Working together in SIEF

November 2008, version 0

Disclaimer

The information contained in this paper is intended for guidance only and whilst the information is provided in utmost good faith and has been based on the best information currently available, is to be relied upon at the user's own risk.
No representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information.

Table of contents

Table of contents - continued

Table of contents - continued

1. SIEF co-operation

A SIEF is formed from a pre-SIEF after the potential registrants have agreed they intend to register the same substance. The participants of a SIEF have different rights and obligations depending on whether they are potential registrants or data holders. This section introduces the way to co-operate in a functional SIEF and the support tools available.

The legal obligations of SIEF may be met by work in a consortium, see below.

For further information on SIEFs and consortia you may consult the Cefic guidance on Preparation for Pre-registration, Cefic guidance on Formation of SIEF and ECHA Guidance on data sharing.

Does the agreement to form a SIEF need to be notified to the ECHA?

No, the European Chemicals Agency (ECHA) does not have a system to register SIEFs when agreed upon and formed by the potential registrants, and there is no legal obligation to do this.

What do I do if I find myself in the wrong SIEF?

See Cefic guidance on Formation of SIEF, Chapter 2

What is achieved from the obligation to work in a SIEF?

As a potential registrant, obligatory participation in the SIEF following pre-registration as stated in Article 29 of the REACH Regulation, is a means to:

- Facilitate the exchange of information between potential registrants, thereby avoiding the duplication of studies, and;
- Agree classification and labeling

The Regulation provides for potential registrants to share information and work together to prepare a joint registration submission. This collaboration aims to increase the efficiency of the registration system, to reduce costs and to prevent duplicate testing, especially on vertebrate animals.

What needs to be delivered as a member of a SIEF?

The ultimate goal of the potential registrants in a SIEF is to submit a joint registration to the ECHA prior to the extended registration deadline associated with the registrant's tonnage band.

Whilst the joint submission of certain information is mandatory, such as information on classification and labeling, for other information, such as guidance on safe use, it is optional. Additionally, individual registrants must submit other information such as information on the manufacture and use of the substance. A tabular overview of this is provided in section 8.1 of the ECHA guidance on data sharing.

A potential registrant is allowed to opt out from the joint submission under the following conditions:

(1) It would be disproportionately costly for them to submit this information jointly;
(2) Submitting the information jointly would lead to disclosure of commercially sensitive information and likely to cause the potential registrant substantial commercial detriment; or
(3) The potential registrant disagrees with the lead registrant on the selection of information.

Further information about these conditions of opt out is available in section 8.3 of ECHA guidance on data sharing

The right to opt out does not apply to the data sharing obligations, or to opting out of a SIEF. Any exercise of the opt out must be justified (as described in section 8.4 of ECHA guidance on data sharing) in each case as prescribed by the REACH text.

The actual deliverables for each company in this process will depend very much on the company's substance specific strategy. Key considerations described below include the relative importance of the product and the availability of company resources. Therefore the deliverables for a single company can range significantly. Minimal effort would be required in the case of a dormant SIEF participant when a company decides not to register and has indicated he owns no relevant data. The maximum effort would be required to prepare a full registration dossier and, if chosen to be submitted jointly, a Chemical Safety Report, by the lead registrant. In practical terms, the deliverables will be either financial, the provision of expertise, or information, or a combination of these. In all cases a SIEF participant has obligations to respond to questions regarding data sharing posed by potential registrants.

How can I participate effectively in the SIEF?

The first extended registration deadline of 30 November 2010 is likely to create a sense of urgency for preparation of the registration data for all potential registrants. There will be limited time between formation of a SIEF and preparing a joint submission. It will be important to plan ahead to ensure adequate time to prepare the technical dossier and (if to be prepared collectively) the Chemical Safety Report. The preparatory phase of defining the form and organisation of the SIEF co-operation (e.g. on the choice of the co-operation model agreement, discussions on its content, the data sharing model …etc) should be kept to a minimum. Individuals should avoid taking too much time on SIEF co-operation matters and seek pragmatic solutions.

Efficiency, compromise and pragmatism will be essential within limited timescales.

Can I use the ECHA REACH-IT system to co-operate with other SIEF members?

The ECHA REACH-IT system may be used for pre-registration and submitting dossiers. The pre-SIEF webpage on REACH IT provides contact email addresses for each SIEF member, however SIEF participants must organise their own form of co-operation.

What electronic tools are available to facilitate SIEF co-operation?

SIEFreach is an IT system recommended by Cefic to facilitate the co-operation of SIEF participants.

The user-friendly system facilitates the exchange of information between companies with the final goal of submitting the registration dossiers as foreseen by the REACH Regulation. SIEFreach is a reliable, secure and efficient collaboration tool based on the state-of-the art solutions provided by IBM that was launched on 21 August 2008.

More information can be found at www.siefreach.com.

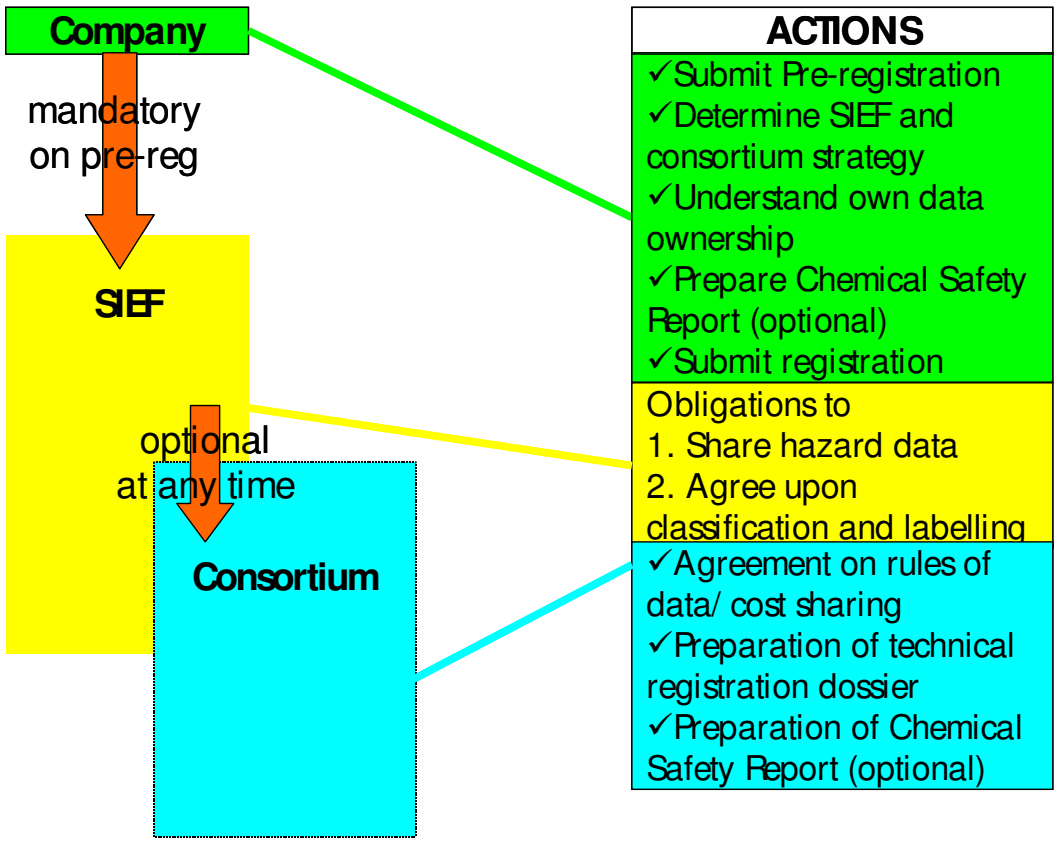
Would the formation of a consortium be helpful?

It is not mandatory for SIEF participants to form a consortium. However, it is recommended that parties who will cooperate within a SIEF agree in advance in writing at least on the main rules of data sharing, on the ownership of the studies jointly developed and on the sharing of costs.

As a voluntary platform for data cost sharing, preparing the Chemical Safety Assessment and organising the joint submission, a consortium is a more formal agreement with a contractual framework that will allow a more structured cooperation. It is advisable to have the rules of co-operation agreed up front as the SIEF participation may not be constant over time with the arrival of late pre-registrants (first time manufacturers and importers after the close of pre-registration), registrants and de-activation of potential registrants).

Management of intellectual property including confidential business information will be more efficient in a consortium as it will be possible to check the status of companies involved. This may also limit the exposure of confidential information.

Transparency may be improved by applying effective competition compliance of intercompany activities, thereby reducing the potential for breach of competition law. At the same time, members will benefit from technical and scientific advantages since the consortium will optimise the quality of the registration dossier. Finally consortia may provide members with a stronger position when evaluating dossiers with ECHA.



Actions of the company as registrant, as a SIEF participant and a consortium member

Can consortium agreements be simplified?

Consortium agreements cover the many facets of co-operation between parties with regard to data sharing and therefore tend to be lengthy documents. Agreement models or templates can be used to help simplify the initial drafting of the agreement. However, every agreement will need to be tailored to the needs of the parties concerned. A checklist of the most important clauses, which can provide a useful means to reference the consortium agreement, is attached.

checklist consortium rules.xls

What is the relation between SIEF and consortia?

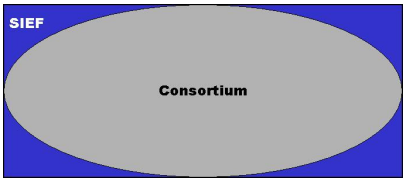
SIEFs are mentioned in the REACH Regulation whereas consortia are not. The process for forming a SIEF is given in the Cefic guidance on Formation of SIEF.

Since the members of the SIEF are single legal entities and a consortium can include all interested companies globally, there is no obligation for the composition of a consortium to reflect that of the SIEF. A consortium can deal with several substances, since its members define the scope of the consortium, while a SIEF is legally required to deal only with one

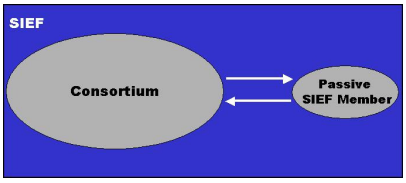
substance. A consortium can be seen as a practical means to meet the legal obligations of SIEF participants and prepare for registration.

Consequently, you can find very different situations, as for example:

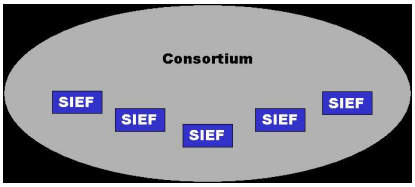
A consortium that covers all SIEF participants



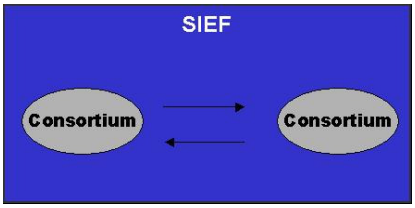
A monitoring / dormant SIEF participant that stays outside the consortium – they may fulfill their REACH registration data requirements via a letter of access to data owned by the consortium members:



A super-consortium that covers several SIEFs, e.g. consortium covers a group of structurally related substances:



A decision by the SIEF participants to constitute two or more consortia, for example in the cases where 1) after substance sameness discussions it is agreed that the available hazard data is not appropriate for all pre-registered substances in the pre-SIEF and / or 2) multiple consortia exist for the same substance for any number of reasons including different applications.



Does competition law apply to my activities in a SIEF?

Yes, EC competition law may apply to co-operation to fulfil REACH legal obligation as for any activities conducted between companies. This guidance contains advice to ensure compliance with these rules. More information can be found in Cefic guidance Preparation for Pre-registration.

