

REACH – FAQ v4 (Feb11)

General

What is REACH?

REACH is the regulation that brings together many chemical legislative requirements under a single set of regulations. REACH stands for the Registration, Evaluation, Authorization and restriction of Chemicals.

Who is responsible for the enforcement of REACH?

This depends on where you are based; each Member State has appointed an enforcement agency to oversee the regulations.

Scope

Does REACH apply to substances manufactured or imported in quantities less than 1 tonne per annum?

Yes. There is no need for the registration of substances manufactured or imported in such small quantities; however, other requirements of REACH such as provision of Safety Data Sheets, Authorizations and Restrictions will apply.

Do substances registered under the Biocidal Products Regulations or as a Plant Protection Product need to be registered under REACH?

The use as an active ingredient in a Biocide or Plant Protection Product is deemed to be registered under the REACH regulations; however, other uses not covered by these regulations are not considered to be registered so would need to be covered by a REACH registration – see Article 15(2).

Does REACH apply to substances occurring in nature?

Yes. Only some naturally occurring chemicals are exempt from REACH registration if they have not been chemically modified. Naturally occurring substances that are classified as hazardous under the regulations will still require a Safety Data Sheet and may be subject to other controls. Substances occurring in nature are described in Article 3(39 & 40).

Are modified substances derived from substances listed in Annex IV also exempt from registration?

Modified substances are only exempt from registration if the modified substance is covered by the same EINECS registry number as the substance listed in Annex IV.

What is an intermediate?

An intermediate is a substance that is only used to make other substances. If the intermediate is handled under strictly controlled conditions and the substance that is manufactured from it is registered separately, the intermediate will not require a full registration dossier to be comply with REACH.

What is a SVHC?

A **S**ubstance of **V**ery **H**igh **C**oncern is identified by ECHA following consultation with interested parties. These are usually substances classified as CMRs (Carcinogen, Mutagen or Reproductive Toxicant) or vPvB (very Polluting, very Bio-accumulative) and have been entered on to a candidate list of substances that might need to be restricted or replaced. The current version of the candidate list of SVHCs can be found on the ECHA website using the link http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp in your web browser.

Are polymers included in REACH?

Polymers as such are exempt from REACH but monomers and additives contained are in scope of REACH. Monomers are the substances that form the repeated building blocks of the polymer and need to be registered by the respective manufacturer or importer. Additives that are used in polymers also need to be registered under REACH. The monomers and additives fall within scope of REACH if they are present in the polymer at greater than 2% by weight of the manufactured or imported polymer and make up more than one tonne per year of manufactured/imported polymer. Further guidance on Monomers and Polymers is available from ECHA via their website.

Are recovered or recycled substances within scope of REACH?

Waste is not within scope of REACH; however, substances that are recovered or recycled are within scope of REACH to the same extent as the pure substances. For example: solvents that are recovered from waste streams are outside the scope of REACH whilst they are classified as waste, but once extracted from the waste stream fall within scope and must be registered; polymer that is recycled remains outside the scope of REACH whilst it is classified as waste but when used in recovered articles, the monomers and additives used will need to have been registered.

Is Packaging covered by REACH?

Packages are articles within the REACH regulations. Manufacturers of packaging within the EEA are therefore downstream users. Imported Packaging would fall within scope of REACH and require registration of the substances used to make the packaging if they are imported in quantities of more than one tonne per year **and** the substances used are intended to be released from the packaging.

Import of Substances

What countries do the REACH regulations apply to?

The REACH regulations apply to the European Economic Area (EEA) which is comprised of the EU countries plus Norway, Iceland and Lichtenstein.

What are the REACH obligations on non-EEA companies?

REACH only applies within the EEA so that companies without a presence in the EEA cannot register substances on their own behalf. They can appoint an Only Representative within the EEA to undertake registration for them or the individual importer would need to ensure substances are registered. (internal use only)

Registration

Who has to register a substance?

The Manufacturer or Importer established in the EEA or an Only Representative of a non-EEA manufacturer has to register substances placed on to the market in quantities greater than 1 tonne per annum.

Which substances have to be registered under REACH?

All substances manufactured or imported in quantities of 1 tonne per annum will need to be registered unless covered by an exemption or already deemed to be registered under another regulation (e.g. Biocidal Products) – see Articles 2, 9, 15 & 24.

What are the registration deadlines?

All substances that were pre-registered are considered phase-in substances and were assigned a registration deadline. There are three registration deadlines based on production volumes and hazards.

