Guidance on SIEF Formation

June 2008, version 0

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June 2008

WARNING

Every company has a responsibility to ensure that it implements REACH in accordance with the Regulation. As stated in the legal notice on RIP Guidance Documents, information contained in the guidance does not constitute legal advice and only the REACH Regulation can serve as an authentic reference. Although RIP guidance is issued by the European Chemicals Agency, the Agency does not accept liability with regard to the content.

REACH implementation requires a case-by-case approach. Each company is responsible for ensuring that it is compliant with the REACH Regulation. To help companies implement REACH, Cefic is producing a number of documents that can be used in conjunction with guidance from the RIPs.

It is for each company to establish the most appropriate and suitable method to meet regulatory requirements. This can depend on many factors such as its products, management systems, customers, suppliers, etc. In every case, the company must check that it is meeting the requirements of the REACH Regulation.

This is the second in a series of three guidance documents to be provided by the Cefic Pre-registration Working Group to guide Cefic member companies through the key REACH challenges in 2008 and early 2009 including pre-registration, SIEF and data-sharing. This document provides guidance for preparatory work ahead of pre-registration and working together in SIEF and consortia. The third guidance on working together in SIEF and data/cost sharing is planned for mid October 2008.

About this document

This current guidance covers the next period after pre-registration through to the formation of SIEF. In this period the critical tasks for potential registrants are to:

- Ensure that you have pre-registered correctly
- Be aware of the different rights and obligations of all the various pre-SIEF members
- Prepare to collaborate efficiently in pre-SIEF by:
  - Nominating a SIEF Formation Facilitator
  - Complying with EC competition law
  - Protecting confidential business information
  - Considering use of the ReachLink SA SIEFreach system
- Agree on substance identity, thereby creating a SIEF

Only when these initial yet important pre-SIEF tasks are complete can the key steps to joint registration, i.e. collection, evaluation and reporting of data and cost sharing, be negotiated.

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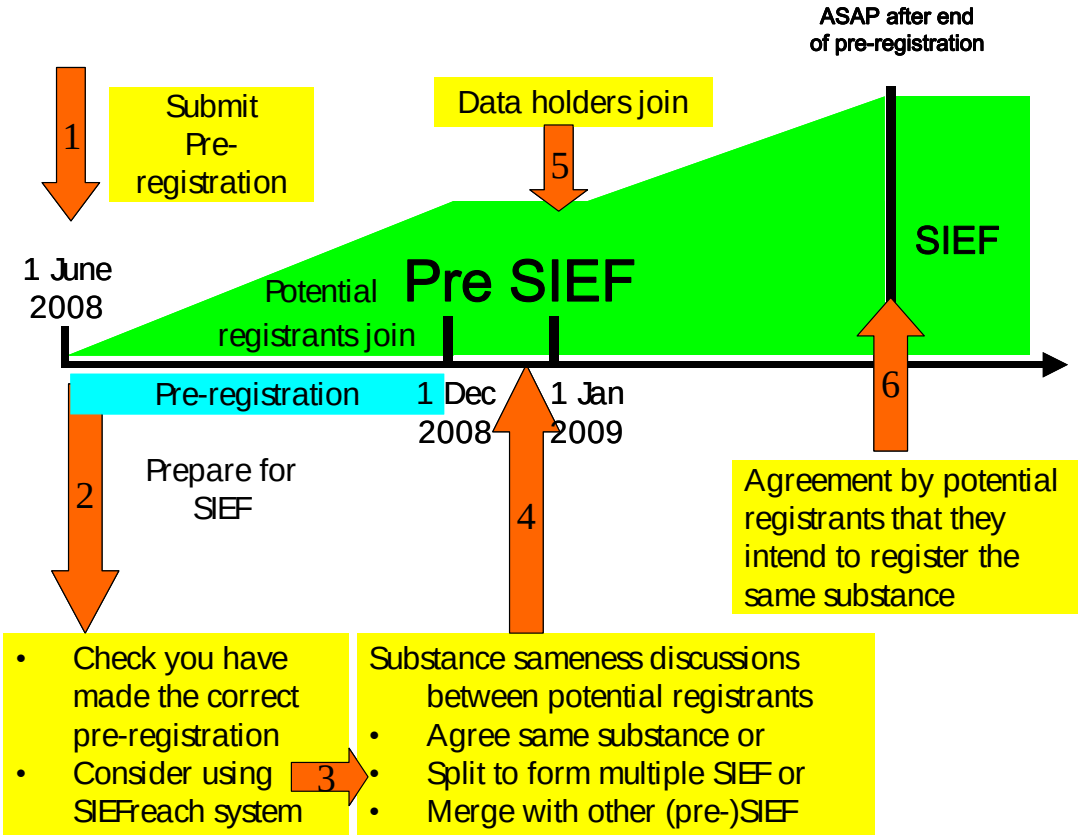


Figure 1: Overview of SIEF formation

1. Pre registration number

WHAT IS A PRE-REGISTRATION NUMBER?

The European Chemicals Agency (ECHA) upon successful submission of the pre-registration information provides a pre-registration number assigned to each substance and legal entity combination regardless if it is a bulk or a manual on-line pre-registration (See Chapter 5 of Cefic Guidance on Pre-registration for further details of how to submit a pre-registration and the different types). The number is communicated via REACH-IT to the user who submitted the pre-registration. Pre-registration numbers are not referred to in the REACH regulation.

Pre-registration numbers are related in structure, yet are different to registration numbers. Both numbers are referred to in REACH IT as reference numbers

The generic structure of ECHA reference numbers is as follows:

Type - Base Number - Check Sum - Index Number

- **Type** is a 2-digit number describing:
  - 01 - Registration
  - 02 – Classification and Labelling Notification
  - 03 – Substance in Article
  - 04 – Product and Process Oriented Research and Development (PPORD)
  - **05 – Pre-registration**
  - 06 - Inquiry
  - 07 – On site isolated Intermediate registration
  - 08 – Transported isolated Intermediate registration
  - 09 – Data Holder Notification

  Therefore all pre-registration numbers will start with 05.

