Preparation for Pre-registration

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Preparation for Pre-registration

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.

As an informative tool, this paper aims to assist companies with the application of RIP 3.4. Responsibility for REACH compliance remains with a company; the authors of this paper assume no liability whatsoever for the contents or use of this document.

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.

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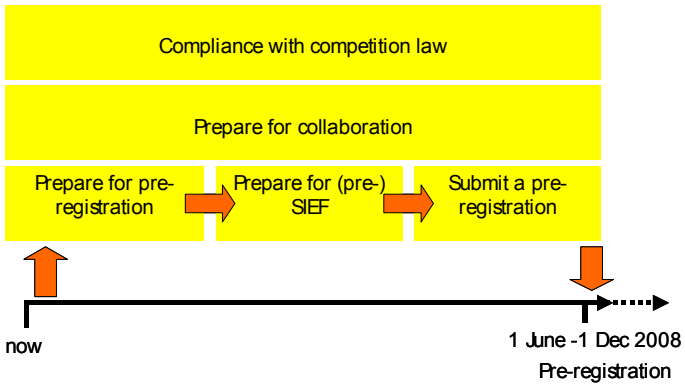
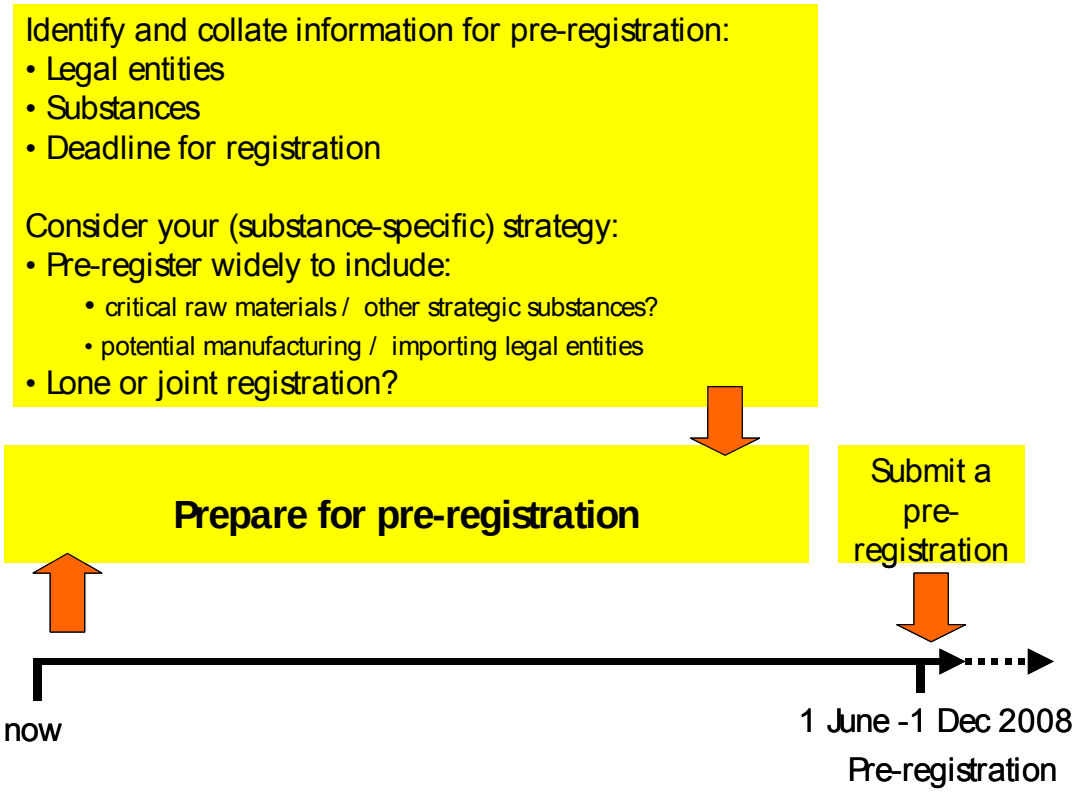


1. Preparation for pre-registration



WHAT IS PRE-REGISTRATION AND WHY IS IT IMPORTANT?

Pre-registration is the means by which potential registrants including European Economic Area (EEA) manufacturers and importers of phase-in substances above 1 tonne per year[1], inform the European Chemicals Agency (ECHA) of their intent to register. Pre-registration via the ECHA's REACH IT system is without a fee and will be of benefit to potential registrants in the following ways:

- Benefit from extended timelines in which potential registrants can prepare for and submit their registration dossiers without interruption of manufacturing or importing. This provides additional time to organise the collection, sharing and assessment of available data and the collective generation of missing information

- Receipt of information regarding all other pre-registrants of the substance to enable them to start the process of verifying substance sameness and form a Substance Information Exchange Forum (SIEF). The purpose of this forum is to share data, thereby avoiding duplication of studies in particular vertebrate animal testing, to submit testing proposals for more advanced tests, to agree on classification and labeling and to work together towards registration

Pre-registration, which takes place in the six-month period from 1st June 2008 to 1st December 2008 inclusive, is not a legal requirement under REACH. However, the manufacture and importation of phase-in substance without pre-registration or without immediate registration is in breach of the REACH regulation.

It is not mandatory to register following pre-registration, if for example, the manufacture or importation is stopped prior to the registration deadline.

Further Information: See "What happens if I do not Pre-register?"

[1] For phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years

WHAT ARE THE PRACTICAL IMPLICATIONS OF PRE-REGISTRATION?

The result of pre-registration is to place automatically the pre-registrant into a virtual group of pre-registrants of the same EINECS number or other same identifier, called a pre-SIEF. Potential registrants in the pre-SIEF shall work together; lead by the SIEF facilitator (if available), to understand whether they intend to register the same substance. Once this has been agreed a SIEF is formed and its members will decide upon the substance classification and labeling and share data required for registration.

Within both pre-SIEF and SIEF, potential registrants and data-holders are obliged to respond to relevant questions from other potential registrants. Data Holders, however, are not entitled to request data. In pre-SIEF the relevant questions are regarding substance identity. Questions on substance physical chemical properties, toxicology, eco-toxicology and classification might be relevant only in the SIEF when the potential registrants have decided on substance identity. The successful progress of potential registrants through these initial stages will require a pragmatic focus on the end point of registration.

According to the REACH Regulation, the SIEF will exist until 1 June 2018 and companies may need to actively participate in the SIEF activities. ECHA will decide on any remaining testing proposals until 1 June 2022.

Further Information: See "Preparation for pre-SIEF.

Information on other pre-SIEF members will be listed in a closed ECHA webpage to which you will have automatic access following pre-registration. This webpage can be seen by:

- Potential registrants of that substance;
- Potential registrants of the substance(s) listed at pre-registration as candidate(s) for read across;
- ECHA and national authorities.

