Frequently asked questions on REACH by Industry

1) Scope

Does REACH apply to substances and preparations imported or manufactured in volumes below 1 tonne per annum?

Yes

However, substances (on their own or in preparations) do not need to be registered as long as the manufactured or imported volume is below 1 tonne per registrant per annum.

Any obligations regarding Classification and Labelling need to be met regardless of the tonnage. If the substance is classified as dangerous, is a PBT or vPvB or is included in the candidate list of substances for authorisation a safety data sheet has to be produced and provided to the recipients of the substances.

If the substance is placed on Annex XIV (a list of substances subject to authorisation) you need to request an authorisation for its use, irrespective of the volume. Similarly, restrictions contained in Annex XVII apply, irrespective of the volume.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.1 on the ECHA website.
- Articles 6, 31 of the REACH Regulation.

Does REACH apply to substances occurring in nature?

Yes

However, with some exceptions, substances occurring in nature do not have to be registered.

The following substances occurring in nature are exempted from registration if they are not chemically modified: minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal and coke.

Other substances occurring in nature are exempted from registration if they are not chemically modified, unless they are classified as dangerous according to Directive 67/548/EEC.

Annex V covers substances, for which a registration is considered inappropriate or unnecessary. These substances are also exempted from Titles V (downstream user obligations) and VI (evaluation) of the Regulation.

Annex IV contains a list of substances, for which sufficient information shows that they cause minimum risk because of their intrinsic properties, and which are therefore exempted from registration. These substances are also exempted from tittles V (downstream user obligations) and VI (evaluation) of the Regulation. Many of the substances in Annex IV are naturally occurring substances.

You can find more information on this issue in

- Article 2(7), Annex V (7) and (8), Annex IV, of the REACH Regulation.

Does REACH apply to substances in food?

No, except to a very limited extent.

Substances used in food or feedingstuffs are exempted from registration, evaluation and authorisation as well as from downstream user obligations.

Food or feedingstuffs preparations in the finished state, intended for the final user, are exempted from the provisions on information in the supply chain.

The reason for these exemptions is that Regulation (EC) No 178/2002 on food safety already requires that food for humans and feed for animals cannot be placed on the market unless they are safe. The entry into force of REACH will not affect the application of the EU legislation on foodstuffs. However, substances used in food or feeding stuffs can be made subject to restrictions under the REACH Regulation.

Restrictions are a general safety net in REACH, which could apply to substances in food and feedingstuffs if necessary.

You can find more information on this issue in

- Article 2(5b)(6d) of the REACH Regulation.

Does REACH apply to imported clothes and shoes from outside the EU?

No, usually not, unless they contain substances of very high concern.

The REACH Regulation applies in certain cases also to articles. These include in principle clothes and shoes. Substances contained in the articles are to be registered if they are intended to be released. This is unlikely to be the case for clothes and shoes.

If the articles contain substances of very high concern which are listed on the "candidate list", the importer and all distributors of the article have the obligation to notify these substances to the Agency, if the substance is present in those articles in quantities over 1 tonne per producer/importer per year and the concentration is above 0.1 % (w/w). On request, the importer also has the duty to communicate information on substances of very high concern in articles to users and consumers, enabling them to use the substance safely.

In addition, substances used in articles, including imported articles, can be subject to restrictions under REACH.

It should be noted that the same requirements apply to articles produced within the EU and articles imported to the EU.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.8 on the ECHA website.
- Articles Art. 3 (3), 7 and 33 of the REACH Regulation.

Does REACH apply to nano-particles?

Yes.

Substances in the nano-scale fall under the scope of REACH and their health and environment properties must therefore be assessed following the provisions of the Regulation. The nano-form of a substance can be registered as part of the registration for the non-nano form of the substance.

Methodologies for identifying hazards and evaluating risks of substances at the nano-scale need to be further refined. The European Commission is funding research projects to assess the health and environment impacts of nano-particles under the 7th Research Framework Programme.

I think my substance should be on exempted from registration and added on Annex IV. Will the annex be reviewed?

Yes

The Commission is required to carry out a review of Annex IV by 1 June 2008 with a view to proposing amendments, if appropriate. Annexes IV may be amended with the committee procedure, and third parties may give their input in the process. To keep up-dated with the process please follow the internet site of DG Environment.