A SIEF is not a forum to conduct business with competitors. As a general principle, you should consider using SIEFs for REACH related activities, and only these, and not mix these with other activities. It is important to avoid any misunderstanding by competition authorities about what you are doing.

- ✓ DO limit your activities to what is strictly required under REACH
- × DO NOT go beyond activities that are strictly required under REACH

In addition, even when co-operating with other companies in a SIEF you should pay attention to what you discuss, as they will typically be your competitors.

For REACH in particular:

× DO NOT discuss business related issues that ought to be decided individually by each company. This applies for example to:

- Changes in sales, supply, purchasing and marketing strategy resulting from REACH, including company business plans;
- Possible de-selection of substance or use. This is to be defined on an individual basis only and there should not be any “collective de-selection”;
- Exact tonnage manufactured and imported, market share.

2. Company preparations

How to estimate resource allocation?

There is a wide range of internal and external factors to consider when deciding how much, and what type of, resources are required. These will be different for each company. There are however, a number of common items, which each company, regardless of its size or circumstances, will need to consider.

Participation in a SIEF is mandatory and will require two distinct skill sets: technical and business management. In most cases, this is likely to require multiple participants, co-ordinating together in a SIEF. Technical individuals should have a working knowledge and understanding of the technical aspects of their substance. Business Managers will need to have the authority to make funding and budget decisions on behalf of their organsiation to ensure efficient progress.

Organizations will also need to consider what role they want to play within the SIEF and consortium if available. The level of resource, will differ significant between a lead registrant for a substance and a company who simply wants to maintain a monitoring / dormant presence in the SIEF.

It is highly advisable to distinguish the company's level of engagement per SIEF, depending on the market situation per substance and the volume, but also on the use of a Third Party Representative (TPR) for the SIEF-activities. Internal cooperation with the business is crucial. Resource requirements will be different depending on the level of activity, and on the extent to which the market expects leadership to be assumed by the SIEF member.

Levels of SIEF involvement may be described as: **Solo, lead, active or monitoring/dormant**.

The table below identifies the *relative* resource requirements per internal function for each of these levels of SIEF involvement. It covers both internal and outsourced resources.
A ++ for Tox/Ecotox probably requires more man-hours than a ++ for Legal.

Involvement in SIEF	Finance Acounting Insurance	Legal	Tox Ecotox	Risk assessment In case CSA/CSR is managed collectively	Information & Technology	SIEF coordination	Business involvement
Solo participant	+/++	0	++	+	+	++	+
Lead registrant (market leader)	++	++	++	++	+	++	++
Active participant (owns relavant studies)	+	++	+	+	+	+	+
Monitoring/ Dormant	+	0/+	0	+	+	0/+	0/+
Peak years Tonnage bands have to be taken into account	2008-2012	2008-2012	2008-2018	2009-2018	2008-2009	2008-2018	2008-2012
Main tasks	Paying / Receiving REACH related invoices Tracking of cost per SIEF	SIEF agreements CBI IP review Competition law awareness	Support lead registrant Inventory & review existing studies + ID data gaps Assess Data quality Follow up of studies Outsource & review tests Grouping Read across Alt. Testing Select key studies	Inventory of intended uses Exposure modelling Establish Risk Management Measures	Sameness of Substance Substance identity expertise PhysChem data	Overall guidance SIEF status administration & Project management REACH interpretations	Business impact (e.g. meeting non-EU customers in SIEF due to indirect exports) Assemble end use data Final internal decision on registration Ensure registration of critical procured materials

The table below lists the key tasks that each SIEF will have to consider when producing a registration dossier for submission to ECHA. For each task an estimated FTE (full time equivalent) resource level is provided for a SIEF participant. These estimates, based on the input of several Cefic member companies, should only be considered as a guide as each SIEF is likely to be different and will be influenced by a range of possible factors, some of which may only become apparent of the formation of the SIEF, such as:

- Does the SIEF intend to appoint a consultant to manage a certain task?
- Is the substance classified as CMR 1&2 or R50/53?

- Are there differences between products in the SIEF in terms of purity/impurity/classification?
- Is the product a well-defined single substance or is it a UCVB?
- How many participants are in the SIEF and what is the skill level of the individual companies?
- What are the tonnage bands of SIEF participants?

Many companies will be participating in multiple SIEFs, which may lead to some benefits of scale. The degree of benefit will only become clear once the SIEF formation process has started.

What is clear though is each company should consider SIEF resourcing and seek to address available options as early as possible.

	Estimated range of Full Time Equivalents (FTE)	
	Lead Registrant	Co-registrant
Set boundaries of the SIEF		
Develop SIEF Agreement and Structure	2-6	1-3
Agree on substance sameness	1-5	1-3
Technical activities		
Attend SIEF meetings	4-8	4-8
Prepare agenda and document meetings	1-3	
Determine basis for data sharing - Full or partial	0.5-1	0.25-1
Complete test data table and locate original study data	1-3	0.5-2
Produce & review summary of available test data	1-5	0.5-2
Determine which studies to select for dossier preparation	1-3	0.5-2
Agree on cost for each study & plans to fill data gaps	1-5	1-3
Reach agreement on common C&L position	1-3	0.5-2
Development generic exposure scenarios (if applicable)	1-5	1-3
Prepare core data for dossier / CSR / CSA (if applicable)	3-7	1-4
Review dossier with members of Consortium / SIEF	3-7	1-5
Submit dossier to Agency	0.5-1	0.5
Business activities		
Attend SIEF meetings	2-6	2-6
Prepare agenda and document meetings	1-3	
Oversee appointment of a Secretariat / Task Forces	1-3	0.5-2
Prepare and review funding and budgets	1-3	0.5-2
Appoint and direct technical committee	1-3	0.5-2
Review and endorse technical committee decisions	1-3	0.5 - 3
Approve core dossier data to be submitted	1-3	0.5 - 3
Decisions on admission of new members & financial contribution	1-3	0.5-2
Decision on the exclusion of a Member	0.5	0.25-1

How to estimate the necessary budget?

Although it is not possible to come up with an accurate forecast of expected costs, there are tools available to prepare an estimate.

Depending on various factors, including the number of substances, existing studies, evaluation of data gaps, one may select either a purely 'generic' '**top-down**' or a more specific '**bottom-up**' approach. The latter requires more pre-information but can be continually improved, as more information is gathered.

REACH related costs comprise 'external' and 'internal' items. The following list covers the most important cost elements, but is not exhaustive:

1. Preparation for pre-registration;
2. Participation in SIEF / consortia;
3. IT;
4. Preparing Chemical Safety Assessments, Exposure Scenarios, Chemical Safety Reports and Safety Data Sheets;
5. Testing;
6. Communication in the supply chain;
7. Joint submission of registration / consortia;
8. Registration fees;
9. Evaluation & authorization;
10. Reformulation, change of recipes, raw materials, etc.;
11. General REACH administration ('back office', accounting, etc.); and
12. Others, e.g. training, communication, consultancy etc.

For some items, such as the registration fees precise figures are already available in the Fees regulation. For others, such as SIEF or consortia data are hypothetical. The figures included here under are provided as an example and do not imply any mandatory use by companies working in SIEF or consortia.

From the early days of REACH preparation the overall costs have been subject to quite a number of calculations, with a broad range of resultant estimates between approx. 2 bn. and 8 bn. €

Top down approach
For a first 'top down' estimate, published data may be used. For example, the '2004 EU REACH' overview of 36 studies' (Workshop REACH Impact Assessment, 25th - 27th October 2004, The Hague, The Netherlands) could provide a starting point. The average costs, which mainly comprised items 1,2,3,8 and 9 of the aforementioned items – were calculated as 3.94 bn €. This figure contrasts with the EC estimate of 2.4 bn. €.

Further assuming that 30,000 substances would be registered, an average of ca. 130,000 or 80,000 € per substance may appear realistic. Assuming only 2 registrants per substance and 'cost sharing', still 40-80,000 € per substance would have to be invested company-wise. A few published figures indicate that including all cost items, 80-100,000 € per substance and company could be more realistic. Cost dilution by joint submission through consortia, read-across, QSARs etc. is probably overestimated as industry experience proves e.g. from existing consortia.

Bottom-up approach
Theoretically, costs can be calculated or estimated 'substance by substance' from the consolidated company list of 'candidates' for registration. This provides a more precise and reliable result. However, the uncertainties remain high for now, especially when a large number of substances must be registered.

Some companies have developed calculation schemes assuming costs for all steps of the registration process, but do not publish them to protect CBI.

A more generic approach may also here serve as a starting point. First, the distribution of substances over volume bands has been evaluated several times. Two of the most frequently quoted estimates result in the following distribution:

1,000 t/a:	8-10%
> 100 < 1,000 t/a:	10-15%
> 10 < 100 t/a:	15-25%
> 1 < 10 t/a:	50-67%

There are major uncertainties about the percentage of 'low volume' substances, which may be substantially (50%) lower.

The average costs per substance have also been estimated several times. Taking the KMPG study ('REACH', 2005, KPMG Advisory Services) the rounded figures are:

> 1 < 10 t/a	15,000 €
> 10 < 100 t/a:	163,000 €
> 100 < 1,000 t/a:	282,000 €
> 1,000 t/a	323,000 €

A figure of more than 100,000 € per substance will result from simple multiplication. If estimates like that published by VCI (REACH Informationsveranstaltung, 22 March 2007) are taken into account with costs for the 'high volume band' exceeding 3 million €, the costs per substance will increase accordingly.

The figures calculated 'top-down' or 'bottom-up' do not really differ significantly within these broad limits of uncertainty. However, once a company 'fixed' the average costs per substance and volume band, it can easily calculate changes originating from non-average distributions over volume bands.

The costs for REACH implementation do not follow a linear distribution over the time period 2007-2018. A 'peak' some time in the middle of the next decade is much more likely to happen than a uniform distribution over the whole period.

All calculations will improve in quality after SIEFs have been formed; exact test costs will have been calculated, administration costs for SIEF, consortia, and internal administration can be estimated more precisely. Until then 80-100,000 € per substance could be used as a starting point, with potentially much higher expenditures for standalone registrations, but also a potential for substantial reductions due to joint submission of registrations and data waiving possibilities. Deviations from the 'average distribution of substances over volume bands' may also lead to higher or lower figures.

What are the options for internal organisation?

To comply with the REACH Regulation a multitude of tasks need to be fulfilled by every legal entity that pre-registers and/or registers. To complete all of these tasks, every company has to consider optimising its personnel availability.

Depending on the company situation a variety of organizational structures to deal with these tasks can be developed alone or in any combination.

- Certain tasks, such as legal, tox/ecotox, SIEF management, can be **outsourced** to a contracting company. This option may be attractive to companies where there are a number of low-hazard substances and only limited the staff available in-house.
- If the number of substances increases, a company can minimize its personnel involvement and take a strategic decision to become **dormant** in the SIEFs, providing legal requirements concerning data sharing are applied.
- A company can opt for the **back-office** concept if the number of substances continues to increase or the strategic importance of some or all of the substances is high and the number of business units limited. A back-office group is formed of a REACH implementation team, staffed with a legal, toxicological, IT, product stewardship and other expertise. The back-office coordinator functions as the communication center with all SIEF's. The coordinator managers all communications, disseminating information to the various experts and collating responses ensuring that legal timeframes for replies are respected. They also keep a general overview of the situation at all times. The back-office coordinator is preferably a professional understanding the various aspects of REACH.
- If the number of business units is high, the same back-office concept can be used with **several back-office coordinators**, one per business unit or per group of business units
- If the portfolio of substances is well covered by consortia, the consortia might decide to have all SIEF work done by the **consortia representative**, reducing the work for the individual companies
- If a lot of substances are of a highly critical nature, business and/or classification-wise, a company might decide to have one **substance expert** for each SIEF. Especially in the case that a company decides to take a leading, and potentially full time, role as SIEF formation facilitator or lead registrant. It may be necessary to form a team of substance experts to keep an overview

When using SIEFreach as the tool to support SIEF activities, companies are able to cluster legal entities into legal entity groups, in order to make the administrative tasks more convenient to manage, e.g. for a particular company, legal entities Superchem UK, Superchem Belgium and Superchem Germany can be grouped into Superchem Western Europe, whereas some other legal entitities can be grouped in Superchem Southern Europe.