This webpage will be updated every time a new potential registrant pre-registers the same substance and all members of the pre-SIEF will receive a message indicating the webpage updates unless they deactivated this option at pre-registration.

The ECHA will separately publish the following information on its open website by January 1st 2009:

- Names of all pre-registered substances including Chemical Abstracts Service (CAS) numbers, European Inventory of Existing Commercial Chemical Substances (EINECS) numbers and other identity codes
- The first envisaged registration deadlines
- Substances intended to be used for read-across approach, Qualitative or Quantitative structure-activity relationship (QSAR) and grouping.

Pre-registrant company names will not be published on this open website.

WHAT SUBSTANCES CAN BE PRE-REGISTERED?

Only phase-in substances that meet any of the following criteria can be pre-registered:

- Listed in EINECS;
- Manufactured in the EU (not necessarily exceeding the amount of 1 tonne per year), but not placed on the market in the EU by the pre-registrant in the 15 years before 1st June 2007 (e.g. intermediates, R&D substances)
- "No-Longer Polymers (NLP)" and placed on the market before entry into force of REACH (1st June 2007).

All other substances are non-phase-in substances and cannot be pre-registered and shall be registered directly. All chemical substances that have been previously notified in the EU under the Directive 67/548/EC are considered as being registered under REACH according to the original tonnage band they were registered for. A registration number will be assigned to the notification of these substances by December 1st 2008. Therefore pre-registration is not applicable for the legal entities which have notified these substances. This is summarised in Figure 1 (below).

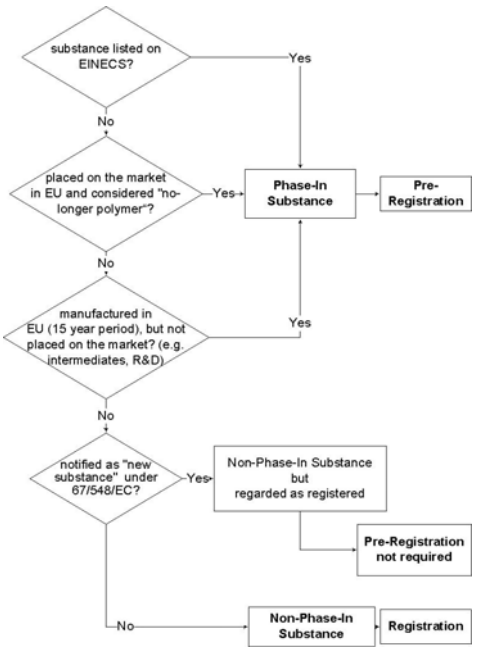


Figure 1. Decision tree for pre-registration for phase in substances

A company's inventory of substances to be pre-registered should contain all substances (except those exempted, see below) that it wants to continue manufacturing/importing in amounts > 1 tonne per year. It may also contain strategically/critically-determined substances at the discretion of the company.

Further Information: See "What do I need to consider before I pre-register?"

It is strongly recommended to pre-register at least your currently manufactured or imported phase-in substances above 1 tonne per year in order to avoid possible compliance issues.

You need not pre-register substances that you source from EU suppliers, because the EU manufacturer or importer shall register them to continue manufacture / import, (no data no market). To ensure continuity of supply, it is advised to seek confirmation from the EU supplier that they will (pre-) register their substances.

Pre-registration, and indeed registration, is for substances only and not for preparations (blends or mixtures) or articles. The component phase-in substances of a preparation imported above 1 tonne per year need to be pre-registered to benefit from the extended deadlines. The same applies to substances that are intended to be released from articles.

Further Information: For the (pre-) registration and notification obligation of substances in articles, see Article 7 of the REACH Regulation or ECHA's Guidance on requirements for substances in articles (to be published).

Substances that are exempted from registration need not be pre-registered. However, it is advised to consider substances below 1 tonne per year per legal entity depending on manufacture/ importation volume forecasts.

Consult Articles 2 and 9 and Annex IV and V of the REACH Regulation for the complete list of substances exempted from registration (Annexes subject to revision).

The list presented below is not exhaustive list, but provides some examples of exemptions:

- All substances manufactured or imported below 1 tonne per year (note that registration may be exempted, but classification and labeling obligations still apply);
- Polymers (note that polymerised monomers ≥2 wt.% **and** above 1 tonne per year and any other used substances chemically bound to polymers should be registered – refer to the ECHA's Guidance for monomers and polymers);
- Any additive to preserve the stability of the substance are part of the substance and need not be (pre-) registered separately unless they are manufactured separately in quantities > 1 t/a;
- Impurities are part of the substance and need not be (pre-) registered separately
- Waste as defined in Directive 2006/12/EC;
- Substances mentioned in Annex IV (subject to review) of the REACH regulation;
- Substance exempted from the obligation to register according to Annex V (subject to review) of the REACH regulation.

WHO CAN PRE-REGISTER?

Any potential registrant can pre-register a phase in substance. A potential registrant can be represented by a natural or legal person within the EU: an EU Manufacturer, EU Importer, only representative (OR), an EU importer or producer of articles that contain substances that are intentionally released, or any natural or legal EU entity which intends to manufacture and / or import a substance, produce and / or import articles that contain substances that are intentionally released or to become an OR.

If you are a legal entity inside the EEA that would like to continue import of substances from outside the EEA, you are required to register. Import is the physical introduction of substance into the custom territory of the European Community. The obligation to register, and therefore entitlement to pre-register lies with the EU-based legal entity that is **responsible** for the import of substance into the European Community. There is no direct link or interdependence between the transfer of ownership, cost, freight/transport, insurance and customs duty (INCOTERMS) and the role in REACH of an importer.

However, an EU-based importer of substances into the EU may not need to (pre-) register (but is not precluded from doing so) if one or both of the following applies:

- The non-EU supplier has appointed an OR to take on the REACH registration and other REACH-related obligations of the EU importer(s). In this case the importer is considered a Downstream User under REACH and does not need to (pre-) register. If the importer does not wish to become a Downstream User, he will have to do his own pre-registration and registration for his imports.

- The same substances are registered by an EU manufacturer, subsequently exported outside the EU and re-imported into the EU by the same actor or by an actor of the same supply chain and information in accordance with Art. 31 and Art. 32 related to the exported substance has been supplied.

Role of the Only Representative (OR)
Manufacturers and importers of substances outside the EU (eg. Switzerland) cannot (pre-) register. Legal entities based outside the EU who export substances to the EU also cannot (pre-) register themselves, however those which are manufacturers, formulators or article producers (but not distributors) may chose to appoint an OR legal entity based in the EU to take on the REACH obligations of EU importers. An OR is a natural or legal person located in the EU territory having sufficient knowledge and expertise on the substances (e.g. handling).