Annex IV contains substances which are exempted from registration. Substances, for which sufficient information shows that they cause minimum risk because of their intrinsic properties, can be included in Annex IV.

Many of the substances in Annex IV are naturally occurring substances. It is important to point out, that in addition to substances mentioned in Annex IV the following other substances occurring in nature are exempted from registration if they are not chemically modified: minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal and coke.

Moreover, other substances occurring in nature are exempted from registration if they are not chemically modified unless they are classified dangerous according to Directive 67/548/EEC.

You find more information on this issue in

- Articles 2(7)(a)(b), 133(4), Annex IV and V of the REACH Regulation.

When do the main provisions of REACH start: 1.6.2007 or 1.6.2008?

The provisions under REACH on pre-registration and registration, evaluation, authorisation and downstream user obligations apply as from the 1 June 2008. However, the provisions of Title IV (Information down the supply chain) apply as from the 1 June 2007.

2) Pre-registration

Is it possible to benefit from the phase-in registration, if the substance is not pre-registered by 1.12.2008?

NO, with one exception

In order to benefit from the extended registration dead-lines for phase-in substances one has to pre-register the substance within the time period starting 1 June 2008 and ending 1 December 2008. Article 28.6 includes one exception to that.

According to Article 28.6, it is possible to pre-register after the pre-registration deadline (1.12.2008), if a phase-in substance is manufactured or imported by the company for the first time after the pre-registration deadline. In this case the pre-registration must be done within six months of first manufacturing or importing (≥1 tpa) and no later than 12 months before the relevant phase-in deadline for registration (see Art. 23) to still benefit from the phase-in period. The same applies for the production of articles and imported articles, containing a phase-in substance for which registration is required (see also Art. 7) and that is used by the company for the first time.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document 3.1 on the ECHA website.
- Articles 23, 28, of the REACH Regulation.

3) Registration

How much is the registration fee?

The registration fees will be specified in a Commission Regulation adopted by 1 June 2008 at the latest. The Regulation will be adopted with the Committee procedure.

No fee needs to be paid for the registration of substances in a quantity of between 1 and 10 tonnes for which a registration dossier containing the full information in Annex VII to the REACH Regulation is submitted.

You can find more information on this issue in

- Articles 111 of the REACH Regulation.

Do registrants need IUCLID?

The IUCLID5 system will be downloadable free of charge from the Agency website. Registrants are not obliged to use the IUCLID system, but they must submit their registration in the IUCLID format.

You find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.1 on the ECHA website.
- IUCLID 5 website.
- Articles 74, 133(3) of the REACH Regulation.

Do I have to register alloys?

No, but the elements (metals) in the alloys are potentially subject to registration.

Alloys themselves are not subject to registration, but the individual elements (metals) used for the formation of the alloys have to be registered, unless they are exempted by other grounds. Alloys are regarded as special preparations.

The Commission, in close cooperation with industry, Member States and other relevant stakeholders, should, before the entry into operation of the Regulation, develop guidance to fulfil the requirements under REACH related to preparations (in particular with regard to safety data sheets incorporating exposure scenarios) including assessment of substances incorporated into special preparations – such as metals incorporated in alloys. In doing so, the Commission will take full account of the work carried out within the framework of the REACH Implementation Projects (RIPs) and will include the necessary guidance on this matter in the overall REACH guidance package.

The guidance being produced under RIP 3.2 (Preparing the Chemical Safety Assessment) is considering this issue.

You can find more information on this issue in

- Article 3 (41), Annex I, 0.11, Annex II (page 268)

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.2 on the ECHA website.

Which legal entity, e.g. within a multinational company must register a substance upon import/manufacture into/in the European Union?

Within a multinational company, those legal entities (natural or legal persons) manufacturing or importing a substance in the Community are responsible of registration of the substance(s) they each manufacture or import. Only Manufacturers and Importers, which are legal (or natural) persons established within the European Community can be responsible for registration.

- "Branch offices" (in French "succursales", in German "Zweigniederlassung") do not have separate legal personality, and cannot therefore be responsible for registration.