How to communicate and report internally and externally?

Communication of information in the supply chain is among the key elements of the REACH Regulation (as described in Title IV). All companies must comply with these requirements and meet other REACH communication challenges. Processes should be set up at the earliest opportunity to:

- Define the 'internal' and 'external' stakeholders,

- Prepare appropriate communication tools, and
- Define the information to be communicated

Internal Stakeholders
Senior Management should be a priority, as a 'top-down' commitment is essential for effective management of the REACH implementation. The functions directly involved in the up- and downstream communication, procurement and marketing & sales must be involved early in the process. Legal experts, finance, HSE and R&D should also be engaged, as they will play important roles in REACH implementation.

External Stakeholders
Customers, suppliers and authorities are priority partners. Other stakeholders could include the media, NGOs, business analysts and shareholders, which may be interested in the impact of REACH on the company.

Communication tools
Awareness can be created through a number of communication channels, from workshops and presentations to brochures, newsletters and websites. The company intranet is an effective way of providing staff less engaged in the issue with information and in some cases can provide a portal for in-house experts. External websites can provide a platform to inform external stakeholders about the company's approach to REACH. This can also provide a space to meet supply chain communication requirementsproviding web portal questionnaires or contact details for further information.

The Cefic task force on Supply Chain Communication is addressing communication issues and providing tools and guidance. Please consult the Cefic website for further information.

Companies are recommended to work with their internal communication department or consider seeking external communications advice. A "REACH communications" team could be created to develop a communications strategy, including a Q&A document covering likely concerns (see example list below).

- Are you prepared for REACH?
- How many substances do you intend to (pre-) register?
- Do you intend to withdraw substances because of REACH?
- How many and which substances out of your portfolio will be subject to authorization and restriction?
- Are the substances you manufacture or import included in the published Annex XV candidate list?
- What are your estimated costs?
- What is the overall impact on your business?
- Do you act as 'only representative' for non-EU companies?
- Opportunities / improvements?

The "REACH Communications Team" should prepare approved answers consistent with their own companies' position.

How to continue in the SIEF after registration?

A SIEF stays operational until 2018 to assure that when newcomers are entering the EU market, they have a reference body for test results. The SIEF participants can share any eventual income. Although the work intensity after registration drops significantly, the contact should be permanent and all correspondence is administered and answered in time.
Companies should keep in mind that when personnel handling the coordination leave their positions, the company's management of change should take care of a follow up of these tasks.

3. Tonnage and registration deadlines

The relevance of manufactured and imported volumes to SIEF participation for potential registrants is described in the following:

Legal obligations in REACH Regulation:

Article 9 describes the exemption from registration for product and process orientated research and development (PPORD)
Article 10 describes the information to be submitted for general registration purposes
Article 11 refers to the requirement of joint submission in case of multiple registrants
Article 17 describes the registration of on-site isolated intermediates
Article 18 describes the registration of transported isolated intermediates
Article 19 describes the joint submission of data on isolated intermediates by multiple registrants
Article 23 describes the relevant deadlines for registration of phase-in substances
Article 30.1 mentions that registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

ECHA Guidance on data sharing

- Chapter 8 – Registration, joint submission, in particular chapter 8.3 the lead registrant and his tasks
- Chapter 3 – Pre-registration deadlines, in particular chapter 3.11 first envisaged registration deadlines and tonnage bands

Is the deadline for my registration determined by tonnage only?

Yes, with the following exceptions:

- Substances classified as CMR Category 1,2 are to be registered before November 30, 2010 at > 1 tpa and R 50/53 substances need to be registered before this date if produced and/or imported > 100 tpa
- Non-phase-in substances cannot make use of the extended deadlines but should be registered immediately

Keep in mind that annual manufactured and/or import tonnage triggers the registration deadline also for intermediates and substances intentionally released from articles.

What is the actual registration deadline I need to consider?

The dateline / tonnage band submitted at pre-registration has no legal consequences. It is just an indication of the timing of the intended registration and is not binding. However, if you wish to up-date your envisaged registration deadline this can be done via REACH IT at any time.
After the pre-registration period and before the registration the actual amount of manufacture and / or import defines the relevant registration deadline and obligations. The responsibility lies with each potential registrant to provide this data.

For example: Substance A is pre-registered with the envisaged tonnage band > 100 t/a and is manufactured and/or imported as follows:

2008	200 t/a
2009	200 t/a
2010	1100 t/a
2011	2000 t/a
2012	200 t/a

Relevant tonnage calculation for phase-in substances: The average of the three years proceeding registration is always decisive.

Such calculation needs to be made by each company individually as these precise figures cannot be exchanged for competition law reasons.

✓**DO** exchange tonnage bands instead of individual more specific volume information

In 2010 the average is 500 t/a. But, in 2011 the average is 1100. As a consequence the potential registrant has to register immediately and cannot wait until the envisaged deadline of 2013. For strategic reasons you may decide for a higher tonnage level for e.g. when a business plan indicates fast growing market.

Recommendation: It is strongly recommended that each company pay continuous attention to their respective actual manufacture and/or import volume of each of their legal entities and to act accordingly within the SIEF.

How to deal with the different registration deadlines/obligations within a SIEF?

The basic principal is that each potential registrant is only required to share in the costs of information that are required to submit his/her own registration. Compensation is due at the time of full registration by the individual registrant. It is likely that the hazard data for >1000 tonnes per annum registrations are available well in advance of the lower tonnage extended deadlines of 2013 and 2018, due to the work of the 2010 registrants. This would therefore provide the option for registrants of <1000 tonnes per annum to register (and pay compensation for the data) in advance of their extended registration deadlines.

How should a substance that is also an “intermediate” be registered?

One registration dossier is to be submitted covering both the use as an isolated intermediate and the other uses. The deadline should be based on the total volume.

If the tonnage manufactured or imported as isolated intermediate is handled under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirement of the registration dossier. However, as indicated in Article 18.3, a registration for a transported isolated intermediate in quantities of more than 1 000 tonnes per year per manufacturer or importer shall include the information specified in Annex VII of the REACH Regulation.

If the manufacture or use(s) as isolated intermediate are **not** under strictly controlled conditions, then the manufacturer or importer needs to submit a “standard” registration dossier according to Article 10. Nevertheless the use as intermediate should be documented in the dossier, including the volume manufactured or imported for this purpose.

4. Defining information needs

What information is required for registration?

The minimum requirements for information to be submitted at registration are based on the manufactured and importation volumes per legal entity grouped into four tonnage bands:

Tonnage band (tonnes per annum)	Information requirements* described in REACH regulation in:
>1 and ≤10	Annex VII
>10 and ≤100	Annex VII + VIII
>100 and ≤1000	Annex VII + VIII + IX**
>1000	Annex VII + VIII + IX** + X**
* Ensure you fully understand all the derogations that are potentially available ** Testing proposals required in absence of data	

Volumes are calculated individually by each legal entity on the basis of the average tonnage over the 3 years preceeding registration. Knowing the volumes and being able to predict changes will help decide what information is needed and is crucial in order to enter into negotiations with other SIEF participants for testing against specific end points.

Based on the data requirements for registration described in Article 12 of the REACH Regulation taking into account column 2 of annexes VII to X and annex XI, 'Information to be submitted depending on tonnage', page 50 of the ECHA Guidance on data sharing, specifies that "potential registrants identify precisely the information requirements for the substance that they intend to register, considering in particular the tonnage band that is relevant to them, the physical parameters of the substance (relevant for technical waiving of tests) and uses/exposure patterns (relevant for exposure based waiving). .."

Potential registrants are therefore expected to:

- Provide all relevant and available physicochemical, toxicological and ecotoxicological information that is available to them, irrespective of tonnage (this includes data from an individual or collective search of freely available literature);
- At the minimum, fulfill the standard information requirements as laid down in Column 1 of REACH Regulation Annexes VII to X for substances produced or imported in a certain tonnage band, subject to waiving possibilities according to column 2 of Annexes VII to X and Annex XI.

Note: for Annexes IX and X only, testing proposals are accepted in the registration dossier in the absence of data. Testing can be performed only after receiving the formal agreement of ECHA.

The minimum standard information requirements for registration listed in Annexes VII to X depend on the volume bands. However, it is important to remember that **all available existing information** (on the physicochemical, toxicological and ecotoxicological properties of the substance owned by the registrant or available to the registrant without payment of due compensation) **should be submitted, even if not required for the specific volume band** relevant to them. This is needed to avoid duplicate testing by registrants that do need the additional data because they are going to register for a higher volume band.

The table below provides an overview of the data to be submitted for a given volume band, as described in Annexes VII to X of the REACH Regulation.

Please note that - according to Article 12(1)(a) and 12(1)(b) - for phase-in substances registered in quantities between 1 and 10 tonnes, if they do not meet at least one of the criteria described in Annex III of REACH (i.e. substances for which is predicted that they are likely to meet the criteria for classification as CMR cat 1 or 2, or substances with dispersive or diffuse uses, especially in consumer goods, and for which is predicted that they are likely to meet the classification criteria for any human health or environmental endpoints), only the information on physicochemical properties specified in Annex VII, section 7, together with all relevant information available to the registrant, need to be submitted. When the full range of data from Annex VII is submitted, the registration fees are waived (Article 74(2)).