- **Base Number** is a 10-digit number
- **Check Sum** is a 2-digit number derived from the Type and Base Number. The check sum will be the same for the registration number of all members of a joint submission
- **Index Number** is a 4-digit number giving the index of a member in a joint registration submission. When there is no joint submission (i.e. or when the concept is not applicable) 0000 will be used. Therefore the **pre-registration number will terminate in the index number 0000.**

The following form of pre-registration number can therefore be anticipated:

05 – xxxxxxxxxx - xx - 0000

How is a pre-registration number used?

The pre-registration number is the means of confirming to the pre-registrant that the pre-registration has been submitted successfully. **There is no legal requirement to communicate the pre-registration number in the supply chain.**

The provision of a pre-registration number by a supplier does not guarantee his future compliance with REACH or continuity of supply as it is possible to pre-register but not follow through with registration. In addition, not all substances have a pre-registration number, for the simple reason that they have not been pre-registered because, they are not a phase-in substance, that they are manufactured or imported below 1 tonne per year or that they are exempt from REACH. That is why the important REACH statement required by suppliers and submitted to customers can be communicated efficiently as a REACH compliant statement on **product** level. This approach, in particular for preparations, polymer substances or polymer preparations, is independent of the different pre-registration numbers of substances contained in the product.

The pre-registration number will not reveal the substance identity or legal entity. The ECHA will not publish pre-registration numbers so there is no way to check whether pre-registration by a specific legal entity actually took place.

Recommendation: Careful consideration should be given by each Company to the communication of pre-registration numbers in the supply chain.

What is the difference between a pre-registration number and a submission number?

Immediately following successful on-line pre-registration of a single substance, the party who has submitted the pre-registration will receive a submission number and the substance contact person will then receive a pre-registration number.

For **bulk pre-registration** via the REACH-IT system, the party who has submitted the pre-registration will receive an internal REACH-IT message with a submission number. This submission number proves that the user has submitted the bulk pre-registration file. It has been announced by ECHA that the bulk pre-registration option is not available on entry into operation (1 June 08). It is not clear at this stage when this functionality will be available.

Pre-registrants must use the submission number to communicate with the ECHA until a pre-registration number is provided.

The pre-registration number should not be confused with the submission number. The submission number is given every time a submission is made. The submission number could concern multiple substances per legal entity in the case of bulk pre-registration whereas each substance will receive an individual pre-registration number.
An example of a submission number would be ZD120393-43.

2. How to ensure you pre-register correctly?

Before the main activities of SIEF, agreement on classification and labeling and data sharing, can commence, it is vital that each potential registrant is located in a single, correct SIEF per substance. This important step should bring into communication potential registrants and data holders, thereby maximizing the efficiency of future collaboration. Below are some key tips to ensure you pre-register correctly. If you are not in the correct SIEF, you have not pre-registered your substance correctly, because you have made a typing error or have selected the wrong EINECS number. If you do not correct the pre-registration before 1 December 2008, you may be required to make an immediate registration.

1 December 2008, you would be required to make an immediate registration.

USE THE CORRECT SUBSTANCE IDENTITY AT PRE-REGISTRATION

A precautionary approach is advisable in order to avoid difficulties in finding other potential registrants of one's substance after the pre-registration period has passed.

Use of the correct substance identity (see ECHA Guidance for identification and naming of substances under REACH) will avoid having to start a time-consuming search for the right SIEF to join. If that search were unsuccessful, you would then be required to register alone before the correct extended deadline. This may require additional company resource, incur a higher registration fee than a joint submission and potentially result in greater scrutiny of the dossier by ECHA in the evaluation phase.

The REACH-IT system will check automatically the elements of CAS and EINECS number recognition that it can (e.g. the number of digits in the CAS and EINECS numbers). The accuracy of the information however cannot be checked by an IT system. If the EINECS inventory is not used to identify a substance, a typing error in the name will mean that the wrong substance will be pre-registered.

In the case the substance has a CAS number, it is advised to verify whether the name used (the one you would like to pre-register) corresponds to the name in the CAS-database.

In the case the substance has no numerical identifiers (EINECS, NLP or CAS number), verify the IUPAC name with the structural formula and the quantitative composition of the substance.

You can indicate synonyms for your substance without EINECS/ NLP number indicating to other pre-registrants which names are used for your substance.

IF IN DOUBT, PRE-REGISTER AGAIN

There are consequences to being in the wrong (pre-) SIEF so if there is any uncertainty about substance identity (i.e. which CAS, EINECS or NLP identity or number to use), **and only in this case**, it is advisable to submit multiple pre-registrations for your identical substance. Each pre-registration will be checked by REACH-IT and the identifiers will be brought together. When there are no EINECS, NLP or CAS numbers to be used as identifiers the correct IUPAC name should also bring same substances together, but care should be taken in submitting only an IUPAC name as mistakes can easily be made and these may prevent you finding the correct pre-SIEF. The use of trade names or non-chemical names is not advised.

If there are uncertainties about the status of substance (multi-constituent substance versus preparation or UVCB), it is advised to perform pre-registration on the basis of the different options. Note that preparations cannot be (pre-) registered, but their components shall be (pre-) registered.

The use of the read-across option at pre-registration is not a suitable alternative to multiple pre-registrations. You will not have the rights and duties of a potential registrant in the SIEF of substance(s) you have indicated for read across.

Recommendation: The extra work that multiple pre-registrations brings, outweighs the difficulties in finding the right SIEF afterward pre-registration. After finding one's correct SIEF the superfluous pre-registrations can be deactivated. For details and consequences of deactivation: see "How do I deactivate a pre-registration", below.

CHECK THE PRE-SIEF REACH IT WEB PAGE REGULARLY

When a substance is submitted for pre-registration for the first time through REACH-IT a secure associated web page will be created automatically. This web page will then be accessible to all subsequent pre-registrants of the substance with the same name and / or other identifiers, (the pre-SIEF), and will contain certain data submitted at pre-registration including pre-registrant contact details, but excluding the registration deadline and the tonnage band.

