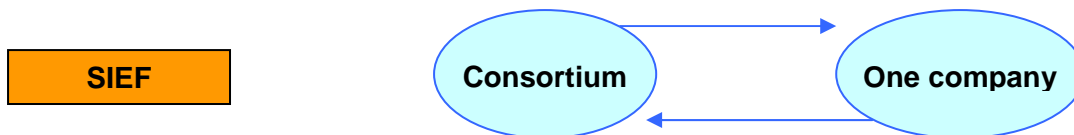




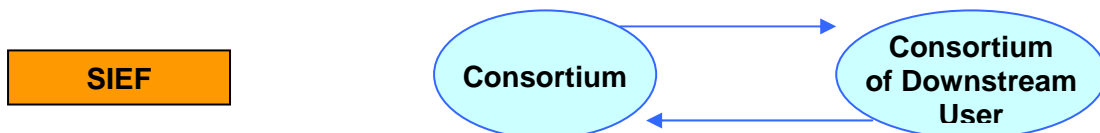
Example 4: Participants in a SIEF may decide to constitute two or more consortia and to organize the co-operation regarding data sharing amongst these consortia (eg if different classification and labelling are foreseen for a substance with the same CAS number). Companies of both consortia are required to cooperate to meet their data sharing and joint registration obligations under REACH.



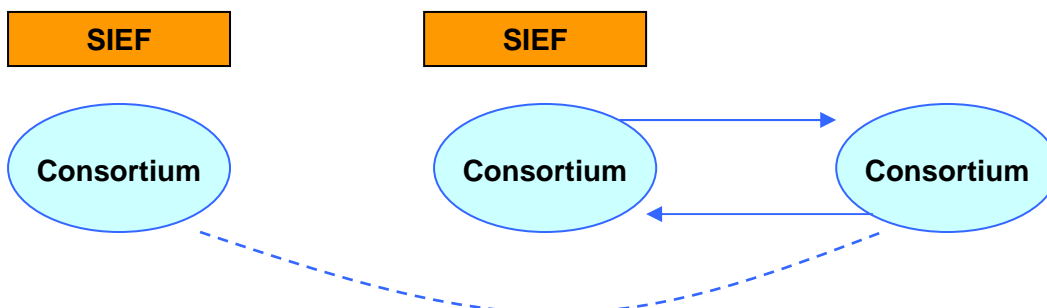
Example 5: A company or a group of companies (participant to a SIEF) decides to stay outside a consortium. In such scenario, the companies that do not belong to the consortia and the companies that belong to the consortia must co-operate regarding data sharing and joint submission (the principles on data sharing within a SIEF described above apply.).



Example 6: Participants in a SIEF (companies, Importers and Data Holders) decide to form a consortium, and Downstream Users decide also to form a consortium to co-operate together, and with the other consortium.

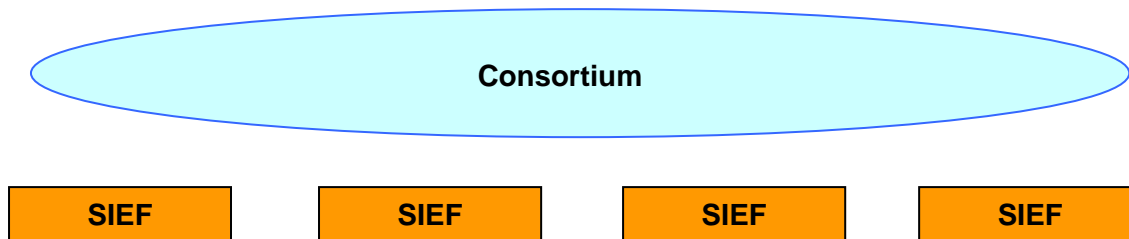


Example 7: Two SIEFs ± with three consortia decide to co-operate for specific purposes eg read-across.





Example 8: A major consortium may also be created (eg for a family of substances) for companies to participate in several, but different SIEFs.



10.5 Elements of co-operation that may be included in a Consortium

- Conduct or document the identity check;
- Designation in a SIEF of the facilitator or the Lead Registrant (in cases where the consortium groups all SIEF members);
- Organization of the co-operation and thus the consortium;
- Consideration of data (existing data, missing data, new data to be developed);
- Defining data to be shared;
- Facilitating data-sharing and coordination;
- Data valuation, data evaluation (including identification, data access and collection);
- Facilitating cross-reading between SIEFs;
- Organization to preserve the confidentiality of business information and data;
- Cost sharing;
- Data ownership;
- Preparation of letter of access to data for non-consortium participants;
- Liability;
- Classification and labelling.