1 Tonne or more Annex VII	10 tonnes or more Annex VIII	100 tonnes or more Annex IX	1000 tonnes or more Annex X		**Physicochemistry**
X	X	X	X	7.1	State of the substance at 20°C and 101,3 kPa
X	X	X	X	7.2	Melting Point
X	X	X	X	7.3	Boiling Point
X	X	X	X	7.4	Relative Density
X	X	X	X	7.5	Vapor Pressure
X	X	X	X	7.6	Surface Tension
X	X	X	X	7.7	Water solubility
X	X	X	X	7.8	Partition coefficient
X	X	X	X	7.9	Flash point
X	X	X	X	7.10	Flammability
X	X	X	X	7.11	Explosive properties
X	X	X	X	7.12	Self-ignition temperature
X	X	X	X	7.13	Oxidizing properties
X	X	X	X	7.14	Granulometry
		X	X	7.15	Stability in organic solvents and identity of relevant degradation products
		X	X	7.16	Dissociation constant
		X	X	7.17	Viscosity
					Sensitization & Irritation
X	X	X	X	8.1	Skin Irritation/ Corrosion: in-vitro
	X	X	X	8.1.1	Skin Irritation/ Corrosion In-vivo
X	X	X	X	8.2	Eye Irritation/ Corrosion: In-vitro
	X	X	X	8.2.1	Eye Irritation/ Corrosion: In-vivo
X	X	X	X	8.3	Skin Sensitization
					Genotoxicity
X	X	X	X	8.4.1	Gene Mutation in Bacteria
	X	X	X	8.4.2	In vitro cytogenicity study in mammalian cells or in vitro micronucleus study
	X	X	X	8.4.3	In vitro gene mutation study in mammalian cells, if a negative result in Annex VII, section 8.4.1 and Annex VIII, section 8.4.2
				8.4	Mutagenicity in vivo
					Acute Toxicity
X	X	X	X	8.5.1	Acute Toxicity: Oral
	X	X	X	8.5.2	Acute Toxicity: Inhalation nose only exposure
	X	X	X	8.5.3	Acute Toxicity: Dermal
				8.6	**Repeated Dose Toxicity**
	X	X	X	8.6.1	Short-term repeated dose toxicity study (28 days),one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.
		X	X	8.6.2	Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure
				8.7	**Reproductive toxicity**
	X	X	X	8.7.1	Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from in vivo methods that the substance may be a developmental toxicant.
		X	X	8.7.2	Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure
		X	X	8.7.3	Two-Generation Reproductive Toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, if the 28-day or the 90-day study indicates adverse effects on reproductive organs and tissues
				8.8	**Toxico-Kinetics**
	X	X	X	8.8.1	Assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information
			X	8.9.1	**Carcinogenicity Study**
				9.1	**Aquatic toxicity**
X	X	X	X	9.1.1	Daphnia Acute Immobilization
X	X	X	X	9.1.2	Algae Growth Inhibition
	X	X	X	9.1.3	Short-term toxicity on fish: The registrant may consider long-term toxicity testing instead of short-term
	X	X	X	9.1.4	Activated sludge respiration inhibition testing
		X	X	9.1.5	Long term toxicity testing on invertebrates (Daphnia)
		X	X	9.1.6	Long term toxicity testing on fish
		X	X	9.1.6.1	Fish Early Life Stage Toxicity
					or
		X	X	9.1.6.2	Fish short-term tox test on embryo & sac-fry
					or
		X	X	9.1.6.3	Fish Juvenile Growth
					Bacteria toxicity
					Aquatic Plant Toxicity
				9.2	**Degradation**
X	X	X	X	9.2.1	Biotic
X	X	X	X	9.2.1.1	Ready biodegradabililty
		X	X	9.2.1.2	Simulation testing on ultimate degradation in surface water
		X	X	9.2.1.3	Soil simulation testing (for substances with a high potential for adsorption to soil)
		X	X	9.2.1.4	Sediment simulation testing (or substances with a high potential for adsorption to sediment)
	X	X	X	9.2.2	Abiotic
	X	X	X	9.2.2.1	Hydrolysis as a function of pH
		X	X	9.2.3	Identification of degradation products
				9.3	**Fate and behaviour in the environment**
	X	X	X	9.3.1	Adsorption/desorption screening
		X	X	9.3.2	Bioaccumulation in aquatic species, preferably fish
		X	X	9.3.3	Further information on adsorption/desorption depending on the results of the study required in Annex VIII
			X	9.3.4	Further information on the environmental fate and behaviour of the substance and/or degradation products
				9.4	**Effects on terrestrial organisms**
		X	X	9.4.1	Short-term toxicity to invertebrates
		X	X	9.4.2	Effects on soil micro-organisms
		X	X	9.4.3	Short-term toxicity to plants
			X	9.4.4	Long term toxicity testing on invertebrates
			X	9.4.6	Long term toxicity testing on plants
			X	9.5.1	Long-term toxicity to sediment organisms
			X	9.6.1	Long-term or reproductive toxicity to birds

What are the adaptations to these data requirements?

Adaptation of the standard testing regime specified in column 1 of Annexes VII to X of the REACH Regulation is possible for each endpoint on the basis of the conditions set out in column 2. In addition Annex XI sets out three other options for adjustments of the regime:

- Testing is not scientifically necessary
  Based on the use of existing data even when they are only needed at higher tonnage levels, and through read-across, grouping, the use of (Q)SARs and scientific justifications described in Annex XI. Furthermore, in-vitro testing may also result in adaptation of the regime because the information obtained is sufficient for the purposes of REACH;
- Testing is technically not possible
  For example for volatile substances for which testing in water, sediment or soil may not be possible;
- Exposure driven testing
  This is substance-tailored testing and omitting testing (waiving) for sections 8.6 and 8.7 of Annex VIII, and Annex IX and X. The waiving needs to be justified on the basis of exposure scenario(s) is commonly referred to as Exposure Based Waiving (EBW). Minimal or negligible exposure and risk can be expected for certain populations or environmental compartments. It is easier to justify EBW for substances with specific uses since all uses need to be covered for the entire life cycle of the substance.

  A quantitative justification is required using an exposure assessment including development of an exposure scenario.

  Note: Annex XI is currently under review and may result in modification of EBW.

How can the SIEF collectively assess data gaps?

It will not be necessary to follow the formal steps described in Article 30 of the REACH Regulation if the SIEF participants can agree to collectively gather and review all available information, including publicly available data. The ECHA Guidance on data sharing recommends applying what is described as the 'collective route', rather than the 'individual route'.

When following the 'collective route', potential registrants will gather all information that they have available individually, including results from literature searches (publicly available data) and any assessment in a previous programme (e.g. EU Existing Substance Regulation), they will jointly evaluate the quality of available information, assessing the relevance, reliability, adequacy and fitness for purpose of all gathered data, and consider the information needs taking into account the volume bands relevant to all registrants as well as the opportunities for data waiving. At this point the registrants will be in the position to compare the information requirements and the information gathered and determine whether there are data gaps and what the possibilities to acquire the missing data are. Data holders within the SIEF must be contacted to verify if they can provide the missing data. If the data cannot be provided by the data holders, in cases where there is potential to apply read across or QSARs the registrants can also inquiry with data owners in other SIEFs.

It is important to mention that data gaps may be different for each of the volume bands and the application/use of the substance, which can modify the route of exposure. It could happen that all necessary data are available for a lower volume band, but not for the highest (>1000 tpa) volume band. In these cases companies that do not need the data for the highest volume band are not required to share in the costs of the studies provided by data holders or generated otherwise. Nevertheless, they should take into account the result of these studies.

As long as the conditions described in Annex XI are met, other methods may also be used to provide information on the intrinsic properties of a substance, e.g. (Q)SAR, read-across, grouping and weight of evidence. Where a data gap still cannot be filled, the potential registrants will need to take different actions depending on the missing data: data required according to Annexes VII and VIII will have to be generated, while where the data gap derives from the requirements in Annexes IX and X, the registrants will have to prepare testing proposals and submit these to the ECHA as part of the registration dossier, regardless of

whether these involve vertebrates or not. When testing proposals are submitted, registrants should implement and recommend interim risk management measures to their downstream users, if relevant, according to the result of the risk assessment.

How can individual companies assess data gaps?

If not already available, an inventory of all relevant studies owned by the potential registrants for the relevant substance should be created. This will facilitate not only the early identification of possible individual data gaps, but also the opportunities to share data with the other participants of the SIEF.

Having taken into consideration the information requirements for the relevant volume band and the opportunities for data waiving, potential registrants should be in the position to establish a first overview of where their data gaps may be by comparing the data needs with the data available to them.

Article 30 of the REACH Regulation, 'Sharing of data involving tests', describes the procedure to follow within the SIEF to request data from other SIEF participants and to respond to requests of other SIEF participants. When a data gap is identified, before testing is carried out, the potential registrant should inquire whether a study is available within the SIEF. If available, he shall (in the case of tests on vertebrate animals) or may (in the case of a study not involving vertebrate animals) request it. This request will trigger the obligation for the data owner to provide the proof of cost within one month and further data sharing obligations.

A company may decide whether to share data obtained from tests not using vertebrates, however it is recommended to share all relevant data.

For further information on the process of data sharing, see also below.

What expertise is required to evaluate this information?

Consider your internal or external (consortium) resource/expertise availability to assess the value and quality of the data and prepare robust study summaries. You will need access to:

- Chemical characterisation (purity profile) and physico-chemical property data will be required to support acceptance of the chemical in a SIEF and should be developed in advance of SIEF formation
- (eco)Toxicology expertise familiar with the Klimisch data reliability rating system
- Structural, physico-chemical, environmental and mammalian toxicity evaluation of trends in support of a category, or read across approach
- Industrial/occupational hygiene expertise to select and / or develop exposure scenarios

In what format is the information required for registration?

Hazard data is required to be submitted to the ECHA via REACH-IT in IUCLID5 format containing (robust) study summaries for each end point, see table above. Potential registrants need to have legitimate possession of the necessary robust study summaries for registration. This may require compensation of the data holder. The provision of a full study report by the data holder for use in REACH or outside the boundaries of REACH may require greater compensation.

Testing proposals are submitted within the IUCLID5 format. Potential registrants need to have co-sponsored any work involved in preparing the test proposal.

The Chemical Safety Report is attached to the IUCLID5 submission. Potential registrants must have legitimate possession of all data referred to in the CSR.

5. Data sharing practicalities

What are the obligations of the data requester / holder?

These are detailed in the ECHA guidance on data sharing. In summary, obligations are more severe if animal testing is involved. They also differ for potential registrants who own data and data holders without intent to register. The former may search for data in other SIEFs (via read across) or outside the REACH system (e.g. information detained by public authorities based in other regions where there is no obligation for such authorities under REACH for mandatory sharing. There is no internationally prescribed mechanism for this.

What is the process of data sharing?

The sharing of information required for registration is one of the key principles of the REACH Regulation. It concerns technical data and in particular information related to the intrinsic properties of substances. The sharing of existing data is obligatory for tests on vertebrate animals, as the avoidance of unnecessary animal testing is a main concern of REACH. For other tests, REACH encourages the sharing of data in order to reduce costs for companies and duplication of testing. Whilst the sharing of non-vertebrate data is optional, potential registrants are obliged to submit a joint registration, unless they chose to opt out. You would find more basic information on data sharing in the ECHA fact sheet and detailed information in the ECHA Guidance on data sharing.

Annex 1 (Chart VI and VII) of the ECHA guidance data sharing contains a schematic overview of the data sharing process. Data shall be shared collectively, be it with all potential registrants of a SIEF or with individual participants. Registrants that follow the individual route shall still participate in the joint submission unless opt out is justified. Depending on the registration strategy, it is up to the registrants to decide which route they will use. In Section 5.3 and 5.5 of the ECHA guidance, the different data sharing scenarios are explained in detail.

How and when can data be shared?

After having agreed within the pre-SIEF on substance sameness (and hence forming a SIEF), you would in each SIEF exchange data and information until a final joint submission can be made. Data sharing and the agreement on classification and labelling will occur at any time during the SIEF preparations of the joint dossier. Data sharing may also occur between SIEF in the case of read across.

There will be several factors that influence the circumstances under which data sharing will operate, such as:

- Study ownership across companies
- Expediency to progress registration work
- Data availability
- Impact and quality of data
- Availability of details of original sponsorship

Data sharing implies several steps that may be conducted collectively, in most cases, or individually (when a member is in disagreement with the other SIEF members). These steps are:

- Define what studies are available (either published or unpublished) within SIEF participation, including data holders, other SIEF and publicly available information, Remember: Potential registrants are obliged under the REACH Regulation to request study data derived from vertebrate animal testing from other SIEF members, and may request data derived from studies not involving tests on vertebrate animals
- Identify those data owners that have made a significant investment in the provision of data. This is to determine whether a cost sharing mechanism should be applied and is open to the case-by-case interpretation of the SIEF participants. In general this refers to significant financial investment and/or impact across a category of substances
- Consider information needs and identify information gaps;
- Evaluate quality of available information;

- Generate new information/testing proposals.

All this will imply companies involved would have to define the way they would exchange data (applicable rules on data sharing and cost compensation mechanism). It is highly recommended that a company does not enter into data sharing without first having sound rules in place. These are typically included in a consortium agreement, which companies could see initially as a hurdle, however it can prove to be a very good tool for defining the rules to ensure efficient management of data exchange.

Data can be shared by e-mail or more preferable for large SIEF using an IT tool, e.g. SIEFreach.

How does competition law apply to data sharing?

