# ESSENTIALS OF HAZARDOUS MIXTURE NOTIFICATIONS

## Elaine Campling of ESMA, explains how time is running out to submit information to poison centres on hazardous mixtures for industrial use

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

The January 2024 deadline requiring the submission of emergency health information for hazardous mixtures, supplied to industrial users, is approaching. A requirement to submit information to national poison centres has been in place since the European Union (EU) Dangerous Preparations Directive (DPD) was introduced in 1999 (1999/45/EC).

***"The DPD was enacted as a 'directive' and not as a 'regulation'"***

The DPD preceded the CLP Regulation – Regulation (EC) No. 1272/2008 – on the classification, labelling and packaging of substances and mixtures. However, member states of the EU transposed the notification requirements in different ways under the DPD. This led to inconsistent systems being put in place as the DPD was enacted as a 'directive' and not a 'regulation.'

### THE DIFFERENCE

A regulation is a binding legislative act that must be applied in its entirety across the EU. It is not subject to interpretation and is therefore implemented consistently in all member states.

A directive is a legislative act that sets out the framework that all EU countries must follow. However, directives are subject to interpretation and, for this reason, are often transposed differently into national legislation by individual, member-state countries.

### HARMONISATION REQUIREMENTS

With enactment of the CLP Regulation, the European Commission reviewed existing poison centre, notification requirements. The aim was to achieve standardisation in a harmonised format.

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The review led to the enactment of Regulation (EU) 2017/542, amending CLP by adding Annex VIII. This addition sets out the requirements for the health-response information to be submitted to poison centres in a new, harmonised format. It also puts in place the establishment of a Unique Formula Identifier (UFI) for each hazardous mixture placed on the market. This UFI must be included on labels and safety data sheets, as specified. The UFI links the product on the market to the submitted formulation.

### SCOPE

The requirements apply to suppliers (including importers) of mixtures placed on the market that are classified for either physical or health hazards.

It does not apply to mixtures classified only for hazards to the environment, or the following exempt product-mixture categories:

- radioactive
- subject to customs supervision
- used in scientific research and development
- medicinal, veterinary and cosmetic products, medical devices and food and feeding stuffs
- only classified as gases under pressure and explosives

### TIMELINE

The following deadlines were put in place:

- consumer use – 1 January 2021 (delayed from 1 January 2020)
- professional use – 1 January 2021
- industrial use – 1 January 2024

There is one remaining transitional deadline – 1 January 2025 – for mixtures already notified to poison centres, pre-Annex VIII, that have not been modified since the original notification.

### ECHA SUBMISSION PORTAL

A system was also developed, so that the information can be submitted centrally via the European Chemicals Agency (ECHA), poison centre portal.

Although the ECHA submission portal facilitates the submission process, information on national submission systems and fees are at the discretion of each member state.

The details are provided in the document 'Overview of member states' decisions in relation to implementation of Annex VIII to the CLP Regulation', available from www.escha.europa.eu/guidance-documents/guidance-on-clp.

### ESSENTIAL INFORMATION

The company information of the submitter, trade name or names of the mixture plus the UFI, must be included in the notification.

Specific hazard information must be provided, which includes:

- classification of the mixture
- label elements
- toxicological information
- colour and physical states
- pH where applicable
- product categorisation (consumer, professional, industrial or combination)
- chemical identity and concentrations of the components contained in the mixture, in accordance with Section 3.2, 3.3 and 3.4 of Annex VIII

### HELP LINE

A reduced-notification option was made available for hazardous mixtures used at industrial sites, limited to the information required to be provided in a safety data sheet. However, rapid access to the full composition must be made available in case of emergencies via a 24/7 help line.

***"These notification requirements will therefore be an ongoing management process for many companies"***

The emergency help line must be available in every member state where the mixture is placed on the market. The capability to provide emergency response information in the language of the member state, where the incident has occurred, is also required.

## INDUSTRIAL USE

Industrial use is generally considered to apply when there is a high level of environmental health and safety management practices in place. These advanced practices are associated with employee training, work instructions, supervision and regular cleaning and maintenance.

***"A directive is a legislative act that sets out the framework that all EU countries must follow"***

However, a mixture is only considered industrial if it is used in this way throughout the supply chain. This means that if some customers use the product for professional use, then the 2021 deadline applies. Printing inks are generally considered to be used in industrial settings.

## SECTOR-SPECIFIC ARRANGEMENTS

Specific arrangements have subsequently been put in place to address issues identified by certain industry sectors. The sector-specific solutions cover fuel, petroleum and construction products, as well as bespoke paints formulated at point of sale. The guidance was updated to reflect these arrangements.

## UNITED KINGDOM

The UK Government recently announced that Annex VIII of the GB-CLP Regulation will be revoked by the end of this year. This means that the submission of information on hazardous mixtures will no longer be a legal requirement in Great Britain. The Annex VIII requirements remain in place for Northern Ireland as it continues to come under the regulations of the EU.

## CHANGES AND UPDATES

Certain specified changes result in an update being required to an already existing submission. For example, in the case that a formulation change results in the concentration level of a hazardous ingredient exceeding permitted variation limits, a new UFI must be generated and an updated notification submitted.

Certain changes require the notification to be updated before the changed mixture is placed on the market. This is specified in Annex VIII.

## NEW CLP HAZARD CLASSES

New hazard classes have been introduced to the EU, CLP Regulation in accordance with Regulation (EU) 2023/707. Mixtures will soon need to be assessed against the classification criteria set out in the regulation, which will result in a new notification requirement for mixtures that become classified for these end points.

***"The UFI links the product on the market to the submitted formulation"***

Other legislation alterations drive formulation changes, such as the substitution of a substance used in a printing ink, due to a harmonised classification and labelling change under CLP. These notification requirements will therefore be an ongoing management process for many companies. ■

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