When a non-EU supplier appoints an OR he should inform his customers in writing. As a result of this, his customers are regarded as Downstream Users under REACH and therefore do not have to (pre) - register that given substance, but have still the obligations of a Downstream User. The OR shall keep information available and up-to-date on quantities

imported and EU customers, together with information on the supply of the latest update of the safety data sheet.

The recommended approach is to ask your non-EU supplier(s) what his REACH intentions will be for the substance you import. If the non-EU supplier has appointed an OR and you do not intend to register as an importer it is mandatory to obtain a written statement from the non-EU supplier. A template questionnaire for this communication is provided on the Cefic website. It is also advisable to obtain information regarding whether an OR has been appointed and has pre-registered well before the end of the pre-registration period (1st December 2008). If no OR has been appointed, or the OR has not pre-registered, you are required to register and would therefore need time to pre-register before December 1 2008. Alternatively you may register your substance immediately taking into account possible interruption of import activities.

It is recommended to ask your non-EU supplier what his REACH intentions will be for the substance you import.

In case your EU suppliers indicate that they will not (pre)-register their substance(s), an alternative supplier or alternative substances may be sought. A Downstream User may chose to pre-register and therefore become a potential registrant, if for example there is no indication that his suppliers will (pre-) register and no other alternatives exist. Article 28 (5) of the REACH regulation indicates that the ECHA may on request support the Downstream Users efforts to find a supplier.

WHAT INFORMATION IS TO BE SUBMITTED IN PRE-REGISTRATION?

The legal requirements for pre-registration are provided in Article 28 and Annex VI Part 2 of the REACH Regulation. The following provides further guidance on the information to be submitted:

- **The name of the substance**:
    - **Name(s) in IUPAC** (International Union of Pure and Applied Chemistry) nomenclature or other international chemical name(s)
    - **EINECS number** (This, together with the name is the most important identifier for pre-registration. Other identifiers such as CAS number and name or the chemical name should be used, if EINECS number is not available);
    - **CAS name and CAS number** (if available) If several CAS numbers for the same substance apply, they may be added as read across substances or as separate pre-registrations;
    - Other names (usual name, trade name, abbreviation or formula);
- **The name and address of the potential registrant** (the legal entity) including name of contact person at legal entity level (email address mandatory). It is recommended to use a functional email box, e.g. REACHlegalentity@companyX.com;
- **The name of the contact person for the SIEF at substance level**. It is recommended to use a functional email box, e.g. REACHsubstance@companyX.com The two contact details above may be different.

It is recommended to provide functional email addresses for the legal entity and substance contact details.

- **The name and address of the Third Party Representative** (TPR) where appropriate. Any manufacturer or importer may appoint a TPR in the (pre-) registration process. Pre-registration using a TPR may be considered if confidentiality is important to you. This is typically the case when a company wishes not to disclose their interest in a particular substance as this may give indications to competitors about production or confidential business information. A registrant nominating a TPR retains full legal responsibility for complying with its obligations

under REACH. The TPR will need to sign up as a legal entity object in REACH IT prior to pre-registration.

Further Information: See How to submit your pre-registration, below.

- **The envisaged registration deadline** for the tonnage band, see Table 1. The manufactured or imported quantities per year may be projected on the basis of the average volumes for the three calendar years preceding registration.

Phase-in substance classification / volumes[2]	Deadline for registration
CMR 1, 2[3] (≥ 1 tonne per year) R50/53[4] (≥ 100 tonnes per year) ≥ 1 000 tonnes per year	30 November 2010
≥ 100 tonnes per year	31 May, 2013
≥ 1 tonne per year	31 May, 2018

Table 1: Registration deadlines according to volume and classification

- Indicate **similar substance(s) which you intend to use for read-across** approach or Qualitative or Quantitative structure-activity relationship (Q)SAR (optional).

  Read across or grouping is the generation of information on intrinsic properties of substances by information from structurally related substances. (Q)SAR may indicate the presence or absence of certain substance properties. Results of (Q)SARs may be used instead of testing when certain conditions are met. Indicating read-across or (Q)SAR in pre-registration, links the pages of the pre-registered substance and the read-across substance in REACH IT. This will directly give pre-registrants mutual access to their contact details.

  Companies should be aware that contact details indicated at pre-registration will be made available to all potential registrants of the substance(s) pre-registered under the same identity as well as to potential registrants of all other substances for which read-across possibilities have been indicated. This opens up a wider virtual population of potential registrants to discuss data, which will not enhance the efficiency of setting up SIEF in the early stages following pre-registration.

  As it will not be known at pre-registration time if missing data will become available in the SIEF, the proper time for finding read-across candidates is when data gaps become known during the data-sharing process. At that time it will also be known if read-across candidates have been (pre) - registered and thus are available for reading across. This read-across entry can be modified after SIEF have been established.

- Indicate **whether you wish to be a SIEF formation facilitator** (optional). During the pre-SIEF period the SIEF facilitator will act as coordinator; initiate and conduct discussions. Depending on the time it will take for the facilitator to be succeeded by the lead registrant, he can also facilitate the exchange of the information and data required within the SIEF including agreement on classification and labeling.
  The role of the SIEF facilitator is entirely voluntary. The role is not legally binding and there are no obligations, nor liability for actions under REACH. However, there might be a liability according to civil law, e.g. if the facilitator does not fulfil contractual obligations. Potential SIEF facilitators may decide to terminate the role at any time without penalty. The SIEF facilitator is not automatically the lead-registrant, but this is possible.

[2] For phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;
[3] Classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC
[4] Classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC

The effort necessary for the SIEF facilitator to co-ordinate the progress should not be underestimated. SIEF participants may consider compensating the SIEF facilitator financially for his services.

Further Information: on SIEF Facilitation, see section 4.5.2 of ECHA Guidance on data sharing

- Indicate the **wish to receive REACH-IT updates of the pre-SIEF** (optional). Selecting this option means that you will receive an email message every time another pre-registrant pre-registers the same substance If you do not want to receive these messages, do not activate this option. Access to the REACH-IT web page to check the latest information is continuously available following pre-registration, regardless of whether this option is selected.

Further Information: The final format for the submission of the pre-registration data is described in "How to submit a pre-registration".

A substance can only be pre-registered once for each legal entity that manufactures or imports that substance. Pre-registration does not require information on the details of substance composition, the use of the substance or whether the substance is an intermediate.

WHAT HAPPENS IF I DO NOT PRE-REGISTER?

If you intend to continue to manufacture or import phase-in substances in quantities over 1 tonne per year after 1st June 2008 and fail to pre-register within the time period 1st June 2008 to 1st December 2008, to be compliant with the REACH regulation, you must either:

- Submit a registration immediately to ECHA after the inquiry process, or
- Immediately stop manufacture and /or import, or
- Restrict manufacture and /or import to amounts below 1 tonne per year.