Phase in registration deadline	Applicable substances
November 2010	<ul style="list-style-type: none"> • all phase-in substances >1000 tonnes/year • substances classified very toxic to aquatic organisms which may cause long term effects in the environment >100 tonnes/year • CMRs > 1 tonne/year
May 2013	<ul style="list-style-type: none"> • phase-in substances >100 tonnes/year
May 2018	<ul style="list-style-type: none"> • phase-in substances >1 tonne/year

How do I know if my product has been registered?

A portion of the registration number will be shown on the SDS to show that the substance has been registered within REACH, it will not show the identity of the registrant.

Authorizations

Are any substances you supply subject to authorizations?

No, the list of authorizations in Annex XIV has not included any of the substances that appeared on the candidate list as yet. These are still subject to review by ECHA and are expected to be revised and published early in 2011. As we become aware of authorizations and restrictions we will update this advice.

Information in the supply chain

Can I continue to use substances that were not (pre)-registered?

Substances can continue to be used, but they cannot be placed on the market. If substances are consumed within a process, they can continue to be used regardless of the registration status; if they are to be sold to a third party, then they must be (pre)-registered.

Does REACH require changes to Safety Data Sheets?

Yes; the requirement for SDS has been transferred into the REACH regulations under Articles 31 & 32, with the guidance for production of SDS being written in to Annex II. The requirements have been adapted slightly to incorporate REACH registration numbers (when available), Exposure Scenarios included in an annex (when required) and additional information to enable the exposures for use to be calculated. It also requires Risk Management Measures to be described.

Are Safety Data Sheets required for all products?

REACH only demands an SDS is produced in the appropriate format where substances are classified as dangerous under the Classification, Labelling and Packaging regulations (CLP). Materials that are not classified as dangerous, once the classification has been established do not require the generation and issue of SDS and Exposure Scenarios in the prescribed formats. However, Univar has a policy of producing and issuing a SDS for all its chemical products even when not classified as dangerous. Low hazard SDS do not include full use and exposure details but will in future carry a statement to indicate that these are not required.

Are CLP changes included in the REACH regulations?

The Classification, Labelling and Packaging regulations are separate regulations but are referenced within the REACH regulations. The CLP changes have to be implemented for pure substances by 1.12.2010 and for mixtures by 1.6.2015. Univar has already updated its SDS for substances to take these classification changes into consideration.

How soon do the changes to SDS have to be re-issued?

Where new information that affects the safe use of the product is included on the SDS, this needs to be communicated to customers 'without delay'; where the re-formatting does not affect the use, the changes can be included at the next scheduled SDS re-issue. The addition of a registration number included on a Safety Data Sheet does not in itself require an immediate re-issue; a change in classification, the addition of an exposure scenario that details changes in use or risk management measures would require communication without delay. This would be automatically sent to existing Univar customers.

Downstream Users

What do I have to do when I receive an extended Safety Data Sheet?

The new eSDS details risk management measures and operational conditions that you will need to follow. If the material supplied is used in a preparation that you send on to other users, the appropriate risk management measures and operational conditions will need to be included in your SDS.

What if my use is not covered on the extended Safety Data Sheet?

You will need to either:

- discuss with your supplier (Univar) what options are available to register your use;
- adapt your use to conform with the uses described on the eSDS; or

- perform your own safety assessment and register the use directly with ECHA

Refer to Articles 37, 38 and 39 of the REACH regulations for further advice.

What should I do if the substance I use is on the Candidate List (SVHC)?

Substances of very high concern on the candidate list just signify that they are being considered for authorization or restrictions. Whilst they appear on the candidate list, you can continue to use the substance in your application. However, it might be prudent to explore options for replacing the substance in your application. If you find that you cannot replace the substance in your application you may need to speak to your supplier to discuss further options.

How do SVHCs progress to the Authorizations list?

The Candidate List of Substances of Very High Concern is a preliminary stage in Authorization and Restriction. Substances on the Candidate List are reviewed by Member States and where it is considered necessary to restrict the uses of these substances a technical decision on how and when these substances are to be restricted is agreed with ECHA. These substances will then be transferred to the list in Annex XIV of the REACH regulations where details of Authorizations and Restrictions are given together with dates for withdrawal (sunset dates) from non-authorized uses.

What if I do not receive an extended Safety Data Sheet?

Extended Safety Data Sheets will only be issued for hazardous substances that are manufactured or imported in quantities greater than 10 tonnes per annum. If the material you purchase is not classified as a hazardous substance at all, you can continue to use the substances in your processes in the same way that you currently do and will not need an ESDS. If the material you purchase is classified as hazardous, you need to check if it is a single substance or a preparation, this will be identified in section 3 of the SDS; if a mixture the components will be registered separately but may not need registration until 2013 or 2018, if a substance it may not be subject to the registration requirements until a later date, but you can check with your local Univar sales office for confirmation.