✓**DO** ensure as a general rule that, where the membership of a consortium is limited, the rules of the consortium do not result in the total exclusion of non-members to access data produced in the context of REACH. Such exclusion may, however, be justified in certain circumstances to be interpreted in the light of REACH and related obligations on data sharing and EC competition law.

✓**DO** respond promptly to data requests made legitimately under the REACH data sharing rules (which may not necessarily imply "immediate communication" of the relevant data, since, among others, a process of negotiation may occur).

6. Ownership, protection of data, confidential business information (CBI) & copyright

Copyright and the legal protection of data are Intellectual Property Rights that are of paramount importance in the ambit of REACH.

How can I share the data I own?

You may decide to:

- Assign "ownership" or become co-owner of the data; or
- Retain ownership and authorise the use of the data by a third party (only for REACH or a broader purpose); or
- Retain ownership and provide the right to refer to the data (letter of access).

Whatever you decide, you have the right to request compensation for this transaction. Data sharing without compensation is only provided for in the REACH Regulation 12 years after the information is submitted for registration see below. However,

✓**DO** ensure that differences in the level of access or ownership are reflected in the amount of compensation.

You may also wish to consider in the transaction provisions for the future support of the study in the case of rejection in the dossier evaluation phase.

How do I prove that I am the owner of a study?

There is no specific legal paper to prove ownership of a study. However you can prove ownership by providing the contract you signed with the laboratory that produced the study, including a clause that ownership of the study produced as a result is yours.

How do I prove that I am the co-owner of a study?

If a study was commissioned by members of a trade association or sector group (because the group had no legal personality) the study will typically be co-owned by the members of that group who paid for it (and not by the trade association or sector group *per se*). Operating rules of a group may define ownership when a member leaves or joins the group. On the contrary, if a group with legal personality commissioned the study, it will belong to that legal body. Of course if in the contract with the research institute to which the study was commissioned a clause reserved ownership to them or co-ownership the situation will be different.

It is therefore important for sectoral organisations to have a list of the data/studies (in particular Klimisch 1 and 2-rated studies) they developed over the years, the associated total costs and individual payments of member companies. If no rule on ownership and other rights were adopted already, it is advised to have such rules adopted by the organisation to "guide" the member companies when entering into a SIEF and sharing co-owned data.

Therefore it is important to check the history of study report distribution and compensation, before a decision is made to request compensation.

Who is the owner of data generated by a SIEF/consortium?

A SIEF or consortium will not normally have legal personality (unless members decide to go for legal incorporation which may be lengthy and cumbersome). As a consequence, data generated by a SIEF/consortium will normally be co-owned by the participants. As already advised in the Cefic Guidance documents "Preparation for Pre-registration" and "Formation of SIEF", the adoption of rules for data ownership and cost sharing is strongly recommended. For this it is advised to form a consortium and have a consortium agreement signed that would typically include rules if new members are joining or leaving a consortium (in the case of full opt out from joint submission).

Can data be re-shared/resold?

This will depend of the specific contract/rules imposed when obtaining co-ownership or the right to use or to refer to data. Clauses on use and sub-licensing need to be included in data sharing rules or consortium contracts in order to clearly spell out such details to all parties concerned.

What is "legitimate possession" of a full study report?

This expression is not defined by the REACH Regulation, but it means that you do not necessarily need to be the owner or the co-owner of the full study report. You need to have obtained at least the right to use it or to refer to it (via letter of access) for the purposes of REACH registration, and, for example, not have obtained a copy fraudulently.

What Intellectual Property Rights may be attached to data?

In most cases, intellectual property rights will be either:

1. Confidential Business Information/protection of undisclosed data (Article 39 of Trade Related Intellectual Property rights WTO Agreement)

CBI is one of the valuable assets of companies that is not defined in the REACH Regulation but reference is made to information the disclosure of which can be harmful to a company's interests (e.g. Articles 10, 118, 119)

Section 11 of the ECHA guidance on data sharing includes a definition on CBI. It is company data that:

- Is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- Has commercial value because it is secret; and
- Has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret;

Or

2. Copyright

This right protects the form of expression of ideas but not mere facts. For example, a scientific article or study in a journal can be copyrighted provided it has a certain creation in expression of factual information. In most of the European languages other than English, copyright is known as the author right. Concerning the economic side of this right (and not the moral one), the owner of the right can decide to publish without "termination" of the right. Copyright rules may be indicated by the journal or website (by the display of the symbol ©), but copyright protection is automatic and does not need to display this symbol to apply in Europe. This may be different in other parts of the world (e.g. Japan).

NB. Neither CBI nor copyright need to be registered, as is the case for patents or trademarks.

How do I protect CBI?

1: Identify at an early stage whether the data you own and will share is CBI. The following guidance has been provided in the Cefic guidance "Formation of SIEF" to identify data with potential for CBI concern:

- No Confidential Business Information concerns e.g. CAS number, tonnage band
- Could be exchanged and discussed in the SIEF, but not for the public e.g. precise chemical identity or a robust summary of hazard data
- Company Confidential Business Information not to be shared e.g. formulation

NB. Company actual manufactured or imported tonnage and market share are sensitive information under EC competition law.

Early identification of CBI allows companies to take precautionary measures at an early stage and not to circulate CBI by mistake.

2: Take appropriate measures to protect data identified as CBI. These may include:

- Application of confidentiality rules or agreement, in a SIEF / consortium.
- Use of a Third Party Representative for pre-registration and data sharing in the case that the association of legal entity and substance identities is considered CBI.
- Decision to opt out from joint submission (see below) or send certain information to ECHA separately indicating (where provided for) that it is confidential.
- Appointment of an independent third party to handle CBI and competition compliance sensitive data, see ECHA Guidance on data sharing.
- Pay fee to ECHA for protection of specified data submitted at registration

Can published articles (including data) be freely used?

Not all information accessible on the web is freely available. Copyrighted work cannot be used freely for the purposes of REACH. Having a physical or electronic copy of a study does not make you the owner. You can only use its copyrighted content if you are in legitimate possession of or have permission to refer to the full study report. In the same way, if you have received a letter of access for another purpose you need to check to what extent you can use such data / information for REACH registration.

The use of the said published copyrighted article / information may be subject to compensation.

Therefore, if you intend to use published data that is subject to a copyright you need to contact the author and publisher or Internet site of the publication to agree on the use of such information. On the other hand, if you notice that another company unduly uses your published data, you could contact this company to explain that they have no legal possession under REACH and engage in negotiations.

If the published data are sufficient to merit a Klimisch 1 or 2 rating in their own right, then this alone can be used to meet the REACH Regulation requirements. However, if the published data alone merit a Klimisch 3 or 4 rating and there is no other source of data to meet the end point, then access to the original study report should be negotiated with the study report owner(s) but only where there is evidence that more detail will raise the value of the study data. Only if the owner(s) have a significant investment in the study, compensation should be discussed, otherwise the owners should be encouraged to share the data freely to support the progress of the SIEF.

Can I use data from public authorities?

In some cases information may be freely available, in others it may be referred to or to be licensed against a payment mechanism. You are advised to check the rules with the particular authority.

Data may be retained by authorities via a registration mechanism (as it is in REACH) with rules of access/use. In REACH there is the inquiry process and the “12-year rule” (Article 25 of the Regulation), a rule by which the right to use or refer to data is granted by the REACH Regulation. In a nutshell, this regulatory mechanism implies that any study or robust study summary of studies submitted in the framework of a REACH Registration more than 12 years previously, can be “freely” used for the purpose of a REACH registration by another registrant (for a new registration), but only for this purpose (see here under and the ECHA Guidance on data sharing). The REACH Regulation “12-year rule” does not mean that data produced 12 years ago or more has no value, on the contrary. The 12 years relates to the time between the original registration submission and the free access of new registrants to this data.

The rules regarding notified new substances under 67/548/EEC are slightly different. For these substances the 12-year rule starts on the date when the notification was granted. This means that a notification done before 1996 would have its data freely available to a potential registrant under REACH.

Other similar mechanism may exist in other sectoral legislation e.g. pesticides and biocides.

Government and authorities may also generate data or studies. Ownership will normally be for the said body.

Whilst some study summaries and/or regulatory assessments can be used in compiling a Chemicals Safety Report, access to the original source, either published or unpublished should be obtained.

Which type of data can and cannot be shared?

It is important for competition law compliance reasons to differentiate between which data can be shared and which cannot. Between these poles is an area for careful management of data exchange using precautionary measures. The table below gives examples of the types of data that can and cannot be shared, and those for which careful management of data sharing is advised.

<table>
<tr><th>NO</th><th>YES</th><th>Careful with</th></tr>
<tr><td>Non-public sensitive information: individual prices, terms of sales, credit terms, cost of production or distribution, sales</td><td>Most of the required information for REACH co-operation (mostly purely scientific or technical information)</td><td rowspan="3">Scientific or technical information may provide competitors the ability to identify individual sensitive company information, alignment of market behaviour and information that are not necessary for REACH.

To be on the “safe side” only share information necessary for REACH</td></tr>
<tr><td>Information on future plans of individual companies concerning actual manufacture and or import volumes, technology, investments, production, distribution, marketing.</td><td>Tonnage bands</td></tr>
<tr><td>Matters relating to individual suppliers or customers, particularly in respect of any action that might have the effect of excluding them from the market</td><td>OR representing several non EU manufacturers</td></tr>
</table>

7. Interface with data holders

How to maximise data availability to SIEF?

In order that all relevant data are available to the potential registrants under REACH there needs to be more encouragement to data holders to make their data available. A data holder will make available as a minimum a (robust) study summary to the potential registrants of a SIEF. The data holder is only likely to be contacted by potential registrants if his data may fill a data gap identified in the SIEF.

Who are the data holders?

Data holders under SIEF are individuals, companies, associations, institutes or academia with the legal rights under copy-write requirements to own valid data that could be used to support a REACH registration.

Four types of data owner exist:

- Full-ownership or co-ownership by potential registrants: SIEFreach offers the opportunity to discuss access and owner rights with participants of the SIEF and with participants of other SIEFs
- Data holders being participants of the SIEF or another SIEF (by read-across)
- Early REACH registrants of a substance and registrants under the Biocide and Pesticide Directives should be considered as data owners within a SIEF. Leads registrants should discuss such data owners the outcome of such early submissions
- Data owners not being participants of the SIEF (source: literature, ICCA HPV, risk assessment reports, authorities and universities)

Vertebrate and non vertebrate data holders (legal requirements)

Data should be regarded as one of two categories *vertebrate* and *non-vertebrate*. In the case of vertebrate data the compensation should be the same as for potential registrants in the SIEF offering data. Other data costs can be defined by the SIEF participants but should not be over inflated.

See also the data sharing obligations above.

The potential registrant as recipient of the information, accepts liability for data quality and that the data can only be used for the purposes of REACH (unless another agreement is made).

Access to a full study and/or robust study summary (decision taken by potential registrants in SIEF) and finally an undertaking to treat any information obtained within the SIEF is confidential and may not be conveyed to any other party without the prior written agreement of the lead registrant.

What is the mechanism of joining SIEF for data holders?

Once the ECHA has released the list of pre-registered substances, potential data holders should contact ECHA to obtain access to the relevant (pre-)SIEF. Potential data holders are encouraged to participate in this initiative in order to support REACH registrations.

Data holders who wish to share data in the SIEF will inform the ECHA of their intention using the REACH-IT system (providing substance identity and contact details similar to the pre-registration process). No further details of the process are currently available.

Upon contact with a SIEF, data holders should be asked to agree in writing to their participation. This agreement should relate to duration of participation (only until an agreement is reached on the use and sharing of their data) after that access to the SIEF would be terminated.

Further information on the role of data holders in the SIEF is available on page 14 of Formation of SIEF

Use of SIEFreach for data holders?