First time (since entry into force of REACH on 1st June 2007) manufacturers and importers of phase-in substances exceeding 1 tonne per year after 1st December 2008 (the closure of pre-registration) can still submit a pre-registration to the ECHA after closure of the pre-registration period. This is on the condition that the pre-registration takes place within 6 months of first manufacture/import and providing the date of pre-registration is at least 12 months before the relevant registration deadline.

This also applies in the following cases:

- Article producers which use a phase-in substance intended to be released for the first time exceeding 1 tonne per year after 1st December 2008
- Importers of an article containing a phase-in substance intended to be released (which needs to be registered) for the first time after 1st December 2008

A late pre-registration cannot be submitted less than 12 months prior to the relevant registration deadline. In this case, a direct registration should be submitted to the ECHA.

Examples:

- Manufacture and/or import of a > 1000 tonne per year substance for the first time on February 1 2009 requires pre-registration before August 1 2009 and registration before December 1 2010
- Manufacture and/or import of a > 1000 tonne per year substance for the first time on February 1 2010 cannot be pre-registered and an inquiry should be submitted to the ECHA.

Manufacture and / or importation without pre-registration in the period 1st June 2008 to 1st December 2008 or without direct registration is in breach of the REACH regulation and may be liable to fines back-dated to 1st June 2008 or the first day of manufacture/import after this date.

Marketing products after 1st December 2008 containing phase-in substances without pre-registration or registration is in breach of the REACH regulation and may be liable to fines backdated to 1st June 2008. Substances delivered before 1st June 2008 to Downstream users

may be still marketed after 1st December 2008 on the condition that it can be proven on the basis of documentary evidence.

WHAT DO I NEED TO CONSIDER BEFORE I PRE-REGISTER?

To determine a pre-registration strategy for your company, the following questions should be considered:

- **What is the role of your company with regard to the substance (Manufacturer, Importer, Downstream User)?**

- **What is the legal structure of the company and which legal entity in which country registers what substance?**

  The legal entity that is responsible for the manufacture or import.

- **Which substances in my portfolio should be pre-registered? The current portfolio or also the future portfolio?**

  This fully depends on your current business policy for portfolio growth and the degree to which future scenarios are detailed for each individual company or legal entity.

  - Are my substances of unknown or variable composition, complex reaction products, or biological materials (UVCB's)?

    It is recommended to consider the ECHA's Guidance for identification and naming of substances under REACH.

  - In the case of imported polymers, preparations (e.g. master batches), multi constituent substances, or UVCB's, do you have sufficient information on the substances used for the (pre-) registration process?

    If you import substances with an unknown composition, you need to obtain detailed information about which substances in what quantities are used. Be aware that this information is the intellectual property of your supplier and that he will be very reluctant to reveal it to you. If your non-EU supplier does not provide this information, seek confirmation that the supplier will appoint an Only Representative.

    In the case of imported polymers and master batches you are not only obliged to pre-register the monomers or other substance chemically bound in the polymer chain (if the conditions according to Article 6.3 of the REACH regulation are met), but also all other used substances like additives, colourants etc, with the exception of stabilizers.

  - What are your strategic and critical substances in your process/portfolio?

    Strategic substances are the key substances in your portfolio. Critical substances are those substances used in your process which are indispensable and for which no direct alternative suppliers exist. An example of a critical substance is a catalyst, but it also could be a special heating transfer agent for your reactor.

- **Do you submit a joint registration or opt out to submit an individual registration?**

  Check whether the opt-out conditions for joint registration in Articles 11 (3) / 19 (2) of the REACH regulation apply. This depends on your business strategy. Individual registrations are possible, but will subject to the evaluation process from ECHA. An individual registration will have a higher registration fee than a joint submission. Note that once you have registered you will remain a SIEF member (as data-holder) for that substance.

- **How "data rich" are you?**

  Make an inventory of all required data available within your company and in the public

domain that are not copyright protected. Data requirements depend on the manufactured or imported volumes (see Annex VI-X of the REACH regulation).

The data owner has to be in possession of the full study report or have a legal permission to refer to the full study report.

- **For which substances can you use read-across and what substances can be categorized? (optional)**

  This fully depends on the nature of your substance. The following substance parameters should be considered: chain length, functional groups, metabolic pathways, isomers and their mixtures, metal and metal compounds. For detailed information feel free to consult the OECD guidance on grouping of chemicals or when available the ECHA Guidance on information requirements and chemicals safety assessment.

After considering the answers to the above questions, one of the following scenarios (or a combination of them) can be used, depending on your business situation and your company strategy.

- **The minimum scenario**
  - Pre-register your current portfolio of manufactured/imported substances above one tonne per year per legal entity
  - Pre-register your imported raw materials that will not be otherwise pre-registered. Rely first on information from your supplier and his confirmation to (pre)-register his substances through an only representative
  - Focus on the current number of legal entities within your company responsible for registration

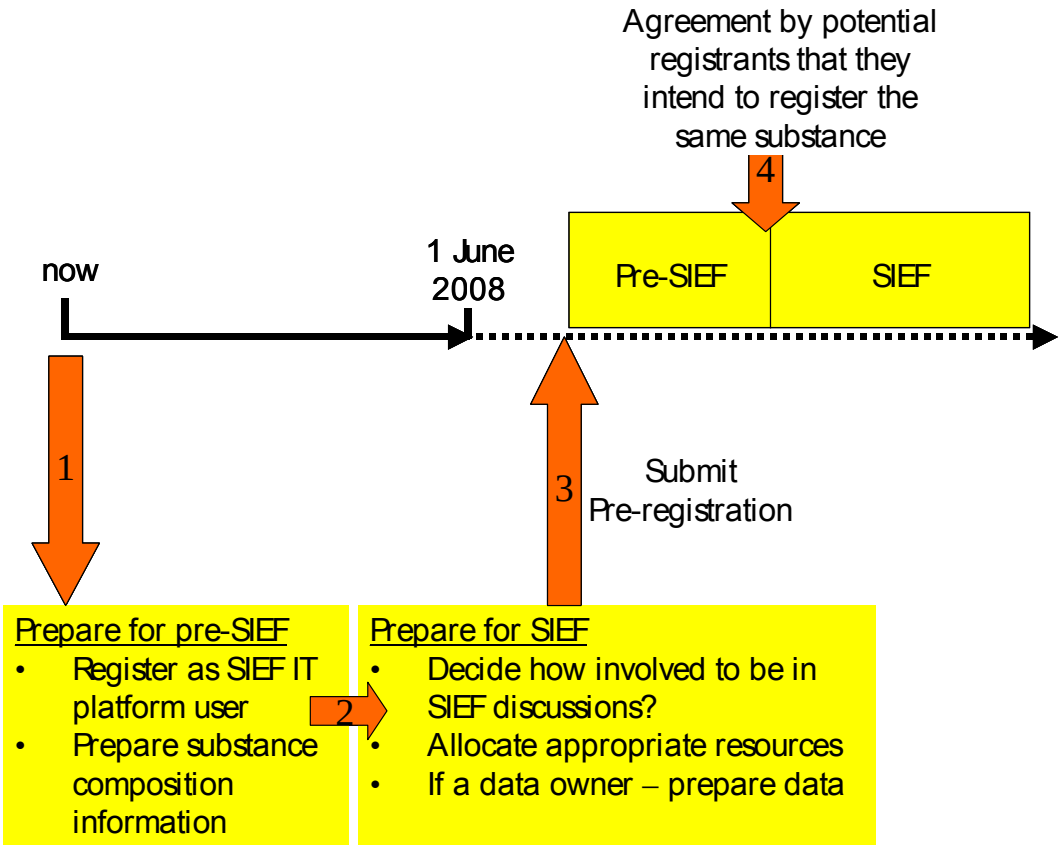
- **The maximum scenario "Keep every option open"**
  - Pre-register your current portfolio of manufactured/imported substances, plus all possible substances with possible future business relevance, plus all R&D substances
  - Pre-register all raw materials directly linked to your production processes independent of supplier's registration intention
  - Pre-register for many / all legal entities
  - Be appointed as an OR to support a global business

