REACH 101 – A basic overview of REACH.

What is REACH?

REACH is an acronym for an EU Regulation entitled **R**egistration, **E**valuation and **A**uthorization of **Ch**emicals. REACH came into force in 2007 and replaced a patchwork of pre-existing legislation.

The key elements of REACH are:

- **Registration** - At the core of REACH is a registration requirement. Do you export 1 ton or more/year of a substance into the EU? If yes, then your substance must be registered, unless specifically exempted by the legislation. Registration involves submitting a standardized dossier of information about that substance to the European Chemicals Agency (ECHA). A registration dossier consists of a standard data set for that substance. Amongst other things, manufacturers/importers are responsible for communicating risks, hazards and safe usage practices with downstream users. If your substances are not registered then the data on them will not be available. As a result, you will no longer be able to manufacture or supply them legally - no data, no market! Companies have until 2018 to register, with deadlines depending on the tonnages they place on the EU market (see below).

  Late Pre-registration - Pre-registration of substances that were already on the market, so-called phase-in substances, ended 1 December 2008. As the deadline has passed the only pre-registration possibility that remains is late pre-registration. You may be eligible for late pre-registration if you meet certain criteria. For detailed information on late pre-registration click here.

- **Evaluation** – Once a Registration dossier has been submitted, ECHA checks compliance (dossier evaluation). Member States Competent Authorities also evaluate the substances to determine whether or not the substance should require authorization or restriction (substance evaluation).

- **Authorization** – REACH introduces an authorization procedure for the most dangerous substances. Member States and ECHA will nominate **S**ubstances of **V**ery **H**igh **C**oncern (SVHCs) to be placed on a list of substances that are candidates for authorization, the so-called Candidate List. Once on the Candidate List the substances may be placed on the List of Substances Subject to Authorization (Annex XIV of REACH). If listed in Annex XIV, the substances cannot be placed on the market or used after a date to be set (the so-called "sunset date") unless the company is granted an authorization for use of the substance by the European Commission. The Candidate list is published by ECHA on the ECHA website.
- **Restriction** –REACH maintains the existing restrictions system. Certain substances may be restricted or banned at EU level. Check REACH Annex XVII to comply with these provisions.

Why was REACH enacted?

REACH aims to (i) ensure a high level of protection for human health and the environment (ii) make the people who place chemicals on the EU market responsible for understanding and managing the risks associated with their use and (iii) promote the use of alternative, i.e. greener/safer chemicals.

What does REACH apply to?

REACH applies to substances manufactured or imported into the EU in quantities of 1 ton per year or more. REACH **registration requirements** apply to:

- *Substances* – any chemical element and its compounds. For example, acetone, copper sulfate.
- *Preparations* – mixtures or solutions of two or more substances in preparations. For example, paints, adhesives and dyes.
- *Substances that are intended to be released from articles (products)* – If your article contains a substance that is intended for release and the following conditions are met, then the article must be registered (Article 7):
    - The substances are intended to be released from the produced or imported article(s) during normal and reasonable foreseeable conditions of use
    - The total amount of the substance present in the articles with intended releases produced and/or imported by that actor exceeds 1 ton per year per producer or importer.

For assistance on how to calculate tonnages, please see the Guidance on Articles.

REACH also contains the following requirements that apply to Articles that contain SVHCs:

- *Notification Requirement:* ECHA must be notified if an article contains a substance listed on the Candidate list and the conditions in Article 7 (2) are met. To see the exceptions to this rule and learn more please see section 2.2 of the Guidance Document on Articles.

- *Duty to Inform:* If an article contains an SVHC on the candidate list there is an automatic duty to inform the recipient of the article (Article 33). This information includes the name of the substance and information of the safe usage of the article. For more information please see section 2.3 of the Guidance Document on Articles.

Other substances have tailored REACH provisions as long they are used in specified conditions:

- Substances used for research & development
- Polymers (although a monomer present in a polymer at a concentrations greater than 2% must be registered) For more information on polymers go to ECHA's ECHA Guidance Documents Guidance for monomers and polymers.

REACH does NOT apply (because of exemption or exclusion) to:

- Radioactive substances
- Substances under customs supervision
- The transport of substances
- Non-isolated intermediaries
- Waste
- Uses regulated by more specific legislation. For example, human and veterinary medicine, food and foodstuff additives, plant protection products and biocides.
- Substances in Annex IV/V – REACH has several Annexes, or attachments, that include tables or lists. Annex IV/V contains substances that are deemed to be safe.

Who is impacted by REACH?

Every actor in the supply chain is impacted by REACH. For US exporters, the role of manufacturer or importer is most relevant and explained below. If you are uncertain about your REACH role and obligations, ECHA has developed a tool, called the REACH Navigator to help you.

Important for US Exporters! If you export 1 ton or more/year of a substance into the EU then your substance must be registered. However, natural or legal persons that manufacture substances formulate preparations or produce articles outside the EU cannot themselves register a substance(s). In order to access the EU market, US companies exporting into Europe have the following three options:

1. Register through an EU subsidiary – If your company has an EU based subsidiary fulfilling the requirements for legal entity in the EU Member State of its location or registration, then the EU subsidiary may register.
2. Register through an EU importer – the legal entity that is responsible for placing your product on the EU market is the EU importer. It may register all relevant substances with ECHA.
3. Register through a so-called '**Only Representative'** – An Only Representative is a legal entity established in the EU contracted to register the imported substances with ECHA. The Only Representative is fully liable for fulfilling all obligations of importers for the substances they are responsible for as a registrant. The Foreign Commercial Service at the US Mission to the EU provides a list of Only Representatives.

For more information on how to register substances go to ECHA's Fact Sheet on Registration.

When do I have to act?

Deadline	Industry's Key Obligations
From 1 June 2008	Registration of new/non-phase in chemicals (not listed on the EU inventories ELINCS and EINECS.
From 28 October 2008	Duty to Inform applies (see above).
December 1, 2008	Pre-registration closed. For late-preregistration possibilities see above.
January 2009	SIEF formation (substance exchange information fora) for data sharing and joint registrations.
November 30 2010	Registration deadline for substances classified as **C**arcinogenic **M**utagenic or toxic to **R**eproduction (CMRs) 1 and 2 above 1 ton/ year/ manufacturer, substances classified as very toxic to aquatic organisms above 100 t/year/ manufacturer and substances as such, in preparations (mixtures) or intended to be released from articles (finished products) in quantities above 1000 t/year/manufacturer.
From 1 December 2010	Notification of classification and labeling of substances, including below 1 ton, to ECHA. A classification and labeling inventory will be maintained by ECHA and made public.
1 December 2013	Pre-registered substances with volumes of over **100 tons/year** must be registered.
1 December 2018:	Pre-registered substances with volumes of over **1 ton/year** must be registered.