The facility to support data holders in the SIEFreach IT tool is expected to be available from 1 December 2008. The tool will facilitate:

- Agreement on pricing policy (or price proposal)
- Permission to use data outside the requirements of REACH.

Literature data – how and when to use

Suitable literature data should be encouraged in the SIEF as a major source of suitable information at no cost to members if the published details alone (without access to the original study report) are of adequate quality. The use of such data must be evaluated by the SIEF to define suitability to the task and to ensure copyright law is fully obeyed.

Further information on published data is provided above.

8. Read across and communication with other SIEFs

What is read-across?

Read-across (R-A) can be seen as the simplest form of grouping, as data are often obtained through a one-to-one comparison of the source and the target chemical.

Grouping or chemical categorization is the generic name for the pooling of a number of chemicals into a group on the basis of structural similarity corresponding with similar physico-chemical, human health, environmental toxicological or environmental fate properties. Details about the grouping of chemicals can be found in the ECHA Guidance on information requirements and chemical safety assessment Chapter R6: QSARS and grouping of chemicals.

R-A is **NOT** to be used as an easy alternative for filling the data gaps of a REACH registration dossier. The R-A approach cannot be used lightly, because its application requires expert knowledge and justification should be given in your registration dossier. There is the additional liability of misinterpretation and it is therefore recommended to obtain legal advice before using R-A data.

How is R-A applied?

R-A is an alternative to testing every substance for every endpoint. It can be applied to well-defined mono-constituent substances, multi-constituent substances and to UVCB's, see ECHA Guidance on information requirements and chemical safety assessment Chapter R6: QSARS and grouping of chemicals.

R-A may be applied to:

- Provide new data when otherwise not available. Example: All available hazard information in the SIEF has been collated but there is none for one or more end points required for the registration dossier. All other methods to obtain the missing data, e.g. literature search or check for other potential data-holders, have failed, and testing is not preferred for time- and cost-saving considerations or in the case of vertebrate animal studies, not allowed.
- Support existing test data if in question
- Help select the most reliable data when several results are available.
- Obtaining dose-response indications and for use in a PBT assessment.

Recommendation: Apply read-across only when all available data have been evaluated and the data gap defined.

Is there a legal obligation to make use of R-A?

No, according to the ECHA guidance on data sharing it is mandatory for participants of the same SIEF's to share data, but this obligation does not extend outside that SIEF. However, the REACH Regulation obliges potential registrants to avoid animal testing and reduce compliance costs, which may be supported by R-A.

Can anyone make use of R-A?

It is recommended that R-A is applied by (eco) - toxicologists. Both the process and outcome of R-A should be well documented.

How can the quality of R-A data be maximised?

Since R-A data may have a higher uncertainty than test data, it is important that this uncertainty and any associated liabilities are restricted as far as possible by:

- Making use of expert judgment. Failure to do so may result in an incorrect conclusion for an end point.
- Ensuring that the source data has been obtained by high quality testing.
- Updating R-A data as new source information becomes available. This necessitates regular communication with owners of the source data.

How can the owner of source chemical data be identified?

Possible source chemicals may be identified in the ECHA published list of pre-registered chemicals (available before 1 January 2009). By updating the pre-registration data on REACH IT with the identity of the source chemical for R-A, mutual access to the pre-SIEF REACH IT webpages of the source and target chemicals for R-A will be provided. Contact details of potential registrants and data holders of the source chemical are listed in this webpage.

What conditions apply to the sharing of R-A data?

For R-A data the same pre-conditions with regard to costs, quality, suitability, property rights, liability, etc. apply as for data shared within a SIEF.

There is no obligation to read across in both directions, but it is unlikely that for one substance a full set of information will be available while major gaps exist for the other substance. A data matrix would help in making this clear.

There is also no obligation to share source data, when these are requested.

Is it necessary to sign a read-across agreement?

Since every request for access to studies across different SIEFs will have to be negotiated on a case-by-case basis by the companies concerned, a read-across agreement would be recommended and may include provisions on the different conditions.

Given that agreeing on read-across may in some cases involve the disclosure of confidential data, such as know-how or sensitive information, companies may want to preserve confidentiality in a secure exchange.

In case the technical information to be exchanged is considered commercially sensitive, a preliminary confidentiality agreement in order to safeguard confidentiality can be proposed separately. Companies willing to protect CBI may enter into confidentiality agreements that limit access to documents or other information to specific named persons, or departments, e.g. only persons working within a regulatory section are allowed to see certain information.

9. Data validation and valuation

Data validation and valuation is described in the following:

REACH Regulation:

- Article 27.3 and 30.1

Parties sharing data must make "every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way".

ECHA Guidance on data sharing:

- Chaper 7, data quality and study valuation

Elements discussed are neither intended to be prescriptive nor mandatory. They can serve as a checklist in order to ensure that all parties identify relevant factors when organising quality review and data valuation.

Which systems can be applied for data validation?

In principle, scientific quality of available data can be determined by checking three aspects: adequacy, reliability and relevance of the available data. These terms are defined by Klimisch HJ, Andreae E and Tillmann U (1997). (A systematic approach for evaluating the quality of experimental and ecotoxicological data. Reg.Tox. and Pharm. 25:1-5)

Adequacy: usefulness of data for hazard/risk assessment purposes

Reliability: evaluation of the inherent quality of a test report or publication

The **Klimisch** approach, applicable to studies conducted according to standard OECD or equivalent approved methods, categorising the quality of toxicological and ecotoxicological or environmental fate studies as follows:

1= reliable without restrictions
2= reliable with restrictions
3= not reliable
4= not assignable

Non-GLP studies in humans and animals can also provide valuable mechanistic information critical to the interpretation of hazard end point data and assessing the applicability of animal data in human risk assessment. These studies should be evaluated on a case-by-case basis to determine their real value in the development of GHS classification, DNEL and PNEC definition.

Relevance: covering the extent to which data and tests are appropriate for a particular hazard identification or risk characterization.

A second approach developed by the **US EPA** (see ECHA Guidance on data sharing) covers also the physicochemical data elements.

How can data validation be efficiently performed in practice?

Efficiency can be highly increased if one qualified SIEF participant, e.g. the lead registrant, or a competent consultant is fulfilling the task of data validation and the other members rely on his/her expertise and judgements. In this case it is recommended to define before starting the assessment how the different types of studies (e.g. literature, High Production Volume studies and Risk Assessment reports) should be considered.

Which factors need to be considered in data valuation?

The overall value of a study consists of different parameters:

- Testing costs

In principle, there are two methods of assessing the testing costs of existing data: Historic costs or replacement costs. When historic costs are used, SIEF participants may want to account for inflation and other relevant elements which are not required if replacement costs

are used. Replacement costs may be calculated as an average of the current prices charged by two or three testing institutes according to their price list or based on study design protocols provided to them. Fleischer has published a useful and recent review of testing costs.

To facilitate the data valuation data owners should aim to have the historic costs of a study already available and the further factors they want to have reimbursed by the potential registrants or the calculated or wanted replacement costs.

Whether using historic or replacement costs certainly additional correcting factors justifying an increase (eg. radioactive test material, risk premium, etc) or a decrease (eg. letter of access, robust study summary, regional restrictions, etc) of the value of a study, might be addressed by the SIEF participants.

- Analytical costs

The following parameters need to be considered for reimbursement of analytical costs:

  - Development of an analytical test method
  - Measurements of instable test substances
  - Use of radioactive material
  - Analysis of the test substance

- Administrative expenses

How can data valuation be efficiently performed in practice?

For maximal efficiency in the SIEF, discussion and negotiation about study values should be focused only on the expensive studies. It may not be economically advantageous, or from a time management perspective, wise, to negotiate costs of inexpensive studies. Compare the maximum value costs of a study with the costs spend for discussion (resources, time and efforts). Define general rules for less expensive studies.

It may be appropriate to define costs for data packages instead of discussing all endpoints individually:

- Package for physicochemical properties
- Package for toxicological or ecotoxicological data according Annex VII
- Package for all studies assessed by the ICCA/HPV or HERA programme

10. Classification and labelling

Introduction

Classification, Labelling and Packaging (CLP) of substances and mixtures will be regulated by the forthcoming CLP regulation, which is expected to enter into force late 2008 or early 2009. This regulation aims at implementing the Globally Harmonized System (GHS) of Classification and Labelling into EU legislation while keeping the classification and labelling rules as close as possible to the existing EU system and ensuring a smooth transition to a new system based on GHS. The existing EU Directives on classification, labelling, and packaging will be repealed on 1 June 2015 (Article 60, CLP).

The European Parliament has adopted the CLP proposal, together with two related acts, on 3 September 2008. The legislation procedure will be finalized with the approval of the European Council that is expected to take place the 18th of November 2008. The deadlines set by the CLP regulation are 30 Nov 2010 for substances and 31 May 2015 for mixtures.

Responsibility for classification and labelling will reside with industry, except for CMR category 1A, 1B, and 2 substances and respiratory sensitizers category 1, which will continue to go through Community wide harmonization (Article 36, CLP).

The SIEF process will need to aim at agreeing a classification and labelling for a substance. Companies are recommended to prepare for implementing the CLP regulation. The first step is to gain an understanding of the CLP regulation and its implications. Gaining an understanding of the work involved is necessary, as for example; substances and mixtures that are currently not dangerous under 67/548/EEC or 1999/45/EC may need to be classified as hazardous under CLP. Moreover, the implications of the new classification of substances or mixtures will need to be assessed taking into account the transition periods for substances and mixtures (Article 61, CLP), the costs and resources anticipated for re-classifying and re-labelling as well as the implications for downstream legislation such as Seveso II. Guidance for implementing the CLP regulation is being prepared through the RIP 3.6 project with significant involvement of industry. The final guidance is expected to be completed in the first half of 2009.

The current situation

A C&L system is already in place in the EU as part of Directives 67/548/EEC (dangerous substances) and 1999/45/EC (dangerous preparations). Annex I of 67/548/EEC, the published list of substances with a harmonised classification and labelling, at present contains approximately 2,700 existing and 1,100 new substance entries, covering approximately 8,000 substances. This list has been translated according to the new CLP criteria in table 3.1 of Annex VI including technical adaptations to technical progress up to and including the 29th ATP. It should be noted that some classifications are minimal and that where a manufacturer has information that a more severe classification is appropriate they must use that (Annex VI 1.2.1, CLP).

The Directives aim to correctly classify and label any dangerous substance or preparation manufactured within or imported into the EU and placed on the EU market.

The new situation

Substances that have been registered under REACH before 1 Dec 2010 should be registered with a classification according to the existing Dangerous Substances Directive, 67/548/EEC. However, the registration may also contain the classification according to CLP as far as available. Substances registered after 1 Dec 2010 should be registered with a classification according to CLP only. Substances that are exempt from REACH registration that are classified will need to be notified to ECHA by 1 Dec 2010.

By derogation, the CLP Regulation foresees that substances classified, labelled and packaged according to Directive 67/548/EEC and already placed on the market before 1 Dec 2010 (i.e. in stock) are not required to be relabelled and repackaged under CLP until 1 Dec 2012 (Article 61.4 of CLP). The same derogation applies to mixtures classified, labelled and

packaged according to Directive 1999/45/EC and already on the market before 1 June 2015: they are not required to be relabelled and repackaged under CLP until 1 June 2017.

What are the proposed actions for companies?

All companies should first make an inventory of substances subject to C&L in their portfolio i.e. substances they place on the market as such or as preparations regardless of the volume they are placed on the market and which are classified as dangerous or substances subject to registration.

Companies should then assess which substances they plan to register before Dec 1, 2010 i.e. for which the classification information will be part of the registration dossier and those for which they will have to notify ECHA with classification information defined in Article 40 in the new CLP Regulation before Dec 1, 2010.