Recommendation: Do not enter any confidential business information or other data you do not want to share with other members of the pre-SIEF.

Recommendation: After receiving a message in the REACH-IT internal user's inbox from ECHA giving the user the pre-registration number, check if indeed the intended substance was pre-registered.

Recommendation: Good verification of the pre-SIEF webpage can alert you to any mistakes.

A further indication of a wrong pre-registration could be the presence of a number of unexpected other potential registrants on the associated pre-SIEF webpage. In this case you may wish to contact the SIEF formation facilitator or other pre-SIEF members to verify. Contact can be made using information provided by ECHA or via the SIEFreach system.

For the reasons above, it is advisable to check the associated pre-SIEF webpage regularly throughout the pre-registration period when new potential registrants join the pre-SIEF. You can either enter the web page voluntarily, or request at pre-registration that you are notified by REACH-IT message of changes to the pre-SIEF web page. These changes include the addition of a new pre-SIEF member, a change of the SFF or changes of another member's pre-registration information. The anticipated number of participants within the SIEF may influence your choice of voluntary access or REACH-IT message notification.

AVOID LAST MINUTE PRE-REGISTRATION

By pre-registering early in the six-month pre-registration period (June 1 to December 1 2008), you have a longer time period to identify any incorrect or unsuccessful pre-registration and repeat the pre-registration before 1 December 2008 and deactivate the incorrect one.

Recommendations:

- Know the identity of your substance well and pre-register right first time;
- When in doubt about substance identity, make additional pre-registrations using other appropriate identifiers;
- Check the REACH IT pre-SIEF web page regularly to verify that you have joined the correct pre-SIEF. If in doubt, contact the SFF, if available;
- Contact other pre-registrants before December 1 2008 to start verifying substance identity. Take into consideration the protection of CBI;
- Don't pre-register at the last minute when time is limited. If unsuccessful or incorrect, you will need time to pre-register again.

WHAT DO I DO IF I FIND MYSELF IN THE WRONG PRE-SIEF?

Before December 1 2008, it is possible to deactivate an erroneous pre-registration (see "How do I deactivate a pre-registration") and pre-register again with the correct substance identity.

After December 1 2008, when the pre-registration period is closed and ALL potential registrants are present in the pre-SIEF a sameness discussion is needed in order to form a SIEF (this discussion may start prior to the end of the pre-registration period but cannot be completed until all potential registrants have pre-registered after 1 December 2008). During the sameness discussion it may become evident that one has joined the pre-SIEF of a different substance. If some of the other potential registrants in the pre-SIEF are in a similar position and have pre-registered for a substance of a same identity, the pre-SIEF may be split to create more than one SIEF (see Pre-SIEF splitting and merging for details).

When there are no other pre-registrants within the pre-SIEF with the same substance, the pre-registrant is advised to check the list of pre-registered substances that is published by ECHA by January 1, 2009 for the presence of similar substances. You may request assistance from ECHA to establish contact with the SIEF formation facilitator or lead registrant of the most appropriate (pre-) SIEFs. If this search is unsuccessful the pre-registrant may submit a registration alone before the relevant tonnage registration deadline.

HOW DO I DEACTIVATE A PRE-REGISTRATION?

The REACH IT system of ECHA will allow pre-registrants to "deactivate" a pre-registration. This does not represent a deactivation from the pre-SIEF, but is an indication that the legal entity will not register this substance.

The consequence of this is that the pre-registrant still has data-sharing obligations, but will not participate in the joint submission.

Recommendation: Deactivate as soon as it is clear that you will not register the substance as it enables the other participants of the (pre-) SIEF who are willing to register to more quickly identify who the other potential registrants are.

PRE-SIEF SPLITTING AND MERGING

Industry may split and merge pre-SIEFs to form SIEFs in the circumstances described below, without the support of ECHA. However, ECHA can question the formation of the SIEF in the evaluation phase.

In practice the splitting of a pre-SIEF is relatively straightforward. During the initial sameness discussions, the pre-SIEF will decide how the substance identity should be split. For instance a general enzyme entry on EINECS could result in multiple SIEFs – one for each IUBMB (International Union of Biochemistry and Molecular Biology) number. The work in the pre-SIEF is then split in several SIEFs and will lead to multiple different (joint) registrations, one for each individual IUBMB number. The reason for the split should be justified in the joint submission.

The merging of multiple pre-SIEF to form a single SIEF is more complex. This may be considered in the case where two Einecs entries represent the same substance. Knowledge of the individual Industry participants of the different pre-SIEFs is required in order to facilitate a merge. This process can be supported if the potential pre-registrants consciously pre-register such substances using the known different identifiers.

The SIEFreach system will support the necessary changes required to SIEF structure, such as splitting and merging of SIEFs after pre-registration.

Further Information: See page 37 of the ECHA Guidance on data sharing.

3. Types of (pre-) SIEF members

WHO ARE THE DIFFERENT MEMBERS OF A SIEF?

The different categories of SIEF members are as follows:

- **Potential Registrants**
  - Current and potential manufacturers and importers of phase-in substances having pre-registered that substance
  - Current and potential importers of preparations containing phase-in substances, having pre-registered that substance
  - Current and potential producers and importers of articles having pre-registered that phase-in substance if intended to be released from articles.
  - Only Representatives of non-EU Manufacturers having pre-registered that phase-in substance
  - Late pre-registrants (first time manufacture or import > 1 tonne per year after 1 December 2008 – see Article 28(6) of the REACH Regulation)

- **Third Party Representatives**
  Manufacturers/importers of phase-in substances who have pre-registered these substances and Producers/Importers of articles who have pre-registered phase-in substances intended to be released from an article can decide to appoint a Third Party Representative to hide their identity vis-à-vis the other SIEF members.

  When this happens, the Third Party Representative will be a SIEF member, but this does not mean that he then becomes a Potential Registrant, as the legal entity nominating a Third Party Representative retains the full legal responsibility for complying with his obligations under REACH. However, the Third Party Representative will carry out all proceedings under Title III of the REACH Regulation 'Data Sharing and Avoidance of unnecessary testing'.