- "Daughter companies" or "subsidiaries" in the EU (in French "filiales", in German "Tochtergesellschaft") have a separate legal personality and therefore qualify as registrants for the purposes of REACH. If a substance is manufactured/imported by two subsidiary companies of the same company, both have to register the substance.

Because Community law does not operate a complete harmonisation of civil and company law, it is the national law of each EU Member State which provides when one is faced with a natural or legal person, and when an entity is "established" in its territory.

A "natural person" is a concept applied in many legal systems to refer to human beings who are capable and have the right to engage into contracts or commercial transactions. A "legal person" (=legal entity) is a similar concept, applied in many legal systems to refer to companies who have been endowed with legal personality by the legal system applicable to them (the law of the Member State where they are established) and therefore are capable of carrying rights and obligations, independently of the people or other companies behind them.

One legal person can work on different sites. It can also open so-called "branch offices" (in French "succursales", in German "Zweigniederlassung") which do not have separate legal personality from the main or head office. In such a case, it is the head office that has the legal personality and that has to be established in the EU to respect the provisions of REACH.

On the other hand, a legal person can also open "daughter companies" or "subsidiaries" in the EU (in French "filiales", in German "Tochtergesellschaft") in which it holds shares or another type of ownership. Such EU daughters have a different legal personality and therefore qualify as a "legal person established in the Community" for the purposes of REACH. They are to be considered as different manufacturers and importers who each may be obliged to register for the respective quantities they manufacture or import. However, these subsidiaries have the obligations of joint submission of data by multiple registrants. Often operators do not use the terms "branch" and "office" in this technical-legal sense and therefore it should be ascertained in detail whether the entity being referred to has legal personality or not.

International companies sometimes have several daughters in the EU acting as importers, often spread over several Member States. Each of those daughters, if it has legal personality, is a legal person within the meaning of REACH. Depending on the distribution of work within the group, each of them can be an "importer" responsible for import. It is for the group or the individual companies to assign the tasks and the responsibilities to companies in the group. Tonnage thresholds for the purposes of REACH registration apply per manufacturer or importer, to the whole tonnage manufactured or imported in the EU, regardless of the distribution among Member States.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.1 on the ECHA website.
- Articles Art. 3 (8)(9)(10)(11), Art. 11, and Art 29 of the REACH Regulation.

Do polymers need to be registered?

No, but the monomers in the polymers need to be registered.

Polymers are exempted from registration and evaluation. However, monomers used to manufacture polymers will need to be registered if they are manufactured or imported in quantities of one tonne or more per year per manufacturer or importer.

If they are manufactured or imported in quantities of 10 tonnes or more, then a Chemical Safety Assessment will be required that will cover the life-cycle of the monomer, including its incorporation in the polymer and its eventual disposal.

In addition, monomer substance(s) and other substances of the polymers that have not already been registered by an actor up the supply chain are to be registered if:

- the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
- the total quantity of such monomer substance(s) or other substance(s) in bound or unbound form makes up tonne or more per year.

Should the monomer substances be phase-in substances they can also be pre-registered and thus benefit from the extended registration deadlines for phase-in substances.

Naturally occurring monomers are exempted from registration unless they meet the criteria for classification as dangerous in accordance with Directive 67/548/EEC (see Article 2(7)(b) and Annex V(8)) or they have been chemically modified."

Other provisions of REACH (e.g. authorisation, restrictions) can apply to polymers. In addition, classification and labelling provisions apply to polymers.

The provisions of on-site isolated and transported intermediates do not apply to monomers (i.e. a full registration dossier must be submitted even if a monomer is used as an intermediate).

The Commission may also present legislative proposals with requirements for the registration of polymers once a practicable and cost-effective ways of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.1 on the ECHA website.
- Articles Art. 2(9), 3(5)(6), 6, 138 (2) of the REACH Regulation.

4) Import of substances to the European Union – only representative

What are the responsibilities of a non-EU company who has nominated an only representative?

Non-EU companies have no obligations under REACH. Compliance with REACH must be ensured by their EU-based importers (i.e. they have to register the substance, provide safety data sheets (SDS) where necessary, etc.). In order to allow importers to fulfil their obligations, non-EU companies will however have to provide the necessary information on the substance to the importer.

If a non-EU company does not wish the importer to be responsible for obligations under REACH (e.g. if the non-EU company does not wish to disclose confidential information), it may appoint an only representative. In this case, the only representative takes over all obligations of the importers under REACH.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.1 on the ECHA website.
- Articles 8 of the REACH Regulation.

5) Data Sharing

How can I get information on Substance Information Fora (SIEF) already formed or in the process of formation?

There is no formal confirmation of the formation of a SIEF as this is a matter for agreement between companies without involvement of the European Chemicals Agency. However, relevant information on the formation of SIEFs can be posted on the substance website where the contact details of pre-registrants are displayed.

Importers and manufacturers are responsible for fulfilling separately the obligations under REACH for the substances that they import/manufacture. Should the substance be a phase-in substance, it could benefit from the extended registration deadlines for phase-in substances.

Potential registrants for the same substance will become part of a Substance Information Exchange Forum (SIEF). A SIEF is a platform within which data needed for registration are exchanged.

In most cases, the SIEFs are formed by all companies who have pre-registered a substance under the same substance identifier (EINECS, CAS number, other relevant identifier). There are however also cases where the SIEFs are not identical with the pre-registrants under the same identifier. This may e.g. be the case when substances under the same EINECS number are too diverse to allow using the same data and preparing one joint registration or when substances in different EINECS numbers are sufficiently similar to allow data sharing and joint registration.

In detail, the process of SIEF formation is as follows:

To benefit from the extended registration deadlines for phase-in substances, the potential registrant must pre-register the substance. The pre-registration period starts on the 1st June 2008 and ends on 1 December 2008. Once potential registrants have pre-registered, they will get access to a substance website where the contact details of the other pre-registrants of the same substance identifier will be shown. It is then for all those pre-registrants to verify whether their substance is the same substance (then they form one SIEF) or whether their substances are too different to allow data sharing and several SIEFs must be formed. After publication by the Agency of a list of pre-registered substances by 1 January 2009, pre-registrants should also verify whether their substance has not also been pre-registered under another EINECS number or other relevant identifier. In such cases, a joint SIEF should be formed. It should be noted, though, that companies are not free to establish several SIEFs for the same substance, as they would violate data sharing obligations.

A SIEF starts its operation once the pre-registrants have agreed that they have the same substance for the purpose of data-sharing and joint submission of registration. Please note that there is no formal confirmation of the formation of a SIEF and that this is a matter for agreement between companies without involvement of the European Chemicals Agency. However, relevant information on the formation of SIEFs can be posted on the substance website where the contact details of pre-registrants are displayed.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.4 on the ECHA website.
- Articles 28, 29, 30 of the REACH Regulation.

6) Information requirements, test methods and quality of data

According to which test methods should new tests be performed?

New tests, if necessary, should be conducted according to test methods which will be laid down in a Commission Regulation, or according to other international test methods recognised by the Commission. The Commission Regulation is under preparation, but has not yet been adopted.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.3 on the ECHA website.

- Articles 13 of the REACH Regulation.

Is the Agency responsible for developing/validating new testing methods?

No, the Agency is not responsible for developing/validating new testing methods.

Please note that the European Centre for the Validation of Alternative Methods (ECVAM) is in charge of the scientific validation of new (alternative) testing methods.

The OECD (Organisation for Economic Co-operation and Development) Guidelines for the Testing of Chemicals provide a collection of the most relevant internationally agreed testing methods.

Validated test methods which are suitable for use under REACH may be included in a Commission Regulation adopted in accordance with Article 13(3) or recognised by the Agency.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.3 on the ECHA website.
- Articles 13 of the REACH Regulation.

Which are the "other international test methods" recognised by the Commission or the Agency and referred to in article 13 (3)?

For the time being no "other international test methods" in the meaning of Article 13(3) have been recognised by the Commission nor by the Agency. Such test methods can be recognized by the Commission e.g. by including them in a Commission Regulation or by the Agency and published at the Agency website.

Are new ecotoxicological and toxicological tests conducted in laboratories accredited according to the EN ISO IEC 17025 standard acceptable?