- **The optimized scenario "The case by case approach "**
  - Make a cost-benefit analysis for all products with respect to REACH.
  - Ensure pre-registration of strategically important products
  - Pre-register the relevant substances for the relevant sites and determine which legal entities are affected.
  - Consider raw material availability in short term/long term

2. Preparation for (pre-) SIEF

As a result of pre-registration, access is provided by the ECHA to a closed substance related web page on the REACH IT system. This dedicated web page contains information regarding all pre-registrants that have pre-registered the same substance or have provided similar substance identity information. The contact details of data-holders who have not pre-registered, but have informed the ECHA that they have relevant data, will also be displayed.

The initial task of the group of pre-registrants is to agree that they intend to register the same substance, based on assessment of the full substance identity information. This exchange of this information within the group of pre-registrants and the decision to form a SIEF will be lead by a SIEF facilitator if available. ECHA will not participate in the discussions between Potential Registrants and there will be no role for ECHA in confirming or rejecting the creation of a particular SIEF.



Preparation for pre-SIEF

- Register as SIEF IT platform user

  Whilst the pre-SIEF webpage of the REACH IT system provides contact details of the other pre-registrants of similar substances, it is not a suitable tool for sharing information. It is therefore recommended to subscribe to the REACHLink SA online SIEF IT platform for SIEF communications.

  Further Information: Cefic will provide further information about the SIEF IT platform before the start of pre-registration.

- Prepare substance composition information

  Substance composition information will be an important part of the pre-SIEF discussions to assess whether pre-registrants intend to register the same or different substances (i.e. form one or more SIEFs). Classified constituents of a

substance above 0.1% should be noted as these may modify the classification requirements. This information is generally available from a company's internal analytical database. Care must be taken not to disclose any confidential information during the exchange of composition information, for example proprietary knowledge concerning processing.

Preparation for SIEF

- Decide how to be involved in SIEF discussions

  The level you would like to be involved in the discussions of the SIEF is related to your obligations if you are an owner of data, your company strategy with regard to the substance and your resource availability. Your (pre-) SIEF activity level may range from inactive (e.g. decision to discontinue manufacture and or importation in EEA), through to full engagement with other companies, leading discussions and decision making of the SIEF facilitator, see graph below.

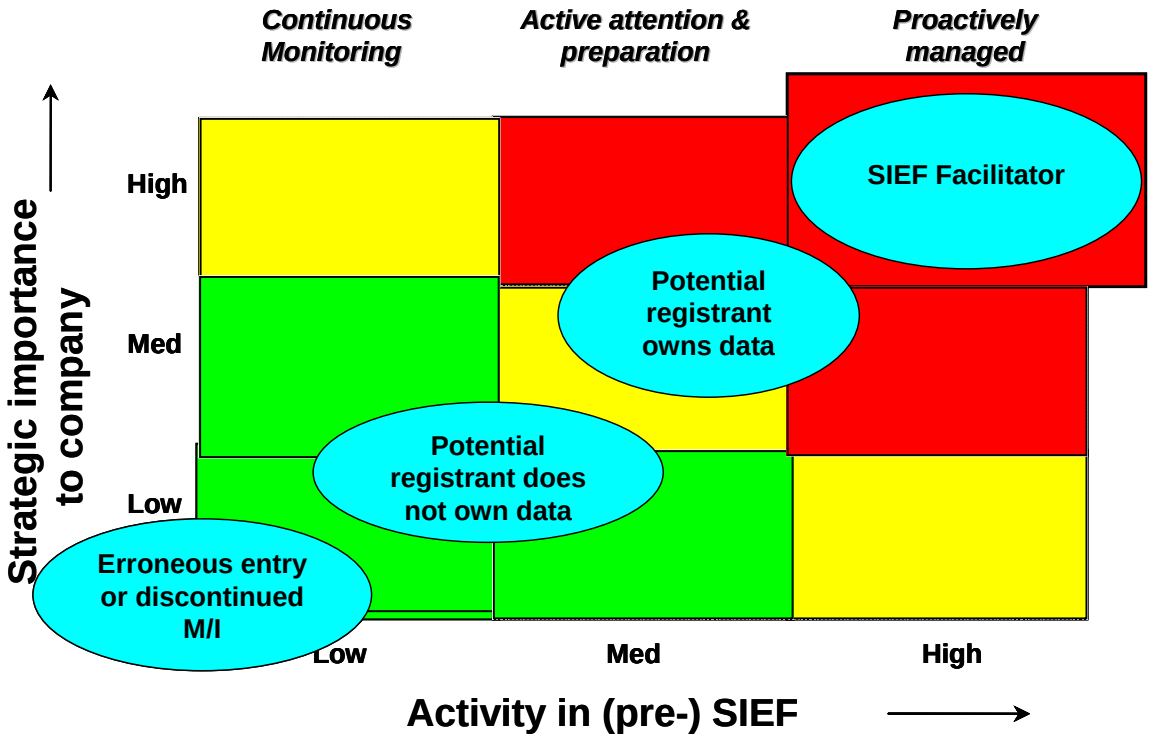


Figure 2: Anticipated activity within a SIEF as a function of strategic importance of the substance

- Allocate appropriate resources

  - The appropriate resource allocation for pre-SIEF activities will depend on the degree of anticipated involvement (see above). However, it is recommended that **all** (pre-) SIEF participants familiarize themselves with EC competition law using the Cefic REACH Dos and Don'ts Guidance and the confidential business information of their company before active participation in (pre-) SIEF

  - Whilst a single person, such as a product steward, HSE manager, product or business manager may be adequate to support low level activity of a company in a pre-SIEF, it may be necessary to allocate a multi-disciplinary team lead by a project manager to engage fully in the breadth of (pre)-SIEF discussions. Such a team could consist of:
    - Process chemist for discussions regarding substance identity
    - (Eco)-toxicologist for assessment of hazard data
    - Lawyer for review and approval of contracts
    - Business manager for discussions regarding costs / resources

- Project managers with ability to communicate and motivate across broad external networks may be well suited to the role of SIEF Facilitator.