- **Data Holders who have expressed their intention to share data via REACH IT:**
  Data holders will join the (pre-) SIEF via REACH-IT following ECHA publication of the list of pre-registered substances before 1 January 2009. They may be:

  - Manufacturers and Importers of phase-in substances in quantities of < 1 tonne per year who have not pre-registered.
  - Downstream Users of phase-in substances.
  - Third Parties holding information on phase-in substances:
    - Trade or industry associations, sector specific groups and consortia already formed.
    - Non Governmental Organisations (NGOs), laboratories, universities, international or national agencies.
    - Manufacturers of a substance who have no interest in registering a substance under REACH because they do not produce or place it on the market in Europe (e.g. a non-EU manufacturer who does not export into the EU).

- **Data Holders who automatically join the SIEF**
  These data holders only will participate in data sharing, classification and labelling discussions and preparation of data for joint submission
  - Any manufacturer/importer who has registered a phase-in substance before June 1, 2018, even without pre-registration. (Early Registrants)
  - Parties that submitted information in the framework of the Plant Protection Product Directive (91/414/EC) or the Biocidal Product Directive (98/8/EC)

- **Others**
  As there are no checks in the REACH-IT system, anyone can pre-register. It is therefore possible that a (pre-) SIEF contains members that are not described above.

  Note: Data holders that have not informed ECHA of their intention to share data will not be SIEF members but may represent a source of data for potential registrants.

Potential registrants and third party representatives may also own data they intend to share and are known as data owners.

How and when data holders are brought into the SIEF

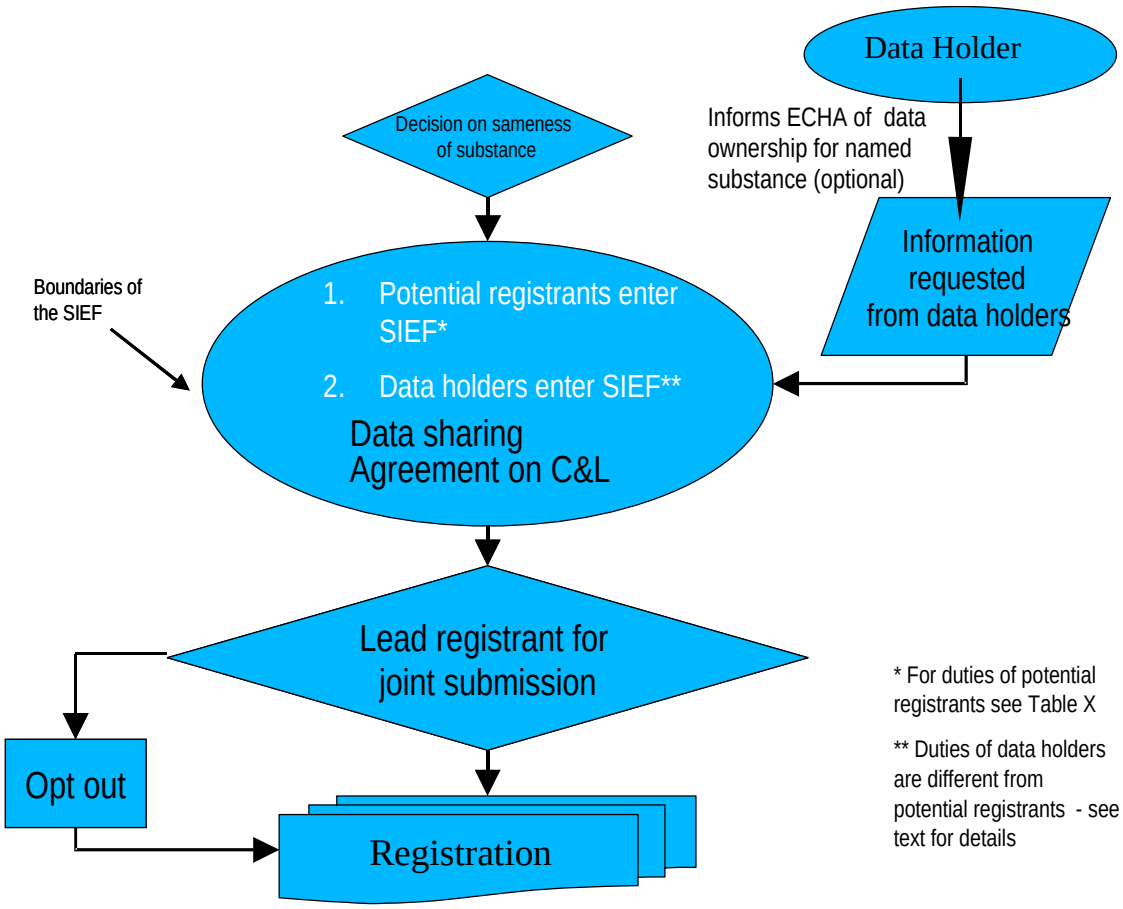


Figure 2: Bringing data holders into SIEF

Further Information: See also section 4.5.3 of the ECHA Guidance on data sharing.

WHAT ARE THE DUTIES OF THE DIFFERENT MEMBERS OF A SIEF?

The different categories of SIEF participant do not share the same duties and rights in the SIEF. The major differences between Potential Registrants (and their Representatives) and Data Holders are summarised in Table 1 below. Although data holders must react to any query from Potential Registrants if they hold data relating to this query (see Article 30 of the REACH Regulation), they have **no** other active role in the SIEF. Data Holders will not decide whether a study is included in the joint submission, nor will they participate in the substance sameness discussions or those related to classification and labelling.