- post-SIEFs actions: e.g. joint submission of data, joint registration, and maintaining the life of the consortium even after the joint registration - jointly to follow-up the file until final registration/evaluation, including interacting with ECHA.

It is important to note that when the SIEF has members that are not part of the consortia, the companies of the consortia must cooperate with the companies that are not part of the consortia. The consortia (e.g. through its secretariat) may facilitate this task but it is ultimately the responsibility of all the SIEF members to ensure that the data sharing and joint submission obligations are complied with.

C. Duration of the consortium :

Parties may also decide to have a consortium either just to achieve together either some activities before the SIEFs, or the two aims of the SIEF or to maintain it for the full duration of the SIEF as mentioned in the REACH Regulation, for 11 years, or even to keep it afterwards in case they have collectively to answer to some queries for example.

10.6 Categories of participants in a Consortium

As mentioned above, there is also no need for the membership of a consortium for SIEF purposes to coincide exactly with the participants in a SIEF.

The following categories of participants may be considered to be members of a consortium/co-operation agreement (this list is not exhaustive):

(A) Categories strictly deriving from a SIEF:

- Manufacturer(s);
- Importer(s);
- Only Representative(s);
- Data owner(s) who are willing to share data: for example laboratories, organisations, consultants, trade/industry associations or downstream user(s) if they have relevant information, for example study data and exposure data.



(B) Other categories may be considered, such as:

- Downstream user(s), in other cases that mentioned in (A);
- Third Parties providing services and assistance to a consortium such as trade/industry associations, sectoral associations, service providers, and law firms;
- Non-EU manufacturer(s) who are also willing to participate directly, and not only through their EU-Only Representative, although not being entitled to register directly;
- Potential Manufacturers and Importers which according to Article 28.6 are considered under the REACH Regulation as Potential Registrants;

Different categories of membership with different rights and obligations associated with these categories may be decided and included in the consortium agreement. For example:

- Full members;
- Associate members;
- Observers (either as Third Parties or not)

10.7 Typical clauses that may be included in a Consortium agreement

The following list of clauses is to be considered as a non-exhaustive checklist:

<p>1. General Information</p>	<p><u>Identity of each party.</u> <u>Contact details.</u> <u>Preamble:</u> including a reference to the REACH Regulation and a declaration of intent to explain the overall purpose of the consortium. <u>Scope cooperation:</u> the substances(s) on which the parties will co-operate. It may also include the criteria chosen to agree on the identification of the substance(s); <u>Subject of the agreement:</u> list of elements of co-operation or tasks on which parties have elected to work; <u>Definitions:</u> general reference to the definitions included in the REACH Regulation (Article 3) and additional definitions, if any; <u>Duration.</u> <u>Identity of a independent third party:</u> if the parties elect to have the assistance from a law service provider, sectoral or trade association to manage their consortium.</p>
<p>2. Membership</p>	<p><u>Membership categories:</u> definition, rights and obligations of each category; <u>Membership rules:</u> admission, revocation, dismissal of members;</p>



	<u>Change in membership</u> : late entrant / early departure.
3. Data sharing	<u>Rules on data sharing</u> <u>Criteria for valuation of studies/tests reports</u> <u>Cost sharing criteria</u> <u>Data Ownership</u> <u>Letter of access</u>
4. Organization	<u>Committees</u> : (membership, attendance, rules of functioning, quorum, voting ...) <u>Working language</u> <u>Role of the facilitator</u> , if any <u>Role of the Lead Registrants</u> , if any <u>Role of third independent party</u> , if any
5. Budget and finances	<u>Budget</u> <u>Apportionment</u> <u>Financial year</u> <u>Invoicing and payment</u> <u>Taxes and other costs</u>
6. Confidentiality and right of information	<u>Confidentiality clause</u> <u>Who is entitled to access information?</u> <u>Measures in place regarding the exchange of confidential and sensitive information?</u> <u>Sanctions in case of breach</u>
7. Liabilities	
8. Miscellaneous	<u>Applicable law</u> <u>Dispute resolution / settlement or choice of jurisdiction</u> <u>Changes to the agreement</u> <u>Dissolution</u>

Sources: European Chemicals Agency (ECHA).

A French version of this document is available – Courtesy of the B-Lands Consulting Staff
<http://www.reach-compliance.eu/french/documents/guidance/ECHA/SIEF-consortia/FEIS-consortiums.html>