EU Poison Centres - How to Keep Up with the Latest Changes

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ABSTRACT

Poison Centres play an important role in ensuring the safe use of chemicals by providing vital information in case of a poisoning incident. EU Poison Centres answer an average of 600,000 calls each year in response to accidental exposure, providing medical advice to general consumers and physicians when health emergencies arise from exposure to hazardous chemicals. Up until recently, industry requirements relating to Poison Centres differed between Member States, however, under Article 45 of the CLP Regulation the requirements on industry are set to change with the aim of harmonisation of requirements across the EU.

Under Annex VIII to CLP, importers and downstream users placing hazardous mixtures on the market will be responsible for submitting information to Poison Centres in the relevant Member State(s) with new online tools and a harmonised EU format aiming to help companies to submit this information. Deadlines for the submissions will apply in a stepwise manner depending on the intended use of the mixture. A distinction will be made between mixtures for consumer use, professional use and industrial use with more information than ever before having to be disclosed on the composition of relevant mixtures.

This poster aims to summarise the main changes to Poison Centre notification requirements and provide a stepwise approach to successfully preparing notifications in order to ensure compliance.

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REGULATORY BACKGROUND

Prior to this new legislation the information submitted to Poison Centres across the EU varied widely between Member States, which created administrative strain and resulted in uneven information levels in relation to hazardous chemicals. Article 45 of CLP made a provision for the European Commission to review the current system and assess the possibility of harmonising the data submitted to Poison Centres. This review led to the proposal of a new annex, 'Annex VIII', to be added to CLP. At the REACH Committee meeting in September 2016 the EU Member States voted in favour of this new proposal, with the new annex being published in March 2017.

The new annex laid out the requirement that each Member State has an appointed Poison Centre (or equivalent body), who is responsible for receiving data from importers and downstream users who place hazardous chemical mixtures on the market. This information is relevant in the event of an emergency health response and is required for any chemical mixtures placed on the market which are classified as hazardous on the basis of their health and physical effects.

The main basis of the new system is that notification needs to be made before an applicable product is placed on the market and different deadlines apply depending on the intended use of the product. Although phased deadlines apply, there will also be a transitional period for mixtures which have already been notified under the current system.

APPLICABLE PRODUCTS

Products falling into the provisions of Annex VIII cover all products which fall under CLP and are mixtures classified as hazardous to human health or for physical effects. Biocides are also applicable, with detergents and cleaning agents also in scope of the regulation.

Out of scope products include all explosives, gases under pressure and mixtures with environmental hazards. Please be aware that some member states have eluded to wanting information on components classified as environmentally hazardous, but this will be at a national rather than EU level. It is also worth noting that if a product falls outside the scope of CLP, it will be exempt from notification requirements. Products which have the sole purpose of R&D will also be exempt from notification requirements.

SOURCES OF INFORMATION

ECHA: https://echa.europa.eu/home

ECHA Poison Centre Website:
https://poisoncentres.echa.europa.eu/

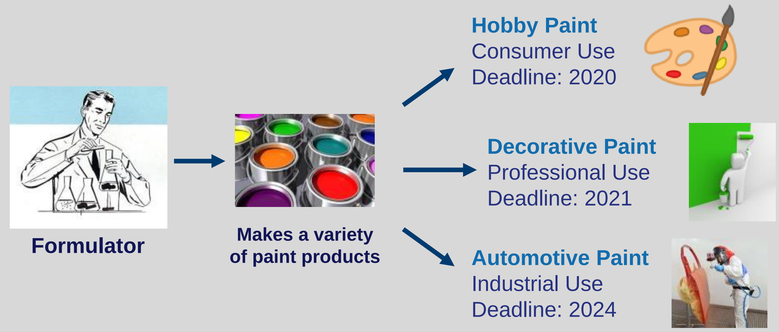
Poison Centre Regulation: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1490275739734&uri=CELEX:32017R0542

DEADLINES

To understand the deadlines in more detail, lets take the scenario of a formulator who supplies several different paint product to different sectors.