The duties and rights of the different members of a SIEF

DUTIES RIGHTS	TYPE OF SIEF MEMBER		
	Potential Registrants = Manufacturers/Importers/Only Representatives and Producers of articles who have pre-registered a phase-in substance	**Third Party Representatives** appointed by potential registrants	**Data Holders who have expressed their intention to share data via REACH IT**
React to requests from other participants	yes	yes	yes
Provide other participants with 'proof of cost' and (access to) existing studies upon request	yes	yes	yes
Request missing information from other SIEF participants	yes	yes	no
Agree on cost sharing mechanism	yes	yes	yes
Receive financial compensation for data shared	yes	yes	yes
Collectively identify needs for further studies to comply with Registration requirements	yes	yes	no
Make arrangements to perform the identified studies	yes	yes	no
Agree on classification and labelling	yes	yes	no
Agree on the appointment of the Lead Registrant	yes	yes	no
Agree on the selection of studies to be included in the joint submission	yes	yes	no
Submit joint registration (or decide to opt-out)	yes	yes*	no
Ensure that data sharing activities do not jeopardise compliance with EC Competition law	yes	yes	yes

* The decision to prepare a joint submission or opt out is made by the potential registrant and communicated in the SIEF by the Third Party Representative.

4. SIEF Facilitation

The first task to be completed on automatic entry into a pre-SIEF following pre-registration is to establish whether the potential registrants plan to register the same substance for the purpose of data sharing and harmonisation of C&L. Only when this is agreed, is a SIEF created and the obligations of data sharing as set out in Article 30 of the REACH Regulation and the task of preparing for joint submission can begin. As registration must take place according to strict and tight deadlines, it is vital that the potential registrants of the pre-SIEF work together effectively and rapidly from the very start. It is recommended that a SIEF Formation Facilitator (SFF) be appointed for each SIEF in order to organise and lead this initial task.

How to become a SIEF Formation Facilitator (SFF)?

It is highly recommended taking the decision to become a SFF prior to pre-registration. Allocation of SFF in the REACH IT system is on a "first come first served" basis so if you intend to become an SFF it is advisable to pre-register at the beginning of the pre-registration period (1 June 2008). Following successful pre-registration, you can select the SFF option in the appropriate pre-SIEF web page to indicate your willingness to act as SFF. The first pre-registrant to do so for a substance during the 6-month-pre-registration period will be appointed to be the SFF. If an earlier pre-registrant has already selected SFF in the pre-SIEF web page, this option will not be available.

It is possible for potential registrants of multiple substances to become SFF for more than one (pre-) SIEF. If more than one pre-registrant would like to become the SFF, or the original SFF reviews its position, the pre-SIEF participants will have to decide internally by mutual agreement who will take that position based on the most capable volunteer or who will be the future lead registrant. Conversely a SFF may not be needed in the following cases:

- The SIEF is small, or
- The lead registrant is already designated, or
- The substance sameness verification has already taken place outside the SIEF, e.g. within a consortium or other form of cooperation in which all potential registrants have been involved.

Recommendation: discuss the SFF role after pre-registration and make a final decision within the pre-SIEF.

What are the duties of a SFF?

An SFF initiates bringing together of potential registrants and third party representatives immediately following pre-registration to lead the pre-SIEF harmoniously and without delay to form a SIEF. This initially requires facilitation of discussions to establish sameness and thereby organise the exchange of information and data on the identity of the substance if necessary.

Initially the SFF may communicate with SIEF members via the email details provided in the REACH IT pre-SIEF webpage (see page 7 of Cefic Pre-registration guidance). Communications may be continued more effectively in the SIEFreach system, as soon as SIEF members have established this.

There are several further tasks that may be undertaken by the SFF or by the designated Lead registrant, who should take up responsibilities soon after the SIEF is created and will remain in operation until June 1, 2018 (see Article 29 of REACH Regulation). Examples are:

- Facilitate discussion between potential registrants on the sameness of the substance
- Find the form of co-operation and internal rules for the SIEF
- Launch the query for data in SIEF
- Prepare an inventory of available data
- Perform the technical work
- Channel the cooperation with other SIEFs and data holders

- Ensure a smooth entry of late-pre-registrants (i.e.; first time Manufacturers and Importers above 1 tonne per year after December 1 2008)
- Facilitate an agreement on cost sharing

As soon as the lead registrant is defined these SFF tasks will be transferred to the Lead registrant, unless another agreement is concluded.

The role of the SFF should not be underestimated and may require substantial resources. It is therefore reasonable to expect that the SIEF members will financially compensate the SFF for their services; especially the services would have otherwise been compensated for. Apart from operational SIEF costs, the decision is up to the members of the SIEF.

Recommendation: If you intend to act as lead registrant, it is recommended that you take the initiative at the SIEF formation stage and indicate your willingness as SFF immediately following pre-registration.

WHEN SHOULD SAMENESS DISCUSSIONS BE STARTED?

Substance sameness discussions may be started before the close of pre-registration (1 December 2008) but should not be completed before this time.

Starting substance sameness discussions before the end of the 6-month-pre-registration period would allow changes of pre-registrations or to pre-registration again (and deactivate the incorrect pre-registration) before December 1 2008, but this activity bears the following threats

- Time is spent ineffectively if discussions start too early without the full complement of input data –discussions before 2 December 2008 should be treated as preliminary and a way to check that you are in the correct pre-SIEF
- Should the first pre-registrants make a decision, the sameness subject may not be dealt with in a fair and collaborative way

All sameness discussions shall be conducted in compliance with EC competition law whilst protecting CBI.

WHAT WOULD HAPPEN IF NO PRE-REGISTRANT TAKES THE ROLE AS SFF?

Whilst there is no legal requirement for a SFF, in practise it is beneficial that these initial stages of working together are facilitated. In the absence of an SFF, the EU manufacturer or EU Importer with the highest capacity of production or import having the first registration deadline and hence the greatest urgency, may wish to initiate the collaboration.

WHAT IS THE LEGAL STATUS OF THE SFF?

The role of the SFF is totally voluntary and does not entail any specific obligations. In contrast to the role of the lead registrant, it has to be emphasised that the role of SFF is not mandatory and does not have a formal recognition in the REACH Regulation.

