Changes to EU Poison Centres regulation:

"harmonised information relating to emergency health response and lubricants: the next burden?

Dr. Stephan Baumgartel,
Executive Director,
Verband Schmierstoff-Industrie eV

The "Commission Regulation (EU) 2017/542 of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging (CLP) of substances and mixtures by adding an Annex (VIII) on harmonised information relating to emergency health response", comes into force in all EU member states from 01.01.2020.

The intention was to replace national legislation on information submission about dangerous mixtures to the Poison Centres. This means that for the first time EU member states will work to a common European-wide standard.

According to article 45 of the CLP regulation, EU member states are still entitled to "appoint a body or bodies responsible for receiving information (…) for formulating preventative and curative measures, in particular in the event of emergency health response". That means to collect all "necessary" information on mixtures classified as hazardous, physical hazards (H2xx category), with some exemptions, and human health (H3xx category) hazards.

All EU member states therefore will still have to appoint a body, or Poison Centre, responsible locally for emergency health response. Thus, Annex VIII does not replace the national requirements. Nationally-appointed bodies may, however, ask for additional information over and above that required by the new EU regulation concerning hazardous mixtures and may also require the payment of registration fees.

The new Annex VIII applies to all mixtures classified as "dangerous" for human health (plus the classification of some physical hazards) for consumer, professional an industrial use. This is hard to understand since industrial end users already receive a Safety Data Sheet (SDS) with all the necessary information on hazards and first aid measures. Industrial users should therefore already know how to handle dangerous mixtures safely. Consequently the new legislation is expected to have little benefit in the case of work accidents. Exempted from submitting information are radioactive mixtures, mixtures used in scientific research, waste, medicinal products, cosmetic products and food, explosives and gases under pressure.

Whenever an importer, formulator, toll blender, or re-packer brings a hazardous mixture (e.g. a lubricant) to the market, they are obliged to submit information on the mixture to the appointed bodies or Poison Centres. "Information" means the full formulation plus physical and chemical data.

This is nothing new to the industry. So far, in many European countries, formulators are already obliged to do so but frequently they are not aware of these duties. On the other hand, in most cases only consumer products had been a subject of local legislation so far.

It is a common understanding that "industrial use" means use in areas without public access, e.g. private premises such as factories, but not workshops or households.

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The timeframe for the implementation of Annex VIII is quite tight, initially January 1st 2020 for consumer products and 2021 for products for professional use and 2024 for those for industrial use, respectively. But it is now (August 2019) very likely, that the first date will be shifted by one year at least for consumer products.

For the lubricant industry, most products are made for industrial use, thus the deadline is 2024. If the information required by local authorities was submitted before the legislation came into force the transition period ends in 2025.

The submission itself can be made via the "Poison Center Notification Portal" (PCN) (**https://poisoncentres.echa.europa.eu/**) and consists of physical and chemical data of the mixture and the detailed formulation including labelled and non-labelled substances in narrow concentration ranges.

Aside from formulation properties, some information on the intended use must also be provided. Therefore, the European Chemical Agency (ECHA) responsible for overseeing Poison Centres, created the "product categorisation system" (PCS). It is a 4-step system code to describe the use of a mixture (**https://poisoncentres.echa.europa.eu/de/eu-product-categorisation-system**), for example metalworking fluids are described with the code "PC-TEC-13", where "P" stands for "product", "C" for "chemical product" "TEC" for end-use products and "13" for metalworking fluids.

In about 5 years from now, the European Union will hold a centralised database with full information and composition of all (labelled) mixtures available on the European market. If someone has concerns about data confidentiality: the only way to avoid the submission of the formulation would be the availability of a "24/7 hotline", with access to the formulation in all languages where the product is on the market. In this case, the submission of the SDS would be sufficient.

Part of the submission is the "Unique Formula Identifier" (UFI) and is a challenge for formulators. It is an alphanumeric code, which can be generated by a tool on the PCN website, e.g. "UFI 37XF-M2CU-2007-9JSP". The UFI is calculated from the VAT number of the formulator and a formulation number, a number between 0 and 268435455 and must be printed on the packaging and can be included in the SDS. This is the first problem: the internal formulation code of the formulator must be translated somehow into a number for generating the UFI.

The UFI allows for the identification of a certain formulation by the Poison Centres. Therefore, for any formulation change (with very few exceptions) a new UFI has to be generated. This is the second problem: users will notify any formulation change, because the UFI changed.

The UFI may also lead to a certain transparency in the supply chain: In case a formulator sells his formulation to various 3rd party suppliers, he needs to generate an UFI for each supplier / re-seller, if they would like keep the supply chain confidential. One may also keep in mind that the submission has to be made for each country where the product is placed on the market, so re-sellers need to inform their suppliers or make the submission themselves. In this case, they don't need the formulation, but submit the product as "ingredient: 100% of mixture of supplier xyz".

How to prepare? There are many things to consider:

- Which products must be notified, i.e. one needs a list of all lubricants labelled as "dangerous".
- In which countries are they placed on the market?
- Are they on the market under different trade names (remember: same/different UFI strategy)? Timeframe: industrial, professional, consumer? Assume that you have 100 products on the EU market: 100 products * 27 languages = 2700 submissions (!).
- One or more than one PCS code (multiple use)?
- Software requirements: formulation number, UFI generation number and UFI must be managed, also formulation changes must be tracked and new UFIs generated. UFI must be printed on the packaging and in the SDS.
- Re-sellers and distributers need to be trained. There are a lot of things to be done until 2021!

Last but not least: Local authorities still have the choice to ask for additional data, require registration fees etc., since this piece of legislation does not replace 100% of the local legislation on information on dangerous mixtures. What is required on a local basis can be found on the Poison Centre website.

LINK
www.poisoncentres.echa.europa.eu/de/prepare-your-submission