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Hazardous mixtures and health emergency, are you ready for the January 1, 2021 deadline?

Companies placing hazardous mixtures on the market have to submit information about these mixtures to specific bodies appointed by European Union Member States. Poison centers use this information to give medical advice in case of an emergency.

The notification requirement, based on Annex VIII to the Classification, Labelling and Packaging (CLP) Regulation, applies from 1 January 2021.

The addition of this new Annex VIII relating to harmonized information relating to emergency health response, implemented in 2017, pursues the objective of harmonizing at the European level the information to be provided and the format for notifying hazardous mixtures placed on the market and, as such, making the management of health emergencies related to these products more consistent.

Who needs to make a notification?

New Annex VIII applies to all importers and downstream users placing on the market mixtures that are classified as hazardous based on their physical and health effects.

When does the notification obligation start to apply?

The date from which the notification obligation starts to apply varies depending on the contemplated end use of the mixture:

- mixtures for consumer use: January 1, 2021;

- mixtures for professional use: January 1, 2021;
- mixtures for industrial use: January 1, 2024.

If a mixture has more than one of the above uses – whether through direct use or through its presence in a product manufactured further down the supply chain – the earliest date applies.

Before the relevant applicability date, the mixture continues to be subject to existing national information requirements (in France, notifications are until now made through the online platform called *Declaration-Synapse*[1]).

Mixtures already notified under national legislation shall remain valid until January 1, 2025. If there is a change to the mixture before this date, companies may need to make a notification based on the new information requirements according to Annex VIII.

What mixtures are subject to the notification requirement?

Annex VIII does not apply to:

- mixtures for scientific research and development and to mixtures for product and process oriented research and development (PPORD),
- mixtures classified only for the following hazards: gases under pressure and explosives.

In case of mixtures placed on the market for industrial use only, submitters may opt for a limited submission, as an alternative to general submission requirements. In that case, the information to be submitted may be limited to the information contained in the safety data sheet (SDS), provided that additional information on the composition is available on request for rapid access.

What format must be used?

Part C of new Annex VIII to the CLP Regulation sets the submission format.

Companies must provide the required information using the harmonized Poison Centers Notification (PCN) format. The format is XML-based and compatible with IUCLID.[2]

What information is required?

A common set of information will be required by all European Union Member States where the mixture is placed on the market.

Part B of new Annex VIII to the CLP lays down the information to be contained in the submissions made by importers and downstream users in connection with the placement of their hazardous mixtures on the market.

The principal new element is the obligation to include a unique formula identifier (UFI)[3] – a code generated

by the UFI generator, e.g. J200- U0CW-500A-Q2DA, in the submission. The UFI must be shown either on the label of the product or on its packaging.

How to make the notification?

A notification portal for poison centers has been set up to facilitate the electronic transmission of the submission.[4]

The portal is an optional tool for submitting a harmonized submission, the main benefit of which is to allow companies to submit the information to several Member States in one go.

To date, Denmark, Estonia, Germany, Lithuania, Norway, Poland and Slovenia have indicated their acceptance of the notifications submitted through this portal.

France[5] has, for its part, indicated that:

- for mixtures intended for consumer or professional use: those subject to the notification requirement must continue to make their submissions in accordance with national law until further notice and at the latest until December 31, 2020;
- for mixtures intended for industrial use: subject to confirmation that France accepts the transmission of notifications through the aforementioned portal, it will accept the submissions transmitted through this portal or through the Declaration-Synapse platform;
- the notification is made in French language only and free of charge;
- those subject to the notification requirements may begin to place the mixture on the market after confirmation of proper receipt of the submission by the competent national authority.

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[1] https://www.declaration-synapse.fr/synapse/jsp/index.jsp

[2] To download the format: https://poisoncentres.echa.europa.eu/poison-centres-notification-format

[3] To generate a UFI: https://ufi.echa.europa.eu/

[4] To access the portal: https://idp.echa.europa.eu/ui/login

[5] See version 4.1 (November 2020) of the Member States decisions in relation to implementation of Annex VIII: https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf

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