The SFF has the same liabilities as any other member of the SIEF. From a liability point of view their obligations are not different compared to the other SIEF members. They are not responsible if the pre-SIEF Members fail to form the correct SIEFs. SIEF members, including the SFF, can only be held liable in case of gross negligence and wilful misconduct, but cannot be held liable neither for non-typical or unforeseeable damage nor for consequential damage and loss of profits.

WHO CAN BECOME A SFF?

In principal any potential registrant or third party representative can become a SFF. Data holders (who have expressed their intent to share data via REACH-IT and who are not potential registrants or third party representatives) and other (pre-) SIEF members cannot become SFF as they are not involved in the pre-SIEF discussions nor can indicate their willingness to be SFF in REACH IT.

ARE CERTAIN SKILLS REQUIRED FOR A SFF?

It is preferable that the SFF has project managerial skills and knowledge of the substance, since he has to organise/facilitate the exchange of data between participants within the (pre-) SIEF or liaises with other SIEFs and finds mutual agreements of sameness of substances.

WILL THE SFF AUTOMATICALLY BE THE LEAD-REGISTRANT?

Neither in the REACH regulation nor its guidelines are rules provided for appointing the lead registrant. It is up to the members to decide by mutual agreement who will take that position. Such a decision may be taken in a consortium or any other form of cooperation. It is potentially preferable that the SFF will become the lead registrant, since he is already involved in the process of organising the pre-SIEF facilitation and data sharing.

WILL THE SFF BE A (PRE-) SIEF REPRESENTATIVE IN CASE OF JOINED CONSORTIUM?

Co-operation in a consortium can be considered by (pre-) SIEF members on a case by case basis, e.g. in the case of structurally similar substances, or for the specific purpose of read-across. A single joint submission is prepared for each SIEF, using the relevant information shared in the consortium. The SFF will act as a link between the participants of the (pre-) SIEF he represents and the consortium.

Further Information: about SIEF Formation Facilitators in the ECHA Guidance on Data Sharing (Section 4.5.2).

5. Agreeing on substance sameness / equivalence

The leading principle in the sameness discussions is whether the pre-registered substances have the same chemical identity to the extent that they may share the same hazard data to be submitted at registration. The chemical identity is based on the composition and / or manufacturing process of the substance and is represented by a chemical name (e.g. toluene). Other ways of representing the identity are for instance the CAS (Chemical Abstracts Service) name and number, the EINECS (European Inventory of Existing Commercial chemical Substances) name and number or the No Longer Polymer name or number. To establish the identity, but also to be able to participate to the pre-SIEF and SIEF discussions, the composition of the substance should in principle be known by the potential registrants.

EINECS AS A STARTING POINT

The same substance is **initially** defined by the same identifier, i.e. same EINECS number equals same substance. The first step to take in the sameness discussion is the checking whether the EINECS entry (or other identifier used) is sufficiently defined to continue the process.

EINECS is an inventory of substances on the market between 1 January 1971 and 18 September 1981. It was published on 15 June 1990 and contains some inconsistencies. In certain cases, the description in EINECS for a substance can be broad to the extent that the physical-chemical and (eco) toxicological properties of the different substances covered by the entry are not sufficiently similar. This may particularly be the case for UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials). Other inconsistencies include substances for which there is more than one entry in EINECS. In those cases the pre-SIEF should be split or merged, which is done by decision of the pre-SIEF members.

ECHA will publish the pre-registration list and will bring the potential registrants of the same substance together in the pre-SIEF. This will be done based on the same EINECS number, the same CAS number or the same chemical name. ECHA is from this point onwards no longer involved into the SIEF activities until the final registration dossier is submitted. This means that industry has the full responsibility but also freedom for the establishment of the SIEFs.

When the EINECS entry sufficiently covers the substances, the next step in the sameness discussion can start. The principle is straightforward: the same name means the same substance.

CHECK THE RELEVANCY OF HAZARD DATA

In cases where hazard endpoint data are clearly not suitable, substances can be regarded as different (e.g. in case of very different physical properties, for example water solubility, which have essential impact on the hazard properties).

However, in most cases, substances will be regarded the same at this stage of the process. It then becomes relevant to have knowledge about the nature of impurities, which are known/expected to be hazardous. For example, a certain impurity will influence the classification of the substance (e.g. carcinogenic). It should be noted that in a case like this it could still be feasible to share the majority of data. **Registrants can agree to have more than one classification for their substance in the registration dossier, which they can submit jointly.**

In some cases a potential registrant may disagree with specific endpoint(s) or decide (or have to) completely opt-out of joint registration – see Article 11(3) of the REACH Regulation. How this opt-out and especially the disagreement with specific endpoints will work in REACH-IT, is not clear at this stage. During the data-sharing and evaluation process it is up to each participant individually to assess whether the selected data is relevant for his substance. When this is not the case the consequences should be discussed, e.g. higher registration fee and greater scrutiny of the dossier during evaluation.

Whilst potential registrants may opt out of joint submission for the reasons provided above, this does not negate his obligation to share data within the SIEF as set out in the REACH Regulation.

WHO SHOULD BE INVOLVED IN SAMENESS DISCUSSIONS?

Whilst the pre-SIEF may contain a number of different actors, see types of (pre-)SIEF members above, it is only the potential registrants and early registrants that are involved in the substance sameness discussions. The SFF may be required to clarify the roles of the members to facilitate this discussion.

HOW DO I PROTECT CONFIDENTIAL BUSINESS INFORMATION IN SUBSTANCE SAMENESS DISCUSSIONS?

CBI issues relating to substance sameness discussions can usually be divided into 3 categories:

1. No CBI concern

The issues below can be openly discussed in SIEF and may be in the public domain:

- EC (EINECS Number), CAS Number, CAS and IUPAC names etc
- Certain physicochemical data:

State of the substance (20°C and 101,3 kPa)
Melting / freezing point
Boiling point
Relative density
Vapour pressure
Surface tension
Water solubility
Partition coeffecient n-octanol / water
Flash-point
Flammability

- Results of studies, classification & labeling and outline of analytical methods used. Although these latter examples may not always be relevant to sameness assessments, in certain cases they will serve as useful tools.