- Data owners should consider the following in their preparations:

  A data owner needs to be in legitimate possession of or have permission to refer to the full study report. The data owner should provide the full study report or full study summary for evaluation upon request within the SIEF.

HOW CAN DATA QUALITY BE ESTABLISHED?

In principle, scientific quality of available data can be determined by checking three aspects of the available data:

- Adequacy - the usefulness of the existing information for hazard/risk assessment purposes?

- Reliability - studies with reliability ratings 1 or 2 are scientifically reliable and possess an economic value. Studies with a reliability rating 3 might also have an economic value if no other study on that endpoint is available

- Relevance - the extent to which the available data are appropriate for a particular hazard identification or risk characterization.

These terms are defined by Klimisch HJ, Andreae E and Tillman U (1997) in A systematic approach for evaluating the quality of experimental and ecotoxicological data. Reg.Tox. and Pharm. 25:1-5.

If the data owners have already information on the Klimisch rating available this would facilitate the data valuation process.

Further Information on data quality and Klimisch rating is available in Chapter 7 of the ECHA Guidance on data sharing.

HOW CAN COST OF DATA BE EVALUATED?

As a prerequisite the scientific quality of the available data has to be assessed before negotiation on financial value of the existing data can be discussed and agreed upon within the SIEF.

In principle, there are two methods for data valuation: Historic costs or replacement costs. When historic costs are used, SIEF members 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 prices charged by two or three testing institutes according to their price list or based on study design protocols provided to them.

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

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, regional restrictions, etc) of the value of a study, might be addressed by the SIEF Members.

Again, preparation by data owners of the reasons why the study value is higher or lower may facilitate the data evaluation process.

HOW IS DATA TO BE SUMMARIZED?

IUCLID 5 offers harmonised data templates for reporting each test result on chemical properties and effects on human health and the environment. Following SIEF evaluation of study summaries, a key study - which most suitably describes the endpoint from the perspective of quality, completeness and representativity - for each endpoint needs to be

identified and reported in IUCLID 5 in the form of a robust study summary. Such a robust study summary reflects the objectives, methods, results and conclusions of a full study report and provides information that allows a technically qualified person to make an independent assessment without going back to the full study report.

If the data owners have study summaries to hand, together with proof of ownership, Klimisch rating and a financial evaluation, this would facilitate the data sharing process.

3. Application of Competition Law to REACH activities

DOES COMPETITION LAW APPLY TO REACH ACTIVITIES?

REACH is not a competition law-free zone!

Rules of competition law adopted at Community level (EC Competition law – Articles 81 & 82 of the EC Treaty and national law may apply.

The application of EC Competition law must not be seen as a hurdle. The REACH Regulation encourages companies to co-operate, however, there are limits to this and authorities would not accept any breach of competition law. Ignorance is not an excuse.

REACH activities most not be misused to engage in illegal activities or to create or cover cartels. As a consequence pro-active compliance is needed.

WHERE COULD I FIND GUIDANCE ON THE WAY TO COMPLY WITH EC COMPETITION LAW FOR MY REACH ACTIVITIES?

Chapter 9 of the ECHA Guidance on data sharing includes some recommendation on the exchange of information.

Cefic has published a more extensive document (embedded below) providing practical guidance. It covers not only the issue of safe exchange of confidential sensitive information, but also on items such as working in SIEF, consortium membership and participation, cost calculation and division, data sharing, items that companies should not discuss, and the do's and don'ts of REACH activity management.

It is strongly recommended that anyone involved in REACH reads and familiarises themselves with this Guidance leaflet in full.

Adobe Acrobat 7.0 Document

4. Preparation for collaboration

WHAT IS A CONSORTIUM?

A consortium is an organised and formal type of co-operation between SIEF participants implying they either have a signed agreement or the adoption of operating rules, or reference to an agreed set of general rules. SIEF and consortia are two different concepts and must be clearly differentiated.

SIEF participants are free to organise themselves in order to meet:

- Their SIEF objectives (data sharing thereby avoiding duplication of studies in particular vertebrate animal testing and classification and labelling)
- The joint submission of data

A SIEF in itself has no prescribed legal form. The REACH Regulation does not organise the way SIEF participants must cooperate to meet their obligations, nor does it regulate possible forms of co-operation between them for SIEF or other purposes.

There are several possible forms of co-operation that companies can chose to organise their activities under REACH. At the two extremes of the spectrum, co-operation could be achieved by:

- A legally binding set of operational rules provided for in a signed agreement, or
- An informal gathering of people working together without any sets of rules

In between these two extremes, various possible forms of legal agreements can be entered into, for example to organise the right of access to data for another party, or to specify the party who shall be conducting testing on behalf of the others. This can be done in the form of a written agreement, an exchange of emails or even orally.

While it is not obligatory, Cefic highly recommends that REACH actors work and co-operate via a consortium.

HOW AND WHEN IS A CONSORTIUM FORMED?

Parties may decide to have a consortium to organise together activities:

- Before the SIEFs
- During SIEF to share data and agree classification and labelling
- For the full duration of the SIEF as mentioned in the REACH Regulation, for 11 years

After registration in case they collectively have to respond to questions

WHAT TO DO WHEN FORMING A CONSORTIUM?

When SIEF participants are deciding what form of co-operation should govern their relationship and whether to enter into a written agreement to document it they, and other REACH actors, should consider several factors, including:

- The need for legal certainty, which would justify entering into a formal agreement;
- The time and effort that may be required to enter into a formal agreement, which may justify opting for a looser type of agreement.

By either signing the consortium agreement, accepting operating rules by a decision in a meeting, or deciding to refer to a common agreed set of rules (hereinafter only referred to as an agreement), participants in the agreement will de facto ‘create the consortium’. There is no need to have any additional formalities. As a consequence, there is no specific requirement that consortia are organised by creating a separate legal entity having legal personality under the legislation of a Member State. It is advisable that the parties agree this in writing (this can be by means of a contract or simply an email).

