

HAZARD WARNING

Poison Centre notification has arrived. Elaine Campling breaks down compliance and definitions related to the submission of information on hazardous mixtures



Elaine Campling is Chair of ESMA's Health, Safety & Environmental Protection Committee

The first compliance date to submit information on hazardous mixtures (for health and physical effects) in a harmonised format, in accordance with Article 45 and Annex VIII of the CLP Regulation, so called Poison Centre Notification (PCN) has already come into force:

- 1 January 2021 for consumer and professional use
- 1 January 2024 for industrial use
- 1 January 2025 for hazardous mixtures already notified (see below)

Article 45 applies to **downstream users and importers** placing hazardous mixtures on the market in the European Economic Area (the Community) i.e. Member States of the European Union (EU) and Norway, Iceland and Liechtenstein.

WHO IS OBLIGATED?

To understand who is obligated, it is useful to review the downstream user and importer definitions and explore downstream user activities.

A downstream user is: any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities (Article 2, CLP).



Different types of downstream user activity include the following:

- Formulators that produce mixtures, which are usually supplied further downstream e.g. printing inks;
- End users who use substances or mixtures but do not supply them further downstream e.g. coatings and inks, cleaning materials and solvents;
- Article producers who incorporate substances or mixtures into or onto materials to form an article e.g. textiles, industrial equipment, household appliances and vehicles;

"Distributors who only store and distribute the chemicals are not downstream users unless they come in contact with the chemical by transferring or diluting it"

- Re-fillers that transfer substances or mixtures from one container to another, generally in the course of repackaging or re-branding.

Distributors who only store and distribute the chemicals are not downstream users unless they come in contact with the chemical by transferring or diluting it. Consumers who use chemicals are not downstream users.

An Importer is: any natural or legal person established within the Community who is responsible for import, where the latter means the physical introduction into the customs territory of the Community (Article 2, CLP).

The submission of information on hazardous mixtures for consumer and professional use is

"The importer will need to state that the hazardous mixture is 100% composition of the 'already notified' mixture"

being undertaken by organisations that are less likely to be familiar with EU regulatory processes. Some organisations will not realise their responsibilities and may not have the resource capability or experience to manage them. Many companies will find themselves obligated by virtue of import from non-EU countries. It is therefore useful to explore the available options that may help to reduce the impact of the requirements.

NOTIFICATION VIA THE ECHA PORTAL

The information required by Annex VIII must be made available to the relevant appointed body in each Member State (MS) where the hazardous mixture is placed on the market. However, for supplies to multiple markets, a single or reduced number of submissions may

only be required, if notification is made via the central European Chemical Agency (ECHA) portal.

It is important to specify all MS where the hazardous mixture may be placed on the market when making the submission, to avoid obligation for further notification within the supply chain.

MIXTURES ALREADY NOTIFIED

Hazardous mixtures that were previously notified to individual MS prior to commencement of Annex VIII will not be required to be re-notified in the harmonised

format until 1 January 2025, providing there is no change in the mixture composition, product identifier or toxicological properties set out in Part B, Section 4.1 of Annex VIII.

If there is any relevant change in mixture composition, product identifier or toxicological properties during the transitional period, the duty holder must submit a PCN in accordance with Annex VIII.

REDUCED SUBMISSION, INDUSTRIAL USE MIXTURES

A reduced submission can be made for hazardous mixtures that are placed on the market for industrial use only, which may be limited to the information contained in the

safety data sheet. However, a 24-hour telephone number that is accessible seven days a week in the language accepted by the specific MS must be provided, to obtain compositional information for the purposes of emergency response.

HOW NON-EU BASED COMPANIES CAN SUPPORT THEIR CUSTOMERS WITH PCN

The first Annex VIII deadline also coincides with the first day of the new relationship between the United Kingdom and the EU/EEA. Northern Ireland is governed by EU Regulation in accordance with the Northern Ireland Protocol. Companies located in Northern Ireland are therefore able and obligated to submit a PCN for hazardous mixtures in accordance with Annex VIII.

Non-EU companies including those located in Great Britain (GB) i.e. England, Scotland and Wales are not obligated to submit PCN. Furthermore, notifications already undertaken by GB companies prior to the UK departure from the European Union will no longer have legal validity, though they will remain in the ECHA system.

Although obligated, importers will not be able to complete PCN in the required format without full product information. A number of options are available to non-EU suppliers that may be reluctant to share product composition due to commercial sensitivity, or who wish to support their importing customers with PCN.

Non-EU companies with a European legal entity will be able to undertake the required notifications on behalf of their importing customers. It is also possible to appoint an organisation located in the EU to undertake the required notifications to support importers. Importers will still be required to notify, but this can be limited by referring to the upstream notification made by the European based company acting on behalf of the non-EU supplier. The importer will need to state that the hazardous mixture is 100% composition of the 'already notified' mixture.

There is another option for non-EU suppliers to assist their customers via allocated access within the ECHA account of the importing company. Once the account is opened, the importing company can provide access to a 'foreign user' to submit the PCN on their behalf.

A third-party user can work in much the same way as a user within the company. Consultants or mother companies can be appointed as foreign users, logging in under one account and switching between one or more accounts that they are appointed to (foreign users can work for multiple companies).

FINAL WORD

It will be far less burdensome for importing companies to notify hazardous mixtures for industrial use, since full compositional information is not required. Non-EU companies can support the requirement to provide a 24-hour emergency telephone number for rapid access to full compositional information. ■

Elaine Campling is Director of Chemical Compliance Advisory Services and Chair of ESMA's Health, Safety & Environmental Protection Committee

Further reading:

Downstream users – ECHA (www.europa.eu)

The list of Member States accepting notifications via the ECHA portal is available here:

<https://poisoncentres.echa.europa.eu/echa-submission-portal>

A list of national appointed bodies is available at the ECHA Poison Centre website:

<https://poisoncentres.echa.europa.eu/>

Further information:

email: info@chemadvisory.com

web: www.chemadvisory.com / www.esma.com

SPECIALIST
printing
WORLDWIDE



For subscriptions, to order future copies or to download highlights from this issue, visit www.specialistprinting.com



Marabu

COLORS MADE FOR LIFE

SCREEN · DIGITAL · PAD

MARABU DIGITAL PRINTING INKS AS A RELIABLE ALTERNATIVE

Developed and produced under the strict tolerances of OEM printing inks, Marabu Switch It products offer improved performance with simultaneous reduction of production costs.

Your link to ink: marabu-inks.com

