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

Under the REACH Regulation ((EU) No. 1907/2006), 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 non-EU/EEA countries such as Great Britain, Switzerland, Turkey, USA and China are 'EU Importers', whereas Irish companies sourcing chemical products from an EU/EEA-based company are not considered the EU importer.

In order to determine whether you are an EU importer for any chemical substance, on its own or in a mixture, that is regulated under REACH the following steps should be taken:

Step 1: Assemble and keep information on the chemical products you procure, as legally required by Art 36 of REACH. 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 <u>European</u> <u>Chemicals Agency</u> (ECHA).

You may meet this obligation in whatever way you see fit, ensuring clarity for inspection purposes. See attached sample <u>inventory</u> for your information/guidance.

- Make a list of all chemical products that you procure, identifying the name and location of the supplier(s)
- Identify your <u>role in the supply chain</u> 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 is used to calculate annual tonnage
- 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: An Irish company that imports one tonne or more of any substance on its own or in a mixture per annum, must register the import with ECHA. There are some <u>exemptions</u> 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. However, in the absence of a valid REACH registration, substances required to be registered cannot legally be imported and/or placed on the EU/EEA market. Due to the withdrawal of the UK from the EU, many Irish companies sourcing chemicals from Great Britain that were once distributors or users are now considered EU importers.

You may not have been an EU importer prior to 2021, however, if you are importing a substance on its own or in a mixture at one tonne or more per year from Great Britain (GB) (England, Scotland and Wales) since 1st January 2021, you need to check whether your GB supplier:

- transferred their REACH registration to an EU/EEA legal entity before the end of March 2021, or
- appointed an EU/EEA-based only representative (OR) and your tonnage is covered under that OR arrangement, or
- sources substances from an EU/EEA registrant (thus allowing you to rely on the exemption for re-imported substances under article 2(7)(c) of REACH)

Contact your supplier to determine whether they have appointed an <u>only representative</u> (OR), transferred their registration to an EU/EEA entity or whether they formulate mixtures sourced from an EU/EEA supplier.

- ✓ If the answer is yes to any of the above, then you have no registration requirements. However, you must keep all information demonstrating compliance with the duties under the REACH Regulation.
- If an OR has not been appointed, or if your GB supplier does not meet the above conditions and you are importing one tonne or more per annum, you may potentially have registration duties and have the following options:
 - Register the imported substance(s) (no placing on market/use of substance until registration complete)
 - Discontinue supply from non-EU/EEA based company and source chemical(s) from another EU/EEA supplier who has a REACH registration in place.

If you are in any doubt of your obligations, contact the chemicals helpdesk for advice at <u>chemicals@hsa.ie.</u>

Step 3: Regardless of your REACH registration duties, as an EU importer, you must also meet the below list of other REACH and CLP Regulation (EU) No 1272/2008 obligations:

- Provide a REACH-compliant <u>safety data sheet</u> (SDS) to distributors, as well as industrial and professional customers in your supply chain as required under Article 31 REACH. A hard copy or a direct link to the SDS must be provided at first sale/supply and following any updates to the SDS.
- 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 <u>National Poisons Information</u> <u>Centre</u> (NPIC), as required under Article 45 CLP. Ensure the NPIC emergency contact number is included in Section 1.4 of the SDS.
- Ensure the SDS lists the EU/EEA supplier information in Section 1, that the SDS is relevant to the Irish market (i.e. NPIC emergency number, Irish OELVs) and complies with the general requirements of Annex II REACH as amended.
- Check that the <u>hazard label</u> where needed in accordance with Article 17 CLP, includes the name, address and contact details of the EU/EEA-based supplier and corresponds to the information in Section 2.2 of the SDS. The UK supplier details may be mentioned in 'supplemental information' on the label, see ECHA Q&A <u>1808</u>.
- Notify hazardous substances to the <u>Classification and Labelling inventory</u> 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.
- Ensure that where a hazardous mixture is intended to be sold to the general public and requires a <u>child-resistant fastening and/or tactile warning of danger</u>, 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 <u>Authorisation list</u> (Article 56 & Annex XIV REACH) or <u>Restriction list of REACH</u> (Article 67 & Annex XVII REACH), or if any substances in the articles you place on the market are listed on the <u>Candidate List</u> (Article 33 REACH), and ensure compliance with any additional obligations required as a result of their listing
- <u>Hazardous substances or mixtures sold on-line</u> 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 <u>www.hsa.ie/chemicals</u> and <u>www.echa.europa.eu</u>, or contact our chemicals helpdesk at <u>chemicals@hsa.ie</u>.