It is important to note that classification may be based on the new CLP Regulation. To help companies in this exercise, Annex VII of CLP Regulation provides a table assisting in translating a classification made for substance or a mixture under DSD 67/548/EEC or DPD 1999/45/EC.

For those substances that are subject to notification and which have been pre-registered by the company, the agreement on the new CLP classification will take place through the SIEF with the other potential registrants as per January 2009.

There are different scenarios possible, depending on the kind of questions that may come up when trying to agree on harmonized C&L in a SIEF. Some cases are described in the following table (cases 2 and 3 are taken from ECHA guidance on data sharing).

Case No.	Registrant(s) A	Registrant(s) B	Option
1	C&L available/proposed	Agree to A	Check C&L and submit
2	C&L based on data owned by A	No C&L due to lack of data	B asks A for data; agreement on common C&L
3	C&L based on data owned by A	Different C&L based on data owned by B	Either agreement on same C&L or different C&L e.g. if substances exhibit different hazard profiles (contaminants)
4	C&L based on data owned by / known to A and B	C&L based on same data but different interpretation	Agreement or expert judgment by 'neutral' third party
5	No C&L because no data available but indications of hazard properties	No C&L because no data available but indications of hazard properties	Jointly agree on tests and C&L if necessary

The responsibility for C&L remains with the individual registrant, who is obliged to justify his decision. However, it should be noted that every effort has to be made to agree on the same entry.

After allocating existing C&L to substances manufactured and imported, the result should be checked for correctness, plausibility, and open issues, e.g. Possible inconsistencies in C&L from other manufacturers or importers of the same substance already known. A prioritization of the open issues is recommended, e.g. in line with volume based or strategic considerations.

On those substances subject to classification notification and which have not been pre-registered by the company, the company will not be involved in the SIEF classification discussion. In this case the company might consider to first discussing with his supplier or with their industry association to define whether an agreed CLP classification has been allocated to their substance before submitting their classification notification to ECHA.

11. Cost sharing

Information and detailed examples on potential cost sharing mechanisms can be found in the ECHA Guidance on data sharing. This chapter highlights certain mechanisms from this guidance as suggested starting points for SIEF discussion and approval. However it is always possible for SIEF participants to agree on different mechanisms as long as the agreed mechanism is fair, transparent and non-discriminatory.

Cost sharing in itself could require resources in excess of the amount of costs to be shared. Therefore careful consideration should be given to the application of any cost sharing mechanism to avoid that more resources are spent on sharing the costs than are gained by compensation. Cost sharing should be applied to the compensation of where significant contributions to the data requirements.

On what basis are costs shared?

Participants of the SIEF may agree that **compensation-free sharing of existing hazard data** is a fair, transparent and non-discriminatory way forward which maximizes the efficiency of progress towards registration. This approach should be explored, particularly when there is no significant investment on the behalf of data owners over and above other potential registrants, and/or efforts to compensate are uneconomical or untimely.

Otherwise, costs can be shared:

- Equally, based on the number of parties involved. Parties could be specified in the data sharing agreement as a company and its affiliates or a registrant legal entity. This approach is the recommended as the most efficient to manage, or
- Proportionally, based on the REACH tonnage band declared by the company or on production or sales volume. In the latter case, special precautions, e.g. use of independent third party to manage volume data, must be taken in order to comply with competition law, or
- A combination of both as for example 60% of equal sharing and 40% of the total with tonnage bands.

How are existing data holders compensated?

The chosen mechanisms for compensation must meet the following conditions:

- It must be acceptable to SIEF members in the possession of data and those who need access to it for the purpose of registration under REACH.
- The method must be fair, transparent & non-discriminatory and allow for flexibility
- Comply with competition law.

Cefic proposes the following basis for cost calculation. This is one proposal and companies are always free to choose another way:

- All potential registrants without a study required for their registration pay the same amount
- Individual payments should be determined by dividing the compensation amount by the total number of potential registrants who plan to use the study – taking into consideration the application of different tonnage bands/data requirements, see here above).
- All participants with a Klimisch 1 and 2 rated study will be compensated; the compensation per data contributor depends on the quality of the study. For details see the ECHA guidance on data sharing Annex V, example 4.
- In case no Klimisch 1 or 2 rated studies exists, and a number of Klimisch 3 studies are available, one of these latter studies might be selected, see the ECHA guidance on data sharing.
- The total amount for compensation will be based on the value of the study with highest quality and lowest cost
- It is advised to agree a standard cost for Annex VII and VIII end-points.
- The access to data is for the purpose of REACH registration unless otherwise agreed.

How is the cost of data generation to be shared?

Companies only need to financially contribute to studies that they need for the registration of the substance according to their tonnage band. Study costs should be divided between the potential registrants according to the options above. SIEF or consortium participants should decide if they prefer to sell the co-ownership or just the right to use/refer. REACH does not request that registrants co-own the data used in a submission. If companies elect to sell co-ownership, all companies contributing will co-own the study. Usually it will be agreed that none of the co-owners will be able to sell the data to other companies without prior consent of all other contributors. However, if a company requests the right to use/ to refer to data, the amount of compensation will be less than for (co-) ownership. Similarly, wording of a letter of use/access may restrict the wording use of data for REACH only, without sub-licensing possibility.

How are costs shared between potential registrants in a SIEF/consortium for studies sponsored by a sectoral organisation?

When studies have been developed in the past by a group of companies for example in a sectoral group, and brought in a SIEF or Consortium, it is logical that companies which have not participated study funding need to compensate those companies who have. This compensation is not only for the costs associated with the studies themselves, but also for the work performed in the sectoral organisation. These costs should be carefully calculated using a coherent and objectively justified methodology that is well documented. Such costs cannot be used to create an artificial barrier to enter a consortium

When should payments be managed?

A continuous stream of invoices regarding the sharing of costs will emerge. This will create a huge administrative burden for companies, as they will need to be reimbursed at different times according to a number of factors including:

- Different REACH registration time lines
- Late comers joining the SIEF
- De-activation, and/or re-activation of potential registrants in the SIEF.

These complications call for rapid agreement on a recommended way to share costs particularly in SIEFs with a large number of participating companies. Given the costs associated with the issuing of invoices, *de minimis* amounts should be considered.

The tax related aspects of payments for studies may need further attention and a meeting of company accountants or tax specialists may be appropriate to examine this matter.

In many existing consortium contracts it has been agreed that internal company hours dedicated to the consortium work will not be compensated. Expenses to third parties to run the consortium are usually equally shared by all participants, independent of the tonnage band.

12. Sharing use and exposure data

A company strategy related to sharing of substance use and exposure data will depend on, and be determined by, a number of factors. These include the:

- Criticality of that substance to the company
- Amount of information available
- Agreements reached within the SIEF / consortium
- Role of the company within a SIEF / consortium and, possibly
- Confidentiality considerations. In this respect, data considered business critical/confidential would have to be treated in a generic manner, so that it can be shared with others.

Is sharing of use and exposure data obligatory under REACH?

Article 25(2) stipulates, "The sharing and joint submission of information in accordance with this Regulation shall concern technical data and in particular information related to the intrinsic properties of substances..."

Article 29 defines the aim of the SIEF. SIEF participants are obliged to share studies that involve tests on vertebrate animals and are encouraged to share studies that do not involve tests on vertebrate animals. **It is not obligatory to share use and exposure data in a SIEF**. However, it is recommended to share a basic set of use and exposure data to enable the initiation of the Risk Assessment; each company can deal with confidential uses separately. The benefit of sharing at least a basic set of use and exposure data will be that a joint initiation of the Risk Assessment resulting in the optimization of effort and resources.

A consistent approach in risk assessment by all joint registrants may also strengthen their position towards the ECHA in the evaluation phase.

Note that in the preparation of the Chemical Safety Assessment which utilises use and exposure data, two further broad types of data are applicable: the hazard end point data and the information obtained from exploratory or mechanistic studies that can for example provide insight into the relevancy of the hazard end point data. The obligation to share vertebrate animal study data within the SIEF applies to both types of studies.

Will use and exposure data be part of the joint submission?

According to Article 11 only the hazard properties of the substance and its classification and labelling have to be submitted jointly, unless a registrant under Article 11(3) opts out.
However, if possible, participants of a SIEF/consortium can decide on a voluntary basis to submit a joint CSR and/or a guidance of safe use of the substance, see, ECHA guidance on data sharing, 8.5 Voluntary Joint Submission, page 87.
Such submissions can be very beneficial for the registrant, since resources and expertise can be shared. This leads to a more efficient submission and a lower burden for the registrant.

Will a consortium deal with sharing of use and exposure data and how will these data be shared within a consortium and between consortia?

Where agreed by the members, a consortium can and will deal with sharing of use and exposure data. If there are no confidentiality concerns, use and exposure data can be shared openly within the consortium.
In order to alleviate confidentiality concerns, a consortium can consider hiring an independent consultant/trustee who can collect all relevant use and exposure data from the consortium members and 'anonymise' them. Care in data management is also addressed in the table above.

Are use and exposure data to be considered confidential?

Use and exposure data can be considered sensitive information, however, it is important to share use and exposure data for the benefit of all participants to the CSA. Only exceptional cases of confidentiality for which the process or the use of the substance must be kept secret,

e.g. market sensitivity/position in the market, competitors, "special" applications, could justify not sharing (either by opt out or third party).

A low level of confidentiality can be kept by:

- Describing generic processes where only the main steps are indicated, or/ and
- Anonymising the data: collection of data coming from different companies by third party, e.g. consultant or association, who calculates each average and gives the outcome of the sector.

What should I consider before deciding whether or not to share use and exposure data?

Before deciding whether or not to share use and exposure data, several factors should be considered, evaluating the advantages and disadvantages of sharing this type of information (see table below).

The type of substance and its volume band should be considered, whether it is a basic chemical with well-known uses, or a substance with very particular, (company) specific uses that would reveal a company technology or specific know-how to others. Market sensitivity/position in the market, possible confidentiality issues from the customers' side should also be taken into account.

Prior to committing to share use and exposure data, a company strategy might be to request to the relevant consortium or SIEF that an third party technical consultant would gather and compile a general list of use and exposure data.

What are the advantages and disadvantages of sharing or not sharing use and exposure data?

Sharing use and exposure data	
Advantages	**Disadvantages**
Limits efforts and resource needs	(Potential) loss of CBI
Common ES approach for specific applications assured, common harmonized risk management measures (RRM) are developed	A larger and extensive CSR is required as all significant impurities in the substance of the joint registrants need to be assessed
Competence and experience is shared	More stringent RMM might result for a specific application of the substance
More waiving options possible?	
Exposure based data gap analysis possible	

Recommendation: A company strategy can differ by substance, but it is recommended to share a basic set of use and exposure data to enable the initiation of the Risk Assessment, confidential uses can be dealt with separately.

13. Joint submission and opt out

What information should be part of the joint submission?

According to Article 11 of the REACH Regulation, it is mandatory for the lead registrant to submit the following information:

- Information on the classification and labelling of the substance
- Study summaries
- Robust study summaries, if requested
- Proposal for testing

Registrants can on a voluntary basis decide whether information on the guidance of safe use of a substance and/or other relevant information that has been reviewed by an assessor will also be submitted mutually in the joint submission.

The lead registrant has also to indicate in the joint submission:

- The name, address, phone number, e-mail address etc. of all other registrants
- Indicate in the case of read-across which parts of the registration apply to other registrants.

Apart from specific parts of the registration such as use and exposure data, the registrants have to refer in their registration to the name, address, phone number and e-mail address of the lead registrant and also which parts of the registration are already submitted by the lead registrant.

