

EU legislation: What exporters need to know about REACH presently

In brief



REACH is the new chemical legislation of the EU that came into force on 1st June 2007. REACH will establish a new single regime throughout the 27 EU Member States for existing and new substances and requires manufacturers in the EU and EU importers of substances/preparations to register them. The Regulation itself counts almost 900 pages besides the many other documents, guidance papers and opinions that can be found on Internet!

➔ What do you need to know about REACH, being an exporter from outside the EU?

This document gives answers on the basic questions on REACH and the possible effects for exporters from developing countries. In general one can say that companies outside the EU (1) manufacturing substances or preparations or (2) using substances or preparations that still can be found in the finished product, are not directly accountable, however:

- EU importers might request additional information from their suppliers in order to do their own registration for REACH.
- Be aware that in some cases you will have to refer to your own suppliers to get all data together.
- When costs are involved, for example to create a dossier, part of the costs might be passed through to the supplier.
- In a few cases EU importers might request from their suppliers to do the registration themselves, then they are directly involved

1. What is REACH?

REACH is the new Regulation in the EU on chemicals and their safe use. It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances. The new Regulation entered into force on 1st June 2007 and will be implemented in phases within the next 10 years. Presently, REACH requirements for pre-registration entered into effect.

➔ For an outline of the REACH legislation itself, see the related document.

2. Which products are included?

The following products are included in REACH:

- substances, such as base chemicals, speciality chemicals, metals, additives, solvents, monomers and natural substances if they are chemically modified
- mixtures or preparations of chemical substances, for instance cleaning products, formulated process chemicals, paints and motor oils
- articles which contain substances which are intentionally released during their use, for example the fragrance in a scented candle
- articles which contain dangerous substances which are not intentionally released during their use, such as a ink cartridge in a copier
- substances which are on a candidate list of "*substances of very high concern*". This list may become available at the website of the European Chemicals Agency from autumn 2008.
- new substances

3. In which countries REACH is applicable?

The REACH legislation is an EU Regulation which means that it is implemented in all 27 Member States in the same way. REACH is therefore fully harmonised. In addition, Iceland, Lichtenstein and Norway, which are part of the European Economic Area, are planning to

transpose REACH to their national legislation. When this has taken place the same requirements apply to exports to these countries.

4. What is pre-registration, am I involved?

Pre-registration

The current phase of REACH: a process kicked off on 1st June and will end on 1st December 2008. In this phase, the chemical producers and importers in the EU have to pre-register the chemicals used (said to be more than 100,000). Pre-registration will provide companies with more time to obtain and compile the information necessary to complete the registration that will follow.

What is needed?

- Name and address of company
- Name and address contact person
- Name and identity of the substance/substances in preparation
- Registration deadline and tonnage
- Possibility to become SIEF facilitator in registration phase

Are you involved?

Indirectly. For imported products these REACH obligations must be fulfilled by the EU importers. They are responsible. However, it could be the wish of your EU importer that his suppliers register, and therefore pre-register, themselves. This is possible through the only representative.

Tip

Check for crucial substances that you are using whether your importer did the pre-registration. Otherwise, at the ECHA website you can check which substances are pre-registered.

5. What happens if the chemical is not pre-registered?

No pre-registration?

The pre-registration is very important, because from 1st December 2008 onwards the manufacture in the EU and import of chemicals will only be allowed if the chemical is proper pre-registered. Substances that are not pre-registered need to be registered as a new substance which is a more complicated process.

6. What is an only representative? Is it relevant for me?

Only representative

REACH allows manufacturers from outside the EU to pre-register and register their chemicals. This is possible by appointing a representative within the EU who will act on behalf of the manufacturer outside the EU. An only representative can represent one or several non-EU companies.

Relevant?

In most cases the EU importer will do the (pre-) registration because he is held responsible. However, it is possible that he will request his supplier(s) outside the EU to do the (pre-) registration themselves. In that case, you have to establish an only representative in the EU.

➔ [For more information](#) on the only representative and its duties, please see the external link.

7. What information is required for the registration? Am I involved?

Substances and preparations

After pre-registration, registration of substances and preparations will start. Deadlines will range from 30 November 2010 to 31 May 2013 or 31 May 2018, depending on the nature and the quantity of the substance. REACH sets different information requirements for chemicals manufactured in the EU or imported in different volumes. Information is required on tonnes

imported per year per producer, intrinsic properties, hazards, use conditions, exposure and safe ways of handling.

Substances released from articles

For substances that are intentionally released, for example the fragrance from a scented candle, the substances need to be registered if:

- the substance is not yet registered for that application
- traded over 1 tonne/yr per producer/importer

For substances in articles that are unintentionally released, for example ink cartridges in copiers, only dangerous substances need to be notified from 1st June 2011 onwards. A list of those dangerous substances will be published before that time.

➔ [For more information](#) on the registration process, see the related document.

Are you involved?