SIGNATURE OF A PRE-CONSORTIUM AGREEMENT AND/OR A CONSORTIUM AGREEMENT

Before entering into discussions and exchanging confidential business information, participants of a pre-SIEF are advised to have a set of agreed rules for the exchange of information agreed in writing. They can either sign a consortium agreement directly, or they can decide to work in two steps: first to have a pre-consortium agreement that will already include a confidentiality clause to allow them to exchange information safely but at the same time, give them more time for negotiating the consortium agreement.

Each company is free to determine who signs the agreement taking into account their internal rules.

TYPICAL CLAUSES THAT MAY BE INCLUDED IN A CONSORTIUM AGREEMENT

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

"Typical clauses that can be included in a (

ELEMENTS OF CO-OPERATION THAT MAY BE INCLUDED IN A CONSORTIUM

- Conduct or document the substance identity check
- Designation of a SIEF facilitator or Lead Registrant (in cases where the consortium groups all SIEF members)
- Organization of the co-operation and thus the consortium
- Adoption of competition law compliance rules
- Definition of liability
- Identification of data ownership
- Consideration of data (existing data, missing data, new data to be developed)
- Organization to preserve the confidentiality of business information and data
- Definition of Classification and labelling
- Data valuation, data evaluation (including identification, data access and collection)
- Definition of data to be shared
- Facilitation of data-sharing and co-ordination
- Definition of cost sharing mechanism
- Facilitation of cross-reading between SIEFs
- Preparation of letter of access to data for non-consortium participants
- Definition of post-SIEFs actions e.g. joint submission of data, joint registration and joint response to ECHA comments in evaluation

A consortium may equally include activities to collate and evaluate use and exposure data and to develop the Chemical Safety Report.

HOW TO FIND OUT WHICH CONSORTIA ARE ALREADY FORMED?

ECHA will not publish a list of consortia. It will however publish a list of those substances that have been pre-registered.

Once pre-registrants have submitted their pre-registration details they can communicate with other pre- SIEF participants to find out whether a consortium has or will be formed.

Companies may also address direct queries or consult the website of relevant associations or sector groups to see whether a consortium has been formed at any time. They may also contact a REACH service provider. Further information regarding consortia formation from Cefic sector groups may be obtained from the Cefic website

WHAT ARE THE CATEGORIES OF PARTICIPANTS IN A CONSORTIUM?

Participation in a consortium is voluntary and may not necessarily incorporate all participants of a SIEF. It may incorporate only some of them or participants of more than one SIEF:

Participant categories strictly deriving from a SIEF:

- Manufacturer(s)
- Importer(s)
- Only Representative(s)
- Data-holders who are willing to share data (for example laboratories, organisations, consultants, trade/industry associations, NGOs)
    - Downstream user(s) if they have relevant information, for example study data and exposure data

Other categories may be considered, such as:

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

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

- Full members
- Associate members
- Observers

5. How to submit a pre-registration

The majority of communications with the ECHA have to use IT systems. In most cases the basic path is that potential registrants prepare files (e.g. using IUCLID 5) in their local IT environment which are then submitted to ECHA via a website.

Before you can start to use the ECHA IT system you need to create a user account, which is related to the legal entity you work for. Current plans of ECHA would mean that you have to set up one account per legal entity that will register. Once you have done that, the IT system recognises which legal entity is submitting information. Therefore, there is no need to include legal entity information in your pre-registration: the system will recognise which legal entity it deals with by the login used. As a result of this, pre-registration information files need to be gathered by legal entity.

Pre-registration can be submitted via a number of routes as illustrated in the Figure 3 (below). The correct route is dependent on the number of pre-registrations that are to be submitted (bulk or manual upload) and whether the substance has a known EC number.

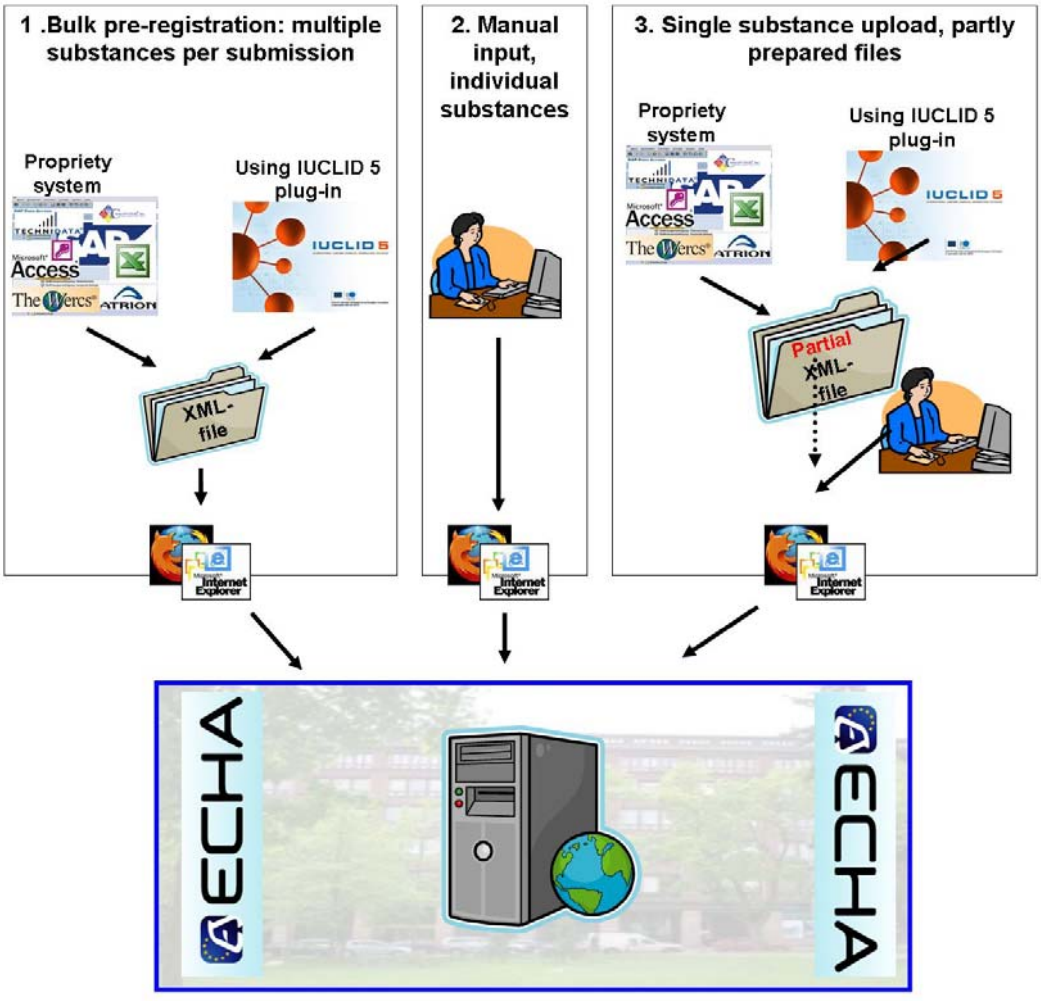


Figure 3. Schematic overview of options for submission of pre-registration files to ECHA

Pre-registration can be done using the “bulk” option (one file contains the information of a number of substances that you want to pre-register) or manual option (for every substance a form on the web-site has to be completed). The file to submit for pre-registration, which has to be an XML file - has to follow certain IT rules. How the file is generated and where the information is coming from is not important for the submission, as long as the file is converted to the established IT-format as described in the IUCLID 5 webpage prior to submission.

