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

Background: Importers and formulators of hazardous chemical products, placed on the Irish market, must notify certain information about the products to the National Poisons Information Centre (NPIC), Beaumont Hospital, as the responsible body appointed in Ireland [i]for receipt of information in accordance with CLP Article 45(1). In addition, where the notified product requires a Safety Data Sheet (SDS), the importer or formulator must include the NPIC emergency telephone number in Section 1.4 of the SDS. This is explained in more detail below.

What chemicals products should be notified? A chemical product must be notified to the poisons centre in Ireland when all of the following conditions are met:

- ✓ ***It is a mixture,*** as defined by CLP Article 2(8) [ii]: '*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,* as stated in CLP Article 45(1) ; and Annex VIII, Part A, Section 2.2; 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."*

Who needs to notify? It is the importer of a chemical product (mixture) into the EU or the formulator of a chemical product within the EU, placing them on the Irish market that is responsible for notification to the poisons centre. Nevertheless, all operators in the supply chain have the obligation to make sure they place on the market mixtures which are in compliance with CLP as a whole , as stated in article 4(10). This means that distributors (in particular rebranders/relabellers or companies distributing a mixture in another Member State) may need to submit themselves if the relevant information is not included in a submission made by the supplier. See also ECHA FAQs https://poisoncentres.echa.europa.eu/questions-and-answers

What information needs to be notified? The information requirements for mixtures intended for **consumer or professional use** are described in Annex VIII to the CLP regulation and ECHA guidance on Annex VIII. The information requirements for mixtures intended for **industrial use only** are set out on the NPIC website http://www.poisons.ie/Manufacturers/Product-Registration.

Note that if your mixture for industrial use is reformulated further down in the supply chain and ends up in a consumer or professional use product, you will need to respect the earliest compliance date for consumer/ professional use.

Where is the notification sent to?

From 1st January 2021 notifications for mixtures for consumer use or professional use must be submitted to the ECHA submission portal. The Poisons Centre Notification (PCN) format and tools, along with Q&A's are

available on the ECHA website, along with the Unique Formula Identifier (UFI) generator. Further information is available at https://poisoncentres.echa.europa.eu/home.

Industrial products can be notified directly to the NPIC at Beaumont Hospital or alternatively to the ECHA submission portal. Notifications sent directly to the NPIC must use the NPIC Product Registration Form. The NPIC cannot accept xml files directly. Further information is available at https://www.poisons.ie/Manufacturers.

Will the information to poisons centres be harmonised? Yes it will; in accordance with CLP Article 45(4), Annex VIII '*harmonising information relating to emergency health response'* [iii] was added to CLP in March 2017 and amended in 2019[iv] and 2020[v]. The legal obligation for submission using this new harmonised format applies to products for consumer or professional use from 1st January 2021 and will apply to productsfor industrial use from 1st January 2024. Note that if your mixture for industrial use is reformulated further down in the supply chain and ends up in a consumer or professional use product, you will need to respect the earliest compliance date for consumer/ professional use. Further information is available at https://poisoncentres.echa.europa.eu/home and the ECHA guidance on Annex VIII (dated May 2020).

Is there a transition period? Yes, if you have existing mixtures on the market and notified them to the NPIC by 31st December 2020, you may benefit from a transition period which ends on 1st January 2025. However, if you make a change to such mixtures during the transition period, you will need to comply with the harmonised information obligations, before you place the changed mixture on the market. Ultimately, after 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. Further information is available at https://poisoncentres.echa.europa.eu/home and the ECHA guidance on Annex VIII (dated May 2020).

Do I need to notify other EU poisons centres? Yes, when a hazardous chemical product is placed on the market in another EU Member State it also requires notification to the poisons centre of that Member State, where established. There is a list of European Poisons Centres available at the following link

> ***CLP Article 45 states:*** *Member States shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, in accordance with Article 24*

Will the obligations to notify hazardous mixtures apply to downstream users and importers based in Northern Ireland? Yes, if they intend to place those mixtures on the EU/EEA market, or Northern Ireland. CLP applies to and in the United Kingdom in respect of Northern Ireland.

CLP does not apply in other parts of the United Kingdom ('Great Britain'). [v] Therefore, the obligations under Article 45 and Annex VIII will not apply to companies based in Northern Ireland if they intend to place a hazardous mixture on the market of Great Britain.

Can UK companies notify products after 1st January 2021?

Companies established in Northern Ireland will be able to 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 will have to 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.

More detailed information on the UK withdrawal from the EU can be found here.

Safety Data Sheets and Emergency Numbers: In accordance with the provisions of Annex II of REACH[vii], it is obligatory to include a poisons centre emergency number in Section 1.4 of an SDS, taking note of the following:

- ✓ Any chemical product that meets the provisions outlined above should be notified to the poisons centre in Ireland and the associated safety data sheet for that chemical product should include the NPIC emergency contact number.

- ✓ 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 an SDS until the notification process, which includes the payment of an annual fee, is complete. The notification process is explained on the NPIC website http://www.poisons.ie/Manufacturers/Product-Registration

- ✓ Where there is a delay in updating the SDS with the NPIC emergency number after the notification process is complete, the company needs to ensure that the additional emergency number, currently 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. Further information is available on the ECHA website under the National Helpdesk contact details. The poisons centre number in one EU Member State may not be used for other Member States.

Annex II of REACH states: "*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 states: *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".*

References

[i] http://www.hsa.ie/eng/Legislation/Acts/Chemicals_Acts_2008_and_2010_and_the_Guide/

[ii] CLP Regulation 1272/2008

[iii] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0542

[iv] https://ec.europa.eu/transparency/regdoc/rep/3/2019/EN/C-2019-7611-F1-EN-MAIN-PART-1.PDF

[v]https://eur-lex.europa.eu/eli/reg_del/2020/1677/oj

[v] https://www.hsa.ie/eng/topics/brexit/clp/

[vii] REACH Regulation 1907/2006