Notification of hazardous chemical products to the National Poisons Information Centre in Ireland

Background

Under Annex VIII to the CLP Regulation, importers and downstream users (formulators) placing mixtures classified as hazardous for human health or physical effects on the EU market must provide specific information on these mixtures to appointed bodies. In Ireland, the National Poisons Information Centre (NPIC), Beaumont Hospital is the responsible body appointed for receipt of information in accordance with CLP Article 45(1).

As of January 2021, the EU has harmonised the information requirements and the information now needs to be prepared in an EU-harmonised Poison Centres Notification (PCN) format.

Is there a transition period?

Yes, different dates of applicability are as follows:

- 1 January 2021: Consumer & professional use
- 1 January 2024: Industrial uses only
- 1 January 2025: End of transition

Notifications made directly to the NPIC before the relevant compliance date remain valid until 1st January 2025, unless changes are made to the product. If a change if made to the product during the transition period, compliance with the harmonised information obligations will be required before the changed product is placed on the market.

At the end of the transition period, all mixtures classified for health or physical effects will be required to comply with the requirements of Annex VIII.

What is the notification procedure in Ireland?

The information on mixtures for consumer, professional or industrial use must be prepared in the EU-harmonised PCN format and submitted to the NPIC via the European Chemicals Agency (ECHA) PCN submission portal (https://poisoncentres.echa.europa.eu/tools).

What chemical products should be notified?

A chemical product must be notified when all of the following conditions are met:

- ✓ It is a **mixture**, as defined by CLP Article 2(8): 'a mixture or solution composed of two or more substances'; and
- ✓ It is **classified as hazardous** on the basis of its health or physical effects; and
- ✓ It is **placed on the Irish market;** CLP Article 2(18) defines placing on the market *as 'supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market'.*

January 2024

Who needs to notify?

The EU importer or the downstream user (formulator) within the EU who places the mixture on the Irish market is responsible for notification. However, in accordance with article 4(10) of CLP, all operators in the supply chain have an obligation to ensure they place compliant mixtures on the market. This means that distributors (in particular re-branders/re-labellers or companies distributing a mixture in another Member State) may need to submit a notification, if the relevant information is not included in their supplier's notification.

What information needs to be notified?

- Name, address, contact details of the notifier
- Trade name(s) of the mixture, and if appropriate, brand names or other names as per the label
- Packaging type and size; size meaning the nominal weight/volume of the packaging
- Product category in accordance with the harmonised European product categorisation system (EuPCS). The category should match the main intended use of the product e.g. 'detergent'
- Unique formula identifier (UFI); Sixteen alpha-numerical product specific code generated by the UFI generator https://poisoncentres.echa.europa.eu/ufi-generator. This code must be affixed to the label
- Human health and/or physical hazards classification. The submission of hazard pictogram(s), signal word, hazard statement(s), supplemental hazard information and precautionary statements is required
- Toxicological information; overview of likely exposure to the mixture (as per section 11 of the SDS)
- Information on physico-chemical properties
- Full mixture composition, including all components, their concentrations in the mixture and classification. Components may be substances or mixtures in mixtures and there are specific rules regarding how they are identified and their concentrations reported

What tools are available to assist companies?

ECHA has developed IT tools, which can be accessed via the ECHA website https://poisoncentres.echa.europa.eu/tools, to support companies with the submission of information.

Do other EU poisons centres need to notified?

Yes, a submission must be made to the appointed body in each Member State where the mixture is placed on the market. The notification must be in the language of that Member State. The ECHA PCN submission portal supports the multi-country submission by dispatching the notification to the relevant appointed bodies.

Can UK companies notify products?

Companies established in Northern Ireland can use the ECHA submission portal to notify mixtures to be placed on the EU/EEA market. However, when placing mixtures on the Northern Ireland market, the UK national system should be used instead.

Mixture suppliers in Great Britain wishing to notify mixtures to be placed on the EU/EEA market have the option of moving their operations related to the mixture to a legal entity within the EU (who can be the formulator or the importer). Alternatively, they can support their EU customers by providing the necessary information to allow them to comply with the submission obligations.

Safety Data Sheets and Emergency Numbers:

In accordance with the provisions of Annex II of REACH, it is obligatory to include a poisons centre emergency number in Section 1.4 of a SDS, taking note of the following:

- ✓ It is permitted to include (in addition) an external emergency number, as appropriate

- ✓ The NPIC emergency number cannot be used in Section 1.4 of a SDS until the notification process, which includes the payment of an annual fee, is complete. See https://poisons.ie/industry-manufacturers/safety-data-sheets/ for details

- ✓ Where there is a delay in updating the SDS with the NPIC emergency number after the notification process is complete, it needs to be ensured that the additional emergency number listed in section 1.4, continues to operate effectively in English. If there are any limitations to its use, this should be clearly stated in the SDS, until such time as the SDS is updated with the NPIC number

- ✓ When placing hazardous chemical products on the market in other EU Member States, the respective poisons centre/appointed body number, where established, is required to be included in Section 1.4 of the SDS. The poisons centre number in one EU Member State may not be used for other Member States.

Annex II of REACH: "*References to emergency information services shall be provided. If an official advisory body exists in the Member State where the substance or mixture is placed on the market (this may be the body responsible for receiving information relating to health referred to in Article 45 of Regulation (EC) No 1272/2008), its telephone number shall be given and can suffice".*

ECHA guidance on the compilation of SDSs: *The supplier must provide a reference to emergency information services. If an official advisory body as defined in the legal text above exists reference to it must be made. Otherwise (or in addition) reference to an emergency service belonging to the supplier himself or to a competent third party provider of such a service must be made. Where the supplier provides his own emergency information service, be it alone or in combination with an official advisory body or other provider, the necessary competence should be available".*

Further information:

NPIC website

ECHA Poison Centres website

ECHA Guidance on harmonised information relating to emergency health response – Annex VIII to CLP

ECHA Poison centre notifications PCN: a practical guide

EU Appointed Bodies

EU National Helpdesks