Further Information:
http://ecbwbiu5.jrc.it/index.php?fuseaction=home.preregistration&type=public.

HOW TO CHOOSE THE CORRECT PRE-REGISTRATION ROUTE?

Phase-in substances can be substances with an EC number (EINECS or NLP number and therefore listed in the EC inventory), but can also be substances without EC numbers (e.g. intermediates, not placed on the market). Substances with or without EC number can therefore be pre-registered, but there is a clear difference in how this can be done, see Table 2 below.

	Manual input (on-line in REACH-IT)	Upload of single substance created in IUCLID or other application*	Bulk upload of multiple substances created in IUCLID or other application*
A substance listed in the EC inventory *or* a multi-constituent substance of which all constituents are listed in the EC inventory	✔	✔	✔
A substance not listed in the EC inventory *or* a multi-constituent substance of which one or more constituents are not listed the in EC inventory	✔	✔	X
Pre-registration as a newcomer, after 1 December 2008	✔	✔	X

"other application" means any other application as long as the format of the created file follows that of IUCLID 5

Table 2. An overview of the optional routes to pre-registration for substances with and without EC numbers

Only substances with an EINECS or NLP number can be pre-registered using the bulk submission option.

HOW DOES BULK PRE-REGISTRATION WORK?

Bulk pre-registration can be used to pre-register multiple substances per legal entity. All substances and constituents of substances must have an EC number to pre-register in bulk. An IT-formatted file (one per legal entity) containing pre-registration information for all substances from a single legal entity is submitted to the ECHA. In order to do so, you need to:

- Create an account in REACH-IT for your company (one for each legal entity)
- Log in to REACH-IT
- Prepare the file for the substance or substances you want to pre-register. This file has to follow the IT format as specified by the Agency, see above
- Select "pre-register in bulk" in the functional menu

REACH-IT will verify the file format, structure and content of the file. The submission is rejected in one or more of the following cases:

- The file format or structure is not correct
- A substance is included without an EC number
- A substance is included with an invalid EC number
- The UUID (a unique IT identifier) of a third party representative included in the pre-registration file does not exist in REACH-IT

After submission of the bulk pre-registration file, users will need to log in again to REACH IT to submit the following information for each substance, which cannot be entered via the bulk process:

- Whether they volunteer to be the SIEF facilitator
- Whether they would like to receive messages when other companies pre-register the same substance identifier or refer to the same substance identifier as a read-across substance.

WHAT HAPPENS ONCE I HAVE PRE-REGISTERED?

After successful pre-registration you will receive:

- A pre-registration submission number after validation
- A message in your internal mailbox, containing:
  - A link to the submission report which contains a summary of the information submitted, when it was submitted and by whom
  - A pre-registration number for each substance and legal entity registered
- Access to the pre-SIEF web pages. You can view your pre-registrations by selecting "view pre-registrations" in the functional menu

The pre-SIEF webpage is personal and can be accessed by the companies that pre-registered the same substance. All companies that submitted the same substance will be able to see each other's contact details on this page.

HOW DO I PRE-REGISTER WITHOUT AN EINECS OR NLP NUMBER?

If the phase-in substance does not have an EC number (i.e. without an EINECS number or an NLP number), or in the case that you do not want to create a bulk file, you will have to submit the information manually via the website. In order to do so, you need to:

- Create an account in REACH-IT for your company (one for each legal entity!)
- Log in to REACH-IT
- Have the information on the substance you want to pre-register to hand
- Select "pre-register" in the functional menu

The steps that follow are:

- Identification of the substance (mandatory).
- Identification of similar substances (optional, but not recommended, see above)
- Specification of tonnage band and envisaged deadline (mandatory)
- Contact of legal entity or third party representative[5] (mandatory)
- Remarks, to indicate for instance further information that would help the SIEF formation process (optional)
- Validation (mandatory)

To follow these steps will typically take between 10 and 45 minutes per substance per legal entity.

[5] There is a special requirement for pre-registration using Third Party Representatives (TPR). The TPR cannot do the pre-registration on your behalf, but you have to indicate –per substance – if you use the TPR. In order to do so, the TPR needs to create a REACH-IT account and supply you with the so-called UUID that has to be incorporated in the pre-registration.

HOW DO I PRE-REGISTER MULTI-CONSTITUENT SUBSTANCES?

Multi-constituent substances are identified as consisting of more than one main constituent. To pre-register multi-constituent substances, the identity of the main constituents should be given. The order in which the identifiers (EINECS or NLP numbers) are given is not relevant.

If the substance can be described using EC numbers, the substance can be part of a bulk pre-registration. In cases where an EC number cannot describe one or more constituents, a manual pre-registration is necessary.

IS THERE ANOTHER ROUTE TO PRE-REGISTRATION?

The third possibility that is offered by the REACH-IT system is the single-substance upload, which combines elements of on-line pre-registration and bulk upload as follows:

- Prepare the file (using the IUCLID pre-registration plug-in or another application), but for only 1 substance.
- Select / confirm / submit the file
- If no EC number is specified for the substance, REACH-IT checks
  - The EC inventory
  - All the previously pre-registered substances
- Confirm whether or not (one of) the presented option(s) is the substance you want to pre-register.

This approach prevents re-typing the same information. For substances without an EC number (e.g. intermediates not placed on the market), this possibility seems to be preferable to the manual data entry option.

WILL THERE BE A PRE-REGISTRATION NUMBER?

Although not indicated in the legal text, the ECHA will provide a pre-registration number per substance per legal entity. This pre-registration number does not guarantee that the pre-registrant will register the substance. ECHA will also provide a pre-registration submission number (for the entire submission) and a summary of what was submitted.

CAN I CHANGE MY PRE-REGISTRATION IF A MISTAKE IS MADE?

You can only pre-register a substance once per legal entity. If you have made an error in the substance identity or the legal entity details, you will need to de-activate the pre-registration as it cannot be withdrawn and submit the correct pre-registration before 1st December 2008. The original pre-registration will remain dormant and readable. If you have made a mistake in entering information unrelated to substance identity or legal entity, then you may re-open the pre-registration and correct the mistake at any time (applicable to on-line pre-registration, bulk or single uploads). REACH IT will overwrite the first entry and update the SIEF web page.

6. 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

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.

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