Chemical Watch

REACH & CLP Hub: Why suppliers still need to act now on harmonised poison centre notifications

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A one-year delay to the harmonised poison centre notifications submission deadline for mixtures for consumer use is an opportunity for suppliers to address the new compliance requirements – not to relax. Knoell Germany's project manager for product safety/poison centre notification Christoph Schwarz outlines the challenges.

Regulation (EU) 2017/542 harmonises the requirements for poison centre notifications (PCN) for all EU member states (including the EEA countries Iceland and Norway). It amends the CLP regulation (EC) 1272/2008 and introduces the new annex VIII.

Receiving the most publicity so far is a new requirement for a unique formula identifier (UFI) that will have to be included in the label of many hazardous mixtures. However, that is only one of the requirements that need to be addressed in the context of PCN according to CLP Article 45/ annex VIII.

The practical challenges described below are just a selection of issues often encountered by companies while preparing for the new harmonised mode of PCN.

These challenges can be highly individual, depending on a company's business area and model, specific circumstances and needs – for example with respect to confidential business information.

The upcoming one-year shift of the first PCN deadline to 1 January 2021 should therefore not be taken as an invitation to rest – but rather as an opportunity to manage compliance with the upcoming regulatory requirements, brought about by regulation (EU) 2017/542 and the new annex VIII to the CLP regulation.

Postponement of the first deadline

Initially, three deadlines were scheduled for notifications with the new format:

- mixtures for consumer use by 1 January 2020;
- mixtures for professional use by 1 January 2021; and
- mixtures for industrial use by 1 January 2024.

During a transition period already existing national poison centre notifications remain valid until 1 January 2025. Resubmission under the new harmonised format is not required until this date, unless changes to the mixture make it necessary, for example because of changes to

the composition, the classification and labelling, the trade name or the member states where it is to be put on the market.

The introduction of the new format, the corresponding submission system and the guidance documents all experienced several delays. With the exception of Germany and Estonia, most of the member states' appointed bodies have communicated that they will not be able to accept notifications in the new format via Echa's submission portal yet.

The first deadline for the consumer use mixtures will therefore be shifted to 1 January 2021, coinciding with the deadline for professional use mixtures. Although this deadline shift was initially planned to become effective by the last quarter of 2019, it may not happen before mid to end of January 2020.

Most national appointed bodies have already communicated that they will still accept notifications under the existing national regime, and will indeed require the old mode of notification until further notice.

But even with this additional year of delay there is no time to lose. In many – if not most – cases, the new requirements will considerably exceed the information and data companies are used to submitting today. Most companies will therefore need to address the topic of harmonised PCN as soon as possible in order to prepare for possible new requirements. These include software changes to existing environment, health and safety (EHS) solutions, evaluation of availability and usability of existing data, supplier communications etc.

Listed below are a number of actions that most companies will want to address early on in order to prevent avoidable non-compliance later.

Identifying products with PCN relevance

Not all hazardous products fall under the new requirements. Exemptions exist, for example mixtures that are only used in research and development under controlled conditions, medical devices, medicinal products, cosmetics, food, feed, radioactive mixtures and other product categories exempt from CLP, mixtures that are only classified as hazardous to the environment according to CLP, or only as gas under pressure or explosive. Assessing which products in your portfolio may not actually require PCN could save you a lot of effort.

Expect your customers to ask you for UFIs

Even for mixtures that do not require PCN for themselves, there is a good chance that a supplier will be asked for the mixture's composition by its customer. For example in a situation where you supply a mixture that does not require PCN itself, but your customer may use it in the formulation of a hazardous mixture. To fulfil the customer's PCN obligation, it will ask you to provide the exact composition of the supplied mixture. In order to protect this confidential business information, you may consider performing a voluntary notification and only communicate the mixture's assigned UFI to your customer, instead of the full composition.

Choose a suitable mode of submission

In general, there are three different ways to generate and submit a PCN dossier to Echa. Subscribers to the agency's Iuclid cloud service can use the provided PCN assistant to manually enter all required information online, and then submit the generated PCN dossier directly from there.

While Iuclid cloud is subject to a subscription fee, you can also download and install it locally free of charge, generate your PCN dossier with the identical assistant and upload it via drag and drop to Echa's submission portal.

Various common EHS systems and safety data sheet (SDS) authoring software can also generate PCN dossiers, while other software providers are in the process of implementing such solutions. Beside the PCN dossier generation in the required new format, some systems will provide so-called system-to-system integration, making automated or semi-automated notifications to Echa possible.

The choice of the most suitable mode of PCN dossier generation and submission is a business decision, usually depending on factors such as portfolio size, number of EU market countries, complexity of compositions, expected rate of submission updates etc.

Locating and assessing the available data

Most of the information required for PCN submission will likely already exist in companies' IT systems, for example EHS or SDS software or databases. However, some data may be more difficult to automatically retrieve or aggregate, such as all relevant packaging types and sizes for each product. Also, the available information from the SDS may be incomplete, such as missing pH values or composition information.

As the new format only allows a limited number of basic colours and intensities like 'light, 'dark' or 'transparent', a reduction or mapping to these possible values may be required.

In addition to the UFI, at least one main use category according to the European Product Categorisation System (EuPCS) must be assigned to each mixture for PCN.

Irrespective of the chosen mode of submission, this can be prepared well in advance.

The UFI will be required to be displayed on the product label, and even slight changes to the classification or composition may trigger a resubmission and the assignment of a new UFI. Depending on how often your UFI can be expected to change, it might be necessary to consider in-line printing of the current UFI to a reserved blank area of the label. Also keep in mind that you might also need to resubmit and assign a new UFI if your supplier informs you of a change in the classification or composition of a raw material supplied to you. This is ever more relevant the further down in the supply chain you are located, and the more mixtures you use as raw materials.

The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch.