

REACH QUESTIONS & ANSWERS

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

Yes, for certain parts.

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 (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.

Reference: Art. 6 & 31; RIP 3.1; ECHA website

What falls under the definition of PPORD (Product and Process Orientated Research and Development)?

Any scientific development of a substance on its own, in a preparation or an article in the course of which pilot plant or production trials are used to develop the production process and /or to test the field of application of the substance, falls under the definition of PPORD irrespective of the tonnage involved.

Substances are exempted from registration for a period of 5 years after notification to the Agency.

Reference: Art. 3.22; Guidance on ECHA website

What are our duties when we import a preparation into the EU?

When you import a preparation from a country outside of the EU, you are an importer of all substances it contains, and therefore you have to register any substance reaching the threshold of 1 tonne per year. This implies that you must know the detailed composition of the preparation.

Note 1: substances which have been registered, exported and then re-imported are exempted from registration

Note 2: non-EU manufacturers exporting to the EU have the option to nominate an Only Representative to cover their registration.

Reference: Art 5 & 6; Art. 2.7.c

What are the duties of a Company importing substances from Norway and/or Switzerland?

As soon as REACH is implemented by the EEA States (Iceland, Lichtenstein and Norway), imports will be considered as intra-Community trade for the purposes of REACH. Imports from Switzerland will be considered as imports from a third country.

Once the EEA countries have adopted the REACH Regulation "as is", and have negotiated with the EU their role within the ECHA, they will label their goods according to the European legislation.

Therefore a company importing substances from Switzerland will have to register them (as long as the total annual volume is above 1 tonne), but not from the EEA countries after they have adopted the REACH Regulation.

Reference: See web site http://reach.jrc.it/actors_en.htm; ECHA website

Does REACH apply to imported articles from outside the EU?

Yes

The REACH Regulation applies both to imported and EU-produced articles in certain cases.

Any producer or importer of articles shall submit a registration to the Agency for any substance that is intentionally released from articles and is present in those articles in quantities of 1 tonne and more per year, unless this particular use is covered in the registration dossier for the substance.

If the articles contain substances of very high concern which are listed on the "candidate list" for authorisation, the EU producer and the importer 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), and if exposure cannot be excluded and if substance is not registered for that use. Producers and importers of those articles have to provide the recipient of the articles with sufficient information to allow safe use of the article including, as a minimum, the name of that substance. Notification applies only as of 1st June 2011, 6 months after the substance is added on the "candidate list" (see Q 27 for further details on "candidate list").

Reference: Art 3(3), 7 & 33; RIP 3.8

How to register fragrances imported into the EU?

Fragrance is a preparation, and each of its constituents (substances) should be registered separately (if they are imported in quantity exceeding 1 tonne per year), not the fragrance itself.

However, its composition is normally not known, as the supplier is not usually willing to unveil its composition. It is therefore recommended that you ask the supplier to appoint an Only Representative in the EU who will take care of the registration.

Such an Only Representative will cover all imports into the EU.

Reference: Art 5 & 6; Guidance on Registration

I think my substance should be exempted from registration and added to 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. Annex IV may be amended following the Committee procedure (comitology), and third parties may provide their input to the Commission, a Member State or Industry Associations that are observers of the REACH CA Sub-Group. To be kept updated with the process please regularly check the website of DG Environment.

The Commission has asked a consultant to develop criteria to be fulfilled for substances to be included in Annex IV.

There is no certainty as whether a substance will be on the Annex IV (even if it is so today).

Reference: Art 2(7)(a)(b), 133(4); Annex IV & V; ECHA website

When are the main provisions of REACH applicable: 1st June 2007 or 1st June 2008?

Titles I (General Issues), IV (Information in the Supply Chain), IX (Fees and charges - except Art. 74), X (Agency), XIII (Competent Authorities), XIV (Enforcement) and XV (Transitional and final provisions - except Art. 138(4)) as well as Article 115 apply as of 1st June 2007.

Title II (Registration of substances), Title III (Data sharing and avoidance of unnecessary testing), Title V (Downstream users), Title VI (Evaluation), Title VII (Authorisation) Title XI (Classification and labeling inventory) and Title XII (Information) as well as Art 74 and 138(4) apply as of 1st June 2008.

When a substance is sold to a third party exclusively to be transformed in another substance, can this be considered a transported isolated intermediate?

Yes.

The definition of transported isolated material does apply to this case:

“transported isolated intermediate means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites”.

Art.18 applies and the intermediate needs be registered following Art 18(2)(3)(4) if their volume exceeds 1 tonne per year.

Intermediates are subject to reduced registration requirements. Intermediates are out of the scope of Authorisation.

It should be noted that it will have to be demonstrated that the substance is handled under strictly controlled conditions in order to benefit from the intermediates status (guidance available on ECHA website). This must be confirmed in writing by the user (being inside or outside of the EU).

Finally monomers that are used as transported isolated intermediates in the production of polymers have to be registered in accordance with the normal registration obligation and not according to specific provisions on the registration for intermediates (Art 6(2)).

Reference: Art 3(15)(c), 18; Art 6; ECHA website

A company A delegates the production of a substance to a third party manufacturer B. Who is responsible for registration?

According to article 6, it is up to the manufacturer to register the substance.

Definition of the manufacturer is given in article 3(9):

"any natural or legal person established within the community who manufactures a substance with the Community".

Therefore, Company B should register the substance.

Of course, it may happen that Company B does not have data for supporting the registration when Company A has them. It is then foreseeable that Company B will not produce for Company A without ensuring first that Company A will provide all necessary information.

Reference: Art 3 & 6; ECHA website

Is a household care product contained in an aerosol packaging considered as being an article?

No.

The function is a decisive element in the definition of article, and is determined by the manufacturer's intention. The main function of a spray can is to release a preparation. A spray can is therefore considered as being a container (i.e. an article). Substances contained in the aerosol container are therefore intended to be released and should be registered under Article 6.

Reference: RIP 3.8 (under development)

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 for the 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.

Note 1: Volumes should be calculated by legal entity for registration purpose.

Note 2: In case a non-EU manufacturer has appointed an Only Representative, this Only Representative acts as a single registrant for all imports into the EU, and therefore individual legal entities do not have to register the substances.

Reference: ECHA website

Does REACH apply to nanoparticles?

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 nanoform 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.

Reference: ECHA website

Does REACH apply to substances used in biocides?

Active substances used in biocidal products are regarded as registered as they are covered by Directive 98/9/EC (Biocidal products Directive). However, several conditions have to be fulfilled to benefit from the exemption:

- the substance must be an active substance for use in a biocidal product
- it must be included in one of the following documents: Annex I, IA, IB to Directive 98/8/EC or Regulation (EC) No 2032/2003.

Only the quantities used in biocidal products are exempted from the REACH obligation.

Reference: ECHA website

Pre-registration and registration

Do polymers need to be registered?

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

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 1 tonne or more per year.

N.B.: Polymers are not exempted from Authorisation or Restriction. They are also subject to Classification & Labeling provisions.

Reference: Art 2(9), 3(5)(6), 6 & 138(2); RIP 3.1; ECHA website

Is it possible to benefit from the specific provisions for phase-in substances if the substance is not pre-registered by 1st December 2008?

Yes, but only in case you are first time manufacturer or importer.

As a first time manufacturer or importer of a substance in quantities of 1 tonne or more per year, you must pre-register at the latest 6 months after the first manufacture/import and at least 12 months before the relevant deadline for registration.

This is very important for a DU who uses a substance which has not been pre-registered: he can use this possibility offered by the Regulation for pre-registering the substance.

How can I pre-register my substances and is there a format to fill in?

There will be 2 possibilities to submit the pre-registration information:

- direct encoding of the information on the REACH-IT website
- submission of a “bulk” pre-registration dossier prepared separately. The file must be of the format produced by IUCLID5.

Can I register a monomer as an intermediate?

Although a monomer can be considered as an intermediate, Article 6.2 specifies that monomers cannot benefit from reduced registration provisions. This means that a full dossier must be submitted even if a monomer is used as an intermediate under strictly controlled conditions.

Reference: Art. 6.2

When a substance has been registered for a specific use in articles, is the registration supply chain specific?

Provided that the substance has been registered by any manufacturer/importer for that use, it is not relevant that the registration was done within the same supply chain or within another supply chain.

Reference: Art 7.6

Data sharing/SIEF

Can a Downstream User join a SIEF?

Yes

If you hold data and have submitted the corresponding information on a substance to the Agency, you will be participant in the related SIEF as a Data Holder.

You can also pre-register a substance as a potential registrant (e.g. in the case you intend to import the substance in the future from a non-EU country). In which case you will have the same status as other registrants in the SIEF.

Reference: Art 29(1)

As a DU, can I sell my data to SIEF members?

As a DU, and if you have submitted the corresponding information to the Agency, you are considered as being a Data Holder. As such, you must respond to any query from potential registrants. However, a Data Holder is not entitled to request data.

Therefore you can sell data only if the SIEF members request them.

Other SIEF members should consider data from data holders.

Guidance on Data Sharing (ECHA website)

Art.29 says that “All potential registrants, downstream users and third parties who have submitted information to the Agency in accordance with Article 28, or whose information is held by the Agency in accordance with Article 15” are entitled to participate to SIEF.

According to Art.30, point 2 “All participants of the SIEF who require a study shall contribute to the costs” in case of sharing data. Does this exclude DU?

Any company can participate to a SIEF under either of the following status: Potential Registrant or Data Holder (but with different rights). A today Downstream User can enter a SIEF as a potential registrant (if he intends to import a substance from a non-EU country) or as a data holder.

In the first case, he will have the same obligation as any other registrant, i.e. he will have to share the cost of missing data (when applicable to his registration file). In the latter case, not.

Guidance on Data Sharing (ECHA website)

How to make known the use of a substance in a preparation known to your supplier?

You should inform in writing (letter or e-mail) as soon as possible your supplier of your own use and uses of your customers of his substance in your preparation. You should provide sufficient information to allow him to prepare an exposure scenario which covers your use.

Also make sure that he intends to cover your use in his registration file.

Guidance on how to do so will be provided under RIP 3.2

If a substance that I use today does not appear on the list of pre-registered substances published on 1st January 2009 by the ECHA, is there a process for the substance to be registered?

You should first inform the Agency of your interest in the substance with the name of your current supplier. The ECHA will then publish on its website the name of the substance and on request provide your contact details to a potential registrant.

This mechanism aims to allow Downstream User to find another supplier. An alternative provided by Art. 28(6) allows this other supplier to pre-register under the late pre-registration procedure described in Article 28(6). The pre-registration should then be completed within 6 months of the notification to the Agency.

The late pre-registration should be no later than 12 months before the registration deadline.

Another possibility is for the DU to manufacture or import the substance for the first time. The same process as above applies to his case.

Reference: Guidance on Data Sharing (ECHA website)

Authorisation

Do I need to apply for authorisation for each use?

Yes.

Authorisations are given per use. Those using or making available substances identified as of high concern will need to apply for an authorisation for each use of the substance within certain deadlines (the application will have to include an analysis of possible substitutes).

Does the candidate list including the substance of very high concern (SVHC) already exist?

So far no candidate list exists. When an Authority (Commission or Member State) considers that a substance may meet the criteria for identification as SVHC, the Agency or a Member State will prepare an Annex XV dossier. Then the substance may be included in the candidate list for possible inclusion in Annex XIV after review by relevant Committees.

The candidate list will be made available on the ECHA website. SHVC will be prioritised. The Agency shall indicate which substances are on its work programme for authorisation (Annex XIV).