2. Open discussion in SIEF but not for public access

- Precise chemical identity, especially where the substance name is broad and / or generic. This may be needed to ensure the substance in question is in the correct pre-SIEF, to facilitate splitting of a pre-SIEF into multiple SIEFs, or to consolidate multiple pre-SIEFs into one, or a reduced number of SIEFs.
- Physicochemical properties and robust summaries when the nature of impurities needs to be openly compared. However, it should not normally be necessary to divulge the exact substance composition and identity of impurities.

3.Company specific CBI

In most cases, potential registrants would not disclose:

- Full composition of the substance
- Chemical route of manufacture

- Purification processes
- Source of substance if the substance is imported
- Precise tonnages
- Down stream uses/users if considered CBI by the company

In circumstances of sensitivity when conducting sameness discussions, it is recommended to consider signing a confidentiality agreement and in case of high sensitivity, to appoint an independent third party.

DO I NEED TO SIGN A CONFIDENTIALITY AGREEMENT WHEN FORMING A SIEF?

Agreement on substance identity at the SIEF formation stage may in some cases require the exchange of detailed technical information on the composition of the substance, the raw materials used, the substance impurities, and possibly on the manufacturing process, since an impurity content can give an indication of the nature of the production process. This applies in particular for process-dependent impurities and for additives necessary to preserve the stability of the substance.

Given that agreeing on substance sameness 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 by one or more potential registrants, the SFF or designated lead registrant can propose a confidentiality agreement in order to safeguard confidentiality. Companies willing to protect CBI may take steps during the SIEF formation to protect the confidentiality by entering 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.

The basic elements of a confidentiality agreement are the definitions of:

- What is regarded as confidential information?
- Who is under an obligation to keep the information confidential?
- Who is considered as a third party?
- Who is entitled to access confidential information?
- How long information is protected?

Confidentiality agreements can foresee implementation measures, as for example by allowing access to certain documents in a “reading room” only, where copying is not allowed.

As REACH does not set any conditions in this respect, parties can agree in addition to have certain documents reviewed by a Third Party expert (independent consultant or industry association), who can handle the confidential information on behalf of Potential Registrants. Consequently, no one from the other SIEF members will see such documents.

6. SIEFreach for efficient SIEF communications

WHAT IS SIEFREACH ? WHAT IS REACHLINK ?

Cefic took the initiative last year to develop a common IT platform to support the processing of SIEFs across industry. The system, named 'SIEFreach' at www.siefreach.com , is currently being built and will be operational early July 2008, in order to be available for Pre-SIEF tasks (e.g. sameness discussions) to be carried out by companies that have submitted Pre-Registration data to the ECHA REACH-IT system.

ReachLink SA www.reachlink.be is the company that has been launched by Cefic and 5 National Federations (VCI – Germany, CIA – UK, UIC - France, Federchimica – Italy and FEIQUE – Spain) in which they are the shareholders. The company will provide IT services to make use of the tool against a fee. REACHLink SA is the owner of the SIEFreach system and will manage the ongoing enhancement of the system during the 10 years of its lifetime.

WHAT ARE THE BASIC CONCEPTS OF THE SIEFREACH SYSTEM?

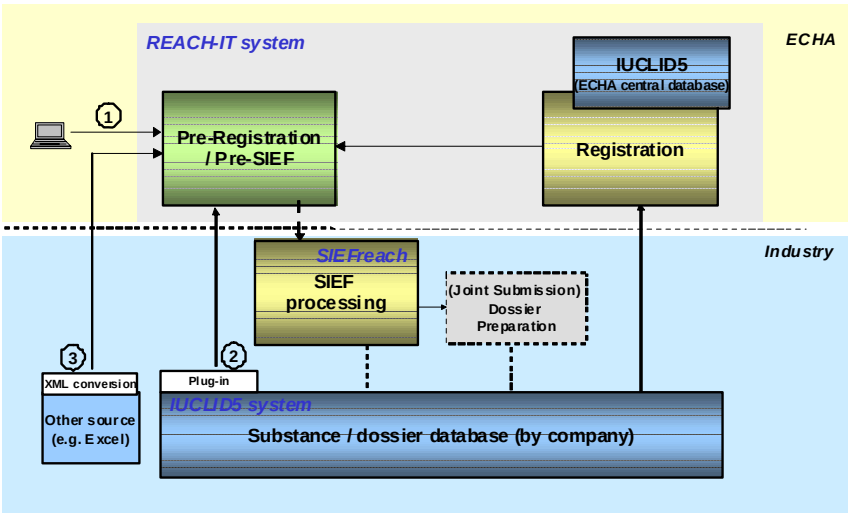
The SIEFreach system is a tool to facilitate data sharing within SIEF from immediately following pre-registration up to submission of a joint registration dossier. It is a totally separate platform to the REACH-IT system of the ECHA that is used for pre-registration and registration. Pre-registration data can be transferred from the REACH-IT system to the SIEFreach system to provide the identical (pre-) SIEF structure available to pre-registrants as in the REACH-IT system. SIEFreach provides a secure platform for the sharing of data within and between discrete (pre-) SIEFs.

WHICH IT SYSTEMS ARE RELEVANT FOR PRE-REGISTRATION / SIEF PROCESSING?

Figure 3 below shows the main systems supporting the Pre-Registration and Registration process:

- REACH-IT system, operational at ECHA, supporting Pre-Registration and Registration process
- SIEFreach system, central platform for industry to support Pre-SIEF / SIEF processing
- IUCLID5 system, operational at companies to maintain Substance data and prepare dossiers.

IT Systems supporting Pre-Registration / SIEF / Registration processes



IMPORT PRE-SIEF DATA INTO SIEFREACH SYSTEM

The ECHA Pre-SIEF data is the basis for the SIEFreach system. Data is transferred in a 2-step action:

1) Transfer of Pre-SIEF data for one substance is triggered by one of the Pre-SIEF participants. The transfer includes data of all actors shown at the Pre-SIEF web page, and
2) Store the data in the SIEFreach system. Since synchronization will not be done automatically, refresh of the data has to be done by repeating the transfer process at regular intervals. This can be done by any of the Pre-SIEF participants.

