An tÚdarás Sláinte agus Sábháilteachta
Health and Safety Authority

Version 2: September 2022

Guide for new importers of chemicals that are regulated by the REACH Regulation

Under the REACH and CLP Regulations, an 'EU importer' is a legal entity established in the EU/EEA (EU Member States including Northern Ireland plus the EEA countries Iceland, Norway and Lichtenstein) who is responsible for the physical introduction of chemical products into the customs territory of the EU/EEA. Irish companies importing chemical products from suppliers based in non-EU/EEA countries, for example Great Britain, Switzerland, Turkey, USA and China, are 'EU Importers', whereas Irish companies sourcing chemical products from an EU/EEA-based company, e.g. France, Spain, are not considered the EU importer. It is important to note that since the withdrawal of the UK from the EU on 1 January 2021, many Irish companies that were once distributors or downstream users are now EU importers with added legal responsibilities. In order to determine whether you are an EU importer for any substance, on its own or in a mixture, the following steps should be taken:

Step 1: Assemble and keep information on the chemical products you procure, as legally required under Article 36 of REACH (EU) No 1907/2006. Keep this information for at least 10 years after the product was last imported, supplied or used. This information may be requested by the Authority or the European Chemicals Agency (ECHA).

- Make a list of all chemical products that you procure, identifying the name and location of the supplier(s). A sample list or inventory for companies is available in link.
- Identify your role in the supply chain for each chemical product
- For products imported from outside the EU/EEA, determine the tonnes per annum for the substance(s) or for the substances in the mixture(s):
    - The tonnes per annum of a pure substance imported from outside the EU/EEA will be equal the total tonnage of the imported product
    - The tonnes per annum of the substances in a mixture imported from outside the EU/EEA must be calculated using the composition outlined in Section 3.2 of the safety data sheet. Where the safety data sheet provides only a concentration range for a substance, the upper range of the limit must be used to calculate annual tonnage. See sample inventory for your information/guidance

- If the same substance is contained in multiple imported products, the tonnage for that substance is calculated based on the cumulative tonnage in all imported products in the calendar year

Step 2: Establish and maintain documentary evidence of the REACH registration status of each substance, on its own or in mixtures, imported from a non-EU/EEA supplier at one tonne or more per annum. Where no REACH registration is in place for a substance, you as the EU importer must register with the European Chemicals Agency (ECHA) **before** importing volumes of one tonne or more per annum. If a substance is not REACH registered, it is illegal to import it and place it on the Irish market at volumes of one tonne or more per year. There are some exemptions from the obligation to register for certain substances listed in Annexes IV and V of REACH or substances covered by other legislation, such as foods and medicines.

For an Irish company with a non-EU/EEA supplier in Great Britain (England, Scotland or Wales) who was not the EU importer prior to 1 January 2021, check whether your supplier has taken any of the below steps to ensure your continued compliance with REACH and ensure that as the EU importer, you have documentation to demonstrate compliance.

1) Your supplier transferred their REACH registration(s) to an EU/EEA legal entity that meets the definition of a supplier under the REACH Regulation i.e. a manufacturer, importer, downstream user or distributor placing on the market a substance on its own or in a mixture, and your purchasing and/or delivery documentation relates to this EU/EEA company or
2) Your supplier appointed an EU/EEA-based only representative (OR) (only possible for non-EU/EEA manufacturers or formulators) and you have written confirmation from that OR that your imported tonnage is covered under the arrangement, or
3) Your supplier sources all substances used in the formulation of mixtures supplied to you from an EU/EEA registrant (thus allowing you to rely on the exemption for re-imported substances under article 2(7)(c) of REACH) and you have documentation to demonstrate this in line with ECHA Q&A 1076

Alternatively,

4) You must register any imported substance(s) on its own or in a mixture, with ECHA **before** importing one tonne or more per annum or
5) You must source the substance from an EU/EEA supplier who has a REACH registration in place

Step 3: Regardless of your REACH registration duties, as an EU importer, you must also meet all regulatory obligations including the below non-exhaustive list:

- Provide a REACH-compliant safety data sheet (SDS) (as required under Article 31 REACH) to distributors and industrial and professional customers in your supply chain. A hard copy or a direct link to the SDS must be provided at first sale/supply and following any updates to the SDS. ☐
- Ensure the SDS lists the EU supplier information in Section 1 (as required under Annex II REACH), that the SDS is relevant to the Irish market (e.g. NPIC number, Irish OELVs) and complies with the general requirements of Annex II as amended. The supplier is the EU/EEA-based manufacturer, importer, downstream user or distributor placing on the market a substance on its own or in a mixture. A legal entity with no clear and active role in the supply chain may not be listed as the product supplier. The non-EU/EEA supplier details may not be included in the SDS, with the exception of the non-EU/EEA manufacturer or formulator who has appointed an OR. ☐
- Check that the hazard label where needed (as required under Article 17 of the CLP Regulation), includes the name, address and contact details of an EU/EEA-based manufacturer, importer, downstream user or distributor and corresponds to the information in Section 2.2 of the SDS. The non-EU/EEA supplier details may be mentioned in 'supplemental information' on the label, see ECHA Q&A 1808. ☐
- Notify hazardous substances to the Classification and Labeling inventory (as required under Article 40 CLP) maintained by ECHA within one month of importing or placing that substance on the market regardless of the tonnage imported. This obligation is specified in Article 40 CLP, however a substance need not be notified to ECHA by importers who have submitted a REACH registration for that substance. ☐
- Notify mixtures that are placed on the Irish market and have a physical and/or human health hazard (but not environment hazard alone) to the National Poisons Information Centre (NPIC) (as required under Article 45 CLP) and include their emergency contact number in Section 1.4 of the SDS ☐
- Ensure that where a hazardous mixture is intended to be sold to the general public and requires a child-resistant fastening and/or tactile warning of danger, it is packaged as such as required under Article 35 CLP ☐
- Check if any substances in the mixtures you place on the market are listed on the Authorisation list (Article 56 & Annex XIV REACH) or Restriction list of REACH (Article 67 & Annex XVII REACH), or if any substances in the articles you place on the market are listed on the Candidate List of REACH (Article 33 REACH), and ensure compliance with any additional obligations required as a result of their listing ☐

- Hazardous substances or mixtures sold on-line to the general public must list the hazard statements according to CLP in the text of the online advertisement or include a readable image of the hazard label in accordance with Article 48 CLP.

If you have any questions in relation to your obligations as listed above, please find resources available at www.hsa.ie/chemicals and www.echa.europa.eu, or contact our chemicals helpdesk at chemicals@hsa.ie.