No, since GLP is currently the only internationally recognised quality assurance system through the OECD's mutual acceptance of data decision. New tests, other than physical-chemical tests, must be performed in compliance with the Good Laboratory Practice (GLP) provided for in Directive 2004/10/EC by an authorised laboratory, independently of whether the laboratory is also accredited under the ISO system.

Please note also that REACH is not meant as a test programme: Registrants should use existing data whenever possible (see criteria in Annex XI, point 1.1), apply non-animal methods whenever possible, share existing data and even if data gaps are identified, send a testing proposal to the Agency first, before embarking on any extensive animal testing.

Any existing data fulfilling the requirements of Annex XI paragraph 1.1 are acceptable independently of whether the data have been provided by testing at a laboratory accredited under the ISO standard or according to GLP.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.3 on the ECHA website.
- Articles 13 of the REACH Regulation and Annex XI.

Is there a list of approved testing laboratories in Europe?

No official list of approved GLP laboratories in Europe exists. In each Member State accreditation authorities keep lists of laboratories accredited in their country and authorised to carry out studies in compliance with GLP.

7) Authorisation

Are there substances on Annex XIV?

No, not yet.

Annex XIV will comprise a list of substances subject to authorisation. No substances have yet been included in Annex XIV.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-documents number 4.3/4.5 and 4.4 on the ECHA website.
- Articles 58 of the REACH Regulation.

Does the candidate list exist already?

No, not yet.

This list has not yet been established. The Agency will publish and update this list on its website once it is available, at the earliest by late 2008.

The Agency shall make its first recommendation of priority substances selected from the candidate list to be included in Annex XIV by 1 June 2009. This list will be made available on the ECHA website

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-documents number 4.3/4.5 and 4.4 on the ECHA website.
- Article 59 of the REACH Regulation.

8) Transitional period

How will PORD exemptions under Directive 67/548/EEC be transferred into REACH?

National Process Orientated Research and Development (PORD) exemptions for the notification of substance under Directive 67/548/EEC are no longer valid under REACH as

from 1 June 2008, because there are no such notifications under REACH. Therefore, manufacturers or importers or producers of articles wishing to continue their PPORD activities need to submit a new notification to the European Chemicals Agency. In order to avoid interruptions of such activities, the notification should be made by 16 May 2008 at the latest because, in the absence of an indication to the contrary, PPORD activities may not start earlier than two weeks after the notification. For this purpose, the Agency will allow notification before 1 June 2008. The exact date by when notification will be possible will be communicated at a later stage.

Please note also that even if the notification is made more than two weeks in advance of 1 June 2008, any activities covered by the notification can always only start on 1 June 2008, when the PORD rules under Directive 67/548/EEC have expired and the new rules under REACH have entered into force.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.1 on the ECHA website.
- Articles 3 (22), 9 of the REACH Regulation.

9) Information in the supply chain

Does REACH require any changes in the Safety Data Sheets (SDS) prepared according to the existing provisions?

Yes. Some changes are required.

The main rules on when a SDS is required, who needs to prepare a SDS and to whom and when it is to be submitted do not change. The main change is that, where required, the Exposure Scenarios developed by registrants as part of a chemical safety assessment need to be annexed to the SDS.

In addition, the order of Chapters 2 and 3 of SDS is reversed. Hazards Identification is now Chapter 2 and Composition/Information on ingredients is now Chapter 3. The email address of the responsible person should be included in the SDS.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.1 on the ECHA website.
- Articles 31 and 32 of the REACH Regulation.

How soon do these changes in the Safety Data Sheet need to be implemented? After all they refer to the format, not its content.

SDS should be updated without delay, if new information e.g. on hazards or risk management measures becomes available.

The provisions of Title IV (Information in the supply chain) and Annex II come into force on the 1 June 2007. The enforcement of REACH is in the scope of tasks of the Member States.

At the meeting of the Commission Working group on the Practical Preparations of REACH the Member States have agreed that the focus of enforcement should at the moment lie in the correctness of the contents of the SDS, rather than formalities of the formats used.
Article 31(9) defines when SDS shall be updated without delay, if new information e.g. on hazards or risk management measures becomes available. In such case the new format should be used.

You can find more information on this issue in

- As long as the guidance is not fully finalised it is recommended to also consult the RIP-document number 3.1 on the ECHA website.
- Article 31 (9) of the REACH Regulation.