Possibly indirectly: the EU importer might need hazard data and safe use information on the chemicals you used. So, an inventory of the substances, preparations and articles that contain substances which will be foreseeable released from the articles will be a very possible requirement from your EU importer. Please note that in case you do not produce chemicals yourself but you buy them, you have to get the specific data from your supplier to make your own data complete (supply chain management).

In case costs are involved during registration the EU importer might address part of those costs to the supplier.

Inventory of substances

- Which substances (including raw materials and additional materials) are being used in your production process and which of those can be found in the final product
- Characteristics of the substances
- Quantities exported to the EU per year
- Where are they coming from
- To whom sold

➔ [For additional information](#) on the registration process, please see the external link.

8. What happens with the data after registration? Are they of any use for me?

All data will be collected in one database by the EChA (European Chemical Agency). Next, all substance specific information will be gathered together and be accessible for the pre-registrants of those substances. They have to function in a so-called SIEF or Substance Information Exchange Forum and come together for one registration of that substance.

Any use?

The idea of the SIEFs is to exchange substance specific information throughout the production chain. So, in time more information about hazards of chemical substances will become publicly available because of the registration by EU companies. If a substance is found to be dangerous and these dangers are communicated properly in the sector, companies all around the world using those substances can either look for alternatives or take the necessary precautions to protect workers and the environment.

9. What are consortia?

SIEFS and/or consortia will be developed for the sharing of test data and the costs of testing. Most possibly, the biggest company of the group will take the lead of the registration which might involve (animal) testing and pass on the costs to the other companies in the group. Procedures are developed for the compulsory sharing of data.

10. Are there any costs involved in REACH?

It depends. Making an inventory of chemicals might bring administrative costs or even testing costs in the case you have to provide data on intrinsic properties and possible hazards. More likely your EU importer will pass on a bill. When your EU importer has to make costs during registration, he might pass on some of the costs to you.

Conclusions

➔ Does REACH affect my company outside the EU?

Not directly. It is the responsibility of the EU industry to register all chemicals being used. So this means that the legislation applies to the EU industry only. However, there might be situations that the EU industry will ask data from its suppliers from outside the EU. This, to improve their own obligation to comply with the REACH requirements. Or, when costs are involved by your EU importer, he might pass a part on to you.

Therefore, it is our advice to stay updated on the main issues of REACH, because your EU trading partners might have additional requirements on providing chemical data. Collecting these data might bring testing and administrative costs when not directly available. It is always wise to have an inventory of your substances.

It might be possible that your EU buyer request that you pre-register and consequently register yourself. This is only possible if you create an only-representative who will represent you in the EU.

➔ Which sectors are most likely to be - indirectly - affected by REACH?

Producers of substances and/or preparations, for instance producers of paint and coatings or fine chemicals and pharmaceuticals might be indirectly affected by REACH. Indirectly, because in most cases the EU importer will take up the REACH requirements and only in cases where there is not enough information or costs are made, he might demand an input or sharing of costs from his supplier.

Sectors such as textiles, toys and electronics are less connected to REACH. In most cases only dangerous substances fall under REACH obligations and only notification of those substances is needed. Again, it will be the EU importer who is responsible.

➔ For more information on the requirements for substances in articles, see the guidance document in the external link section.

➔ What can my company do?

You can wait until your EU buyer might request data on the chemicals that you used or are still traceable in your product. You can also anticipate on the possible request of EU buyers by the following actions:

- Create an inventory of all chemicals used, i.e. 1) all substances or 2) substances in preparations or 3) substances that can be released in the final products.
- It might be necessary to check your suppliers for additional data as well.
- Check the website of the European Chemicals Agency to find out if the substances or uses in your inventory are exempted from the registration under REACH.
- Identify for each substance on its own or in a formulated product the volume per EU importer.
- If a chemical substance in these inventories is imported into the EU ≥ 1 tonne/year it needs to be pre-registered and registered by the EU importer or in case he does not do that, you establish an only representative.

11. Where can my company turn for further information?

- CBI database

- The CBI database gives an analysis of the REACH Regulation, see related document
- The European Chemicals Agency website
 - ➔ The REACH helpdesk of the European Chemicals Agency will give advice to companies in Third Countries. Contact them with your questions. It will generate an answer much quicker and easier than you digging in all the available information!!!
 - Other issues provided at the EChA website:
 - The "About REACH" section gives an overview of the Regulation
 - Navigator tool which will assist importers and Only Representatives to find out their obligations and how to fulfil them
 - Extensive guidance on REACH provisions
 - IT tools for REACH uses and how to operate them
 - Frequently Asked Questions (in general)
- The EU website
 - Guidance documents
 - FAQ section

If you can not find sufficient advice, you should consider consulting:

- CBI through marketaccess@cbi.eu
- Your EU importers: they are good sources for information on sector specific issues
- The National helpdesk in the country of your EU importer or your Only Representative (contact details are available in the external link section)

Last updated: September 2008