What is the deadline for joint submission?

The lead registrant has to submit the joint submission before the other registrants of the joint submission. This submission has to be filed and the payment of the registration fee complete well before the end of the first tonnage band deadline. Therefore it is highly recommended that registrants make an agreement with the lead registrant on the submission date (suggest a minimum of 3 months before the registration deadline), so that the other registrants can check the content of the joint submission and the registrants themselves have enough time to complete their own submission and pay their registration fee before the tonnage dead line.

Who should draft the joint submission?

In principle only one registrant (the lead registrant) can submit the joint submission.
This will not mean that other registrants cannot contribute or cooperate in completing the joint submission. Especially in larger SIEFs/consortia a technical team may be formed who will take care of drafting the joint submission. The lead registrant, who will be formally responsible and liable for the joint submission, will head this team, or another actor according to special agreement. Therefore it is highly recommended that good agreements have been made between the lead registrant and the other registrants on responsibilities and liabilities.

Alternatively the SIEF/consortium can decide to contract out the drafting of the joint submission to an external consultant, but the lead registrant, who has to be a registrant itself, has to submit the joint submission.

How to organise the transition from SIEF work to dossier preparation?

Following submission of the joint registration, the lead registrant will receive a ticket from ECHA to be distributed to all co-registrants. This ticket will allow each co-registrant to complete its dossier preparation and submit its own registration to ECHA. As a company participating in various SIEFs, this transition point will occur at different times. The SIEF work for a series of substances may still continue, while for others the dossier preparation already starts. The two processes require different actions probably by different experts. A coordination function is required to keep track of the progress in the registration dossier preparation. As both processes are running not only simultaneously, but at a different pace and a different stage for the various substances, this coordination function should be done in

close cooperation with the SIEF coordination and if possible by the same person or group of persons.

What is opt out of joint submission?

See also above.

The registrant who wants to opt-out must explain why an opt-out is justified. According to Article. 20 (2) REACH the ECHA checks the completeness of the registration, but Article. 11 REACH is not mentioned as being subject to the completeness check. Nevertheless it can be assumed that at least a conclusive explanation has to be submitted.

1. Disproportionate costs

The ECHA guidance on data sharing, September 2007, p. 85, mentions as an example for disproportionate costs that:

> *"a potential registrant already has a complete set of the necessary test data for his product in his possession, and that joint submission would cause him disproportionate costs"*,

E.g. because of a particularly disadvantageous cost sharing formula within the consortium.

2. Confidential Business Information (CBI)

According to Article. 11 (3) REACH the registrant would have to explain why the disclosure of information in the framework of the joint registration was likely to lead to substantial commercial loss.

According to the ECHA guidance on data sharing, p. 85, the registrant would usually have to demonstrate:

> *"(1) the route by which confidential information would be disclosed*
> *(2) how it could cause a substantial detriment if it was disclosed*
> *(3) that no mechanisms can be used or is accepted by the other party/parties (e.g. use of a trustee) to prevent disclosure."*

Such protective mechanisms are not mentioned in Article. 11 (3) REACH. Consequently, an obligation to install such protective mechanisms might be challenged.

Although Art. 11 REACH does not demand an assessment of the amount of the commercial loss a rough estimation of the loss should be given in order to underline that a **substantial** loss in the sense of Art. 11 (3) REACH is estimated.

3. Disagreement on selection of information

With regard to the disagreement on selection of information the ECHA guidance on data sharing, p. 86, gives three examples:

> *"(i) A registrant may consider the nominated test data is not appropriate to his products specific application(s). In such a case he would have to provide a qualitative explanation for why he held this view. This may be the case for example due to differences in the physical form in which the product was supplied, the processes in which it was used, the exposure risks for Downstream Users, the likelihood of dispersion during use, the probable final disposal routes, and any other relevant arguments.*
> *(ii) A registrant may believe the data proposed for the joint registration is of an unsatisfactory standard, and does not wish to compromise his reputation by being associated with what he sees as inferior material, especially if the authorities later reject it. In such a case there would also be additional administration costs involved with resubmitting a registration dossier with replacement data of higher standard. The registrants view may also be influenced by his ownership or otherwise of relevant data and/or the different purposes for which his product is used.*

(iii) In the opposite case to (ii), a registrant might consider the data proposed for use in the joint registration to be of an unnecessarily high standard (and therefore excessively costly), at least for his applications. Justification of his opt out would be grounded in demonstrating the adequacy of the alternative test data he was using, coupled with the disproportionate cost to himself if he otherwise accepted the data proposed by the Lead Registrant."

14. Lead registrants

What is a lead registrant?

According to Article 11 of the REACH Regulation, a Lead Registrant is a registrant that submits registration information to the ECHA on behalf of other members of a joint registration. The lead registrant may be chosen by a poll of potential registrants. The SIEFreach IT tool can be used to facilitate voting.

The information submitted by the lead registrant concerns classification and labelling, (robust) study summaries, test proposals and, if necessary, indication which of the information was reviewed by an assessor. If the members of the joint registration so decide, the lead registrant may also submit information on safe use and the Chemical Safety Report on behalf of the others. After the lead registrant submits the information, the other members of the joint registration submit the remaining information individually.

Is there any obligation to appoint a lead registrant?

The role of the lead registrant is mandatory and specifically foreseen in the REACH Regulation. If potential registrants cannot agree on the appointment of a lead registrant, are they allowed to send their registrations individually? The consequences (e.g. rejection of the registration, sanctions) foreseen in REACH in this case are that the greater individual registration fee would be applicable and the dossier would receive individual attention at the evaluation phase. ECHA would accept individual registrations if adequate justification to opt out is submitted.

What is the role of the lead registrant during the substance sameness check?

The SIEF Formation Facilitator normally leads the substance sameness check (See Cefic Guidance "Formation of SIEF") but in the case that the lead registrant has been designated before the conclusion of that preliminary step, then the lead registrant has to be sure that in preparing a joint registration he really is preparing the information for the same substance. Its role would be then to facilitate discussion between potential registrants on the sameness of the substance.

What are the tasks of the lead registrant during the information exchange?

At a preliminary stage, in the case that information to be exchanged is considered commercially sensitive by one or more potential registrants, the designated lead registrant can propose a confidentiality agreement or the use of an independent third party or trustee who can handle the confidential information on behalf of potential registrants.

The lead registrant can make proposals related to any or all of the possible following steps:

- To establish the form of co-operation and internal rules for the SIEF including communication and optional consortium formation
- To agree the entity in charge of the performance of the necessary technical work (either the lead registrant, other potential registrants themselves or a contracted third party or a combination of both);
- To prepare an inventory of available data
- To carry out the validation and the valuation of the data
- To facilitate an agreement on cost sharing
- To identify the specific information on the substance, which he as lead registrant has to forward to ECHA;

The lead registrant may also potentially carry out several other organisational tasks on behalf of the potential registrants, such as:

- Channel the communication, as a contact point for communication, with other SIEFs, with which read across applies.
- Ensure a smooth entry of late registrants in the SIEF
- Launch the enquiry for data in SIEF

How can the lead registrant prepare the dossier?

Collecting data available to potential registrants can be done in the form of a questionnaire structured pursuant to Annexes VI to X of REACH that is sent to all potential registrants and data holders by the lead registrant. This could also include a request to communicate the classification and labelling of the substance.

It is important that co-registrants review the final dossier prior to submission by the lead registrant. This may be described in a consortium agreement.

What are the main obligations of the lead registrant when submitting the dossier?

The lead registrant should include in his registration dossier all the information that should be shared with all other registrants as well as of the information that he needs to submit personally.

This means that his registration dossier should contain:

1. The (robust) study summaries which are relevant for any of the registrants or for some of them (according to tonnage band requirements) of the joint submission indicating which information relates to which specific other registrants

2. The other information (e.g. substance identity) and the (robust) study summaries that are specific for his dossier

To prepare his dossier, the lead registrant should select the regular template in IUCLID5 (based on the tonnage band). In terms of timing, the lead registrant will have to submit first his registration dossier.

The lead registrant has to identify him but also all the other registrants who are part of the joint submission (see also section 1.8.4 of ECHA Guidance on data sharing). He has to specify: Their names, address, phone number, fax number and e-mail address; Parts of the registration that apply to other registrants.

If a potential registrant uses a Third Party Representative in a SIEF, he will provide the lead registrant with his identity for this to be included in the joint submission.

The lead registrant will also have to request confidential treatment of data (Article 10(a)(xi), if appropriate.

Recommendation: If you act as Lead Registrant, it is recommended that you submit the joint submission and pay your registration fee at least 3 months before the deadline. Indeed, as lead registrant, you have specific obligations and corresponding liabilities.

Which data may not be submitted by the Lead registrant?

The REACH Regulation imposes the joint submission by the lead registrant of a part of the Technical Dossier including:

- Classification and labelling of the substance;
- Study Summaries;
- Robust study summaries;

- Proposal of testing;
- Whether an assessor has reviewed the relevant information (on a voluntary basis)

But a part of the registration dossier may be submitted jointly by the lead registrant **or** separately on a voluntary basis. This part consists of:

- The Guidance of safe use of the substance
- The Chemical Safety Report (CSR)

Does the lead registrant have to update the jointly submitted information?

After the submission of the joint registration, if the information to be updated is part of jointly submitted information, each registrant (the lead and all the other registrants) is obliged to make their updates individually. In practice, the lead registrant should update the dossier with information about the identity of any new registrants in the joint submission.

Is there a financial compensation for the resources spent by the lead registrant?

The role of the lead registrant requires substantial resources. It is therefore reasonable to expect that the SIEF members will financially compensate the lead registrant for their services and for the responsibilities he assumes. Nevertheless, there is no strict obligation and the decision is up to the members of the SIEF. It is recommended to raise that point when the lead registrant proposes the form of co-operation and internal rules for the SIEF.

What are the liabilities of the lead registrant?

Since the lead registrant assumes specific responsibilities, wrong or non-compliance with REACH may lead to liability claims (e.g. failure to register a substance in time, etc). These issues may be covered by a private law agreement between the members of the SIEF and the lead registrant that would state specific provisions on that issue.

Recommendation: If you intend to act as Lead Registrant, it is recommended that you take into account all the different obligations and responsibilities and that you assume that choice as a strategic business decision based on the most cost efficient registration strategy per substance.

15. Definitions and Further Information

The definition of many terms used in this guidance can be found in the ECHA glossary.

In addition, the following terms are defined:

European Economic Area: The 27 member states of the European Union plus Norway, Iceland and Liechtenstein

REACH has been integrated in the legislation of three EEA Countries: Norway, Iceland and Lichtenstein. Therefore, Legal Entities located in these countries should be considered as "EU manufacturers and importers" and participate to the pre-registration process, SIEFs etc on equal footing with EU Legal Entities.

On 14 March 2008 the EEA Joint Committee decided to include REACH in the EEA Agreement. Since this implies a transfer of powers from these countries to ECHA each country needed to have a decision from their respective parliament. The EEA decision of the Joint Committee took effect the day after each EEA country received their respective notification of the national decision (adopted on 20 May for Iceland and 29 May for Norway).

Data-holder: A legal entity that possesses relevant data to be shared in SIEF but does not intend to register, for example non-registering manufacturers, early registrants, Plant Protection Products (PPP) and Biocidal Products Directive (BPD) authorisation holders and Non-Governmental Organisations.

Data owner: Any legal entity within the SIEF that possesses relevant data to be shared.

Dormant: Pre-registrant who is not active in the SIEF but maintains all SIEF obligations of data sharing.

For further information relevant to pre-registration, visit the ECHA REACH website which contains specific guidance on:

Data sharing

Pre-registration

IUCLID 5

REACH IT

Substance identification

Glossary