SET UP OF COMPANY AND USER ACCOUNTS

The SIEFreach system requires legal entities to be defined, as well as User Accounts to be created, in order to allocate users to one or multiple SIEFs. Legal entities may be grouped into one or more legal entity groups, providing flexibility for companies to manage the administration of SIEFs. A Legal Entity Group Administrator (LEGA) is the coordinator who will take care of legal entity and user creation / activation, as well as the payment of the fees to use the SIEFreach system.

USER ROLES AND SECURITY

The access and update of SIEF data is dependent on the role a user has been assigned to. In a SIEF following roles can be distinguished:

- SIEF Formation Facilitator
- Lead Registrant
- Legal Entity User
- Invited Expert
- Data Holder

FREE ACCESS ZONE IN SIEFREACH

As soon as pre-SIEF data of companies have been transferred from the ECHA REACH-IT system into the SIEFreach system, activated users have access to these pre-SIEF data, and will be able to view the same display as presented at the REACH-IT system. In addition, study data may be made available by potential registrants and data holders in the free-access zone.

As soon as data is posted in a SIEF, a SIEFreach participation fee has to be paid, either by credit card or by purchase order / invoice procedure.

COLLABORATION IN (PRE-) SIEF

From the start of pre-SIEF, the use of the collaboration tools in the SIEFreach system will be of great help to support the substance sameness discussions in order to determine whether companies belong to the same SIEF. Folders are available to enter data and facilitate discussion for sharing of opinions and decisions throughout the life of the SIEF. Available folders include

- Substance Sameness
- Classification & Labelling
- Data Sharing in accordance with Article 30 of the REACH Regulation
- Data Availability
- Cost Sharing

Collaboration on the various folders will continue until complete data will be available to prepare the Joint Submission.

WHAT ARE THE BENEFITS OF USING THE REACHLINK SIEFREACH SYSTEM?

Using an industry wide platform with a pre-defined structure and process guidelines assures consistency and transparency for all SIEF participants. In addition, tracking of SIEF discussions and decisions in a single central system across the SIEF lifetime (11 years) will be of great value to companies. Customised roles and secure processing for both individual companies and consortia members will help meet the data-sharing needs of all actors.

WHAT AM I PAYING FOR?

A one-time fee has to be paid for participation in SIEFreach. The fee is dependent on the role in the SIEF, i.e. a legal entity user pays more than an invited expert and a data holder. Payment will result in becoming an active SIEFreach participant, by which the role responsibilities can be fulfilled. Acting as a SFF or LR does not require additional payment above the normal legal entity user role. The base one-time fee for one legal entity user is 300€ per SIEF.

WHAT ARE THE BENEFITS FOR A SME AND A DATA HOLDER IN USING SIEFREACH?

Working with other companies in SIEFreach will enable storage of data about the substance at a central place and at the same time allows a 'one-stop-shop' for communicating and discussing with other SIEF participants. Even for a SME company, SIEFreach offers a much more efficient and effective communication tool than the alternative of for example email.
A data holder will be able to offer study data to other SIEF participants, who may be interested to use the data in a joint submission. If that is the case, the other SIEF participants will compensate the data holder for the use of the data for registration.

WHAT ARE THE BENEFITS FOR A MEMBER OF A CONSORTIUM IN USING SIEFREACH ?

Although consortia members usually have discussed and agreed on a lot of topics about substances inside the consortium, each member has the obligation to participate in a SIEF for data sharing purposes, after having submitted pre-registration data to ECHA. Consortia will find ways to be efficient and be represented in the SIEF by one of their members or a TPR; however, they have to assure that no issues will arise on data ownership and cost sharing with regard to studies. It should be noted that in the event that voting takes place using the SIEFreach system, each SIEFreach user would have one vote.

7. EC Competition Law Compliance

As described in the previous Cefic guidance companies have to ensure that all activities under REACH comply with competition law; this also applies to SIEF formation. Therefore, the following is recommended:

✓ **DO** ensure, that the issue of sameness and identity check are handled by applying objective and transparent criteria when discussing the SIEF's formation.

✓ **DO** ensure that, before any discussion on the issue of sameness starts with other undertakings, each undertaking individually identifies its own substance(s) and documents its reasons for this approach.

✓ **DO** ensure that any deviation from this approach, following discussions with other undertakings, is clearly and objectively justified and documented.

✓ **DO** ensure that the final decision on sameness is clearly and objectively justified and those reasons documented.

Particular care should also be brought to the exchange of information:

✓**DO** limit your exchanges of information to what is strictly necessary under REACH, and in this case to sameness.

✓**DO** reduce the frequency of exchanges.

✓**DO** exchange tonnage bands instead of individual more specific volume information. If not feasible, and specific volume information or other sensitive data needs to be communicated, use precautionary measures, e.g. organise such exchange via an independent third party or trustee.

✘ **DO NOT** misuse the process of substance sameness discussions to unduly exclude certain competitors.

✘ **DO NOT** exchange non-public sensitive information such as (non exhaustive list):

- Individual company prices, price changes, terms of sale, industry pricing policies, price levels, price differentials, price mark-ups, credit terms etc;
- Costs of production or distribution etc;
- Individual company figures on sources of supply, costs, production, inventories, sales, etc;
- Information as to future plans of individual companies concerning technology, investments, design, production, capacity, distribution or marketing of particular products including proposed territories or customers;
- Matters relating to individual suppliers or customers, particularly in respect of any action that might have the effect of excluding them from the markets.

✘ **DO NOT** exchange technical information if this exchange is not necessary under REACH, especially if this exchange of technical information may provide competitors with the ability to align their market behaviour.

More information can be found in Cefic REACH competition law compliance guidance in the Cefic Pre-registration Guidance.

8. Definitions & 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:

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

Note, data holders that have not notified the ECHA of their intention to share data, may be available outside the SIEF.

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

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