- The formulator supplies hobby paint which is deemed as a consumer product and therefore has a deadline to be notified by Jan 1st 2020.
- The formulator also supplies decorative paint to a painter decorator which would be deemed as professional use and need to be notified by Jan 1st 2021.
- Lastly, the formulator supplies automotive paint to the industrial sector with notification having to be made by Jan 1st 2024.

It mustn't be forgotten that if the formulator has notified under the current regulations they are not obligated to notify under the new regulations until 2025.



NOTIFICATION

Where to Notify
Currently, where notification can be undertaken is not clear. The two proposed options are either directly to the Member State through various portals, or through one centralised notification portal run by ECHA.

The feasibility of a central notification portal is something that ECHA is considering and the results of a study looking into this option has recently been published. This feasibility study recommends the implementation of a central notification portal which will simplify the process of submission of information for industry in addition to harmonising the documentation received by the Member States' appointed bodies and their Poison Centres. Although the study was clear that a centralised system is the best route to go down, the study only serves as part of the decision-making process and the outcome is yet to be decided.

How to Notify
1) 'Poison Centres Notification Format' - defines the data requirements and structure for the submission of information to Poison Centres in an XML format. It has been developed for the benefit of Poison Centres and companies and may be particularly useful for companies dealing with a large number of formulations as the XML allows them to integrate the data requirements into their own IT systems. A draft version can already be downloaded from ECHAs Poison Centre website, however, be aware that this is not the final version and the format is likely to be updated.

2) 'PCN editor' - a basic application that can be used by companies to prepare and update files for the submission of information to Poison Centres in the harmonised format. It has been developed for the benefit of Poison Centres and companies and is particularly intended for small and medium sized enterprises. You can already familiarise yourself with a draft version of the tool; whilst a final version was meant to be published in 2017, this has yet to be released.

What to Notify
There are information requirements associated with the product such as the product name, and details of the submitter, but there are also requirements associated with components of the mixture and a new requirement for a 'Unique Formula Identifier'. As well as general information, submitters are expected to provide information on the hazards associated with the product and a whole host of additional information ranging from product appearance to use type. Along with the requirement for use type comes a new requirement to define the product category according to the EU product categorisation system.

UNIQUE FORMULA IDENTIFIER (UFI)

To make it easier for Poison Centres to give advice in emergency situations, companies will need to submit the a 'Unique Formula Identifier' or 'UFI' to the Poison Centre and put it on the labels of their hazardous mixtures.

The UFI will create a direct and unambiguous link between the mixture they place on the market and the information on the specific mixture they provide to the Poison Centres. This will make it easier for the Poison Centres to instantly find the information they need to provide an appropriate emergency health response.

After Jan 1st 2025, the UFI must appear on the label of consumer and professional products. You may also reference the UFI on industrial product labels, however, Annex VIII states that the UFI can alternatively be referenced in the SDS.

The UFI can be generated using ECHAs online tool, or companies can obtain the logic to integrate the UFI generator into their own IT-system. Once generated, the UFI will be linked to a specific product and be included in the submission to the Poison Centre.

WHAT CAN BE DONE NOW?

Providers of mixtures falling under the provisions of Annex VIII should complete as many Poison Centre notifications as possible now in order to make use of the transitional period allowing current notifications to stand until 2025 and in order to be compliant. This will allow companies to take advantage of the Member States where notification is free as the new regulation is expected to put an extra burden on Member States and consequently increase costs which may be put onto the notifier in the form of notification fees.

As well as getting ahead of the new requirements, now is also the time to start preparing yourself for the new regulation. Put together an overview of the products which trigger the requirement of notification to a Poison Centre and start to collate the data required for submission. That way, when you need to submit, the data will be ready to go and submission should be a quicker process.

STEPS TO NOTIFICATION