What the European Commission's new draft amendments to poison centre legalisation will mean for the chemical industry in Europe

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On Thursday 11 February 2016, the European Commission published its first draft amendments to the Classification, Labelling and Packaging of Substances and Mixtures (CLP) regulations for public consultation. The chemical industry has eagerly anticipated the Commission's comments on CLP, with particular attention focussing on the possible changes to article 45 and the impact this will have on poison centre compliance for businesses handling hazardous goods in Europe. Formal ratification of the amendment is not expected until late 2016; however the draft text offers crucial insight into the Commission's intentions and priorities for the future.

In this article, Larissa Silver and Jonathon Lang from the National Chemical Emergency Centre (NCEC), reviews the key changes in the amendment and explains the steps businesses may have to take to stay compliant and secure business continuity across Europe.

Harmonising poison centre requirements

Article 45 of CLP currently stipulates that countries must appoint a body that is able to receive information on mixtures considered hazardous on the basis of health or physical effects, primarily to use in case of medical emergencies. However, without additional clarification countries have implemented this legislation in a variety of ways. The level of information required by a poison centre on a product's hazards, the registration process, the products that need to be registered and the cost of compliance varies widely between Member States. Therefore businesses operating in markets across Europe need to analyse and determine each particular countries' requirements, as failure to register adequately can result in substantial fines or the removal of that product from the market.

Following consultation with a number of stakeholders, the Commission identified a number of key issues:

- A lack of consistency in the interpretation of the legislation across Europe.
- The likelihood of a business having to make multiple submissions, adding unfair cost and a significant burden on industry.
- In up to 40% of cases, the poison centre was providing advice on the wrong product, risking health and causing unnecessary hospital submissions.

The new amendment aims to overcome these issues by harmonising poison centre registration across Member States and determining new methods for identifying and tracking registered products. However, compliance remains a complex process. With substantial changes on the horizon for product registrations companies risk being caught out when the amendments are eventually introduced. Here are some of the key changes proposed by the Commission that are likely to have an impact on how the chemical industry operates in Europe.

A base level of information

In a move to make the regulations more consistent across Europe, the draft specifies a base level of chemical information that companies must submit to poison centres about their products. The majority of this chemical information is likely to be present on existing compliant safety data sheets (SDS), such as the colour, physical state, pH, hazards and precautionary statements.

New information is also required on the non-hazardous components if they are above a certain threshold, although further safeguards have been introduced to protect intellectual property. New additions include a product categorisation code, a system for statistical analysis yet to be defined by the commission and the requirement to declare the types and size of the packaging if a consumer or professional product is placed on the market.

This partial standardisation aims to make registration easier for companies operating across several Member States. However, there is still scope for wide variation in the information required, as individual countries may request information beyond the EC's minimum level. Therefore understanding the specific requirements for each target market will remain a priority for companies when the new regulations come in.

Clarification on resubmission for mixtures

There is now clarification on the changes that can be made to the concentration of components within products before resubmission is required. This allows manufacturers greater flexibility in their products design, without incurring resubmission costs. However, there are a number of complexities and caveats within this proposal. Member States still have the option to choose to accept a supplied concentration range or require an exact concentration. The accepted range may vary between hazardous components and non-hazardous components, and substances deemed to be a major concern for emergency health response, such as serious eye damage category one. This two-tier system may result in continuing variations in requirements between Member States.

Changes required to packaging information

A Unique Formulation Index (UFI) will be required on all packaging to make product identification quicker and easier once it is registered with the poison centre. UFIs will be managed by the Commission, which will bear the cost of allocating and maintaining a database. However, the cost for altering packaging to show these codes will be on the organisation that places the product on the market, potentially adding an additional overhead to manufactures and distributors.

Protecting intellectual property

In a move to protect intellectual property, it will be permissible to use generic terms for components of mixtures - assuming they are not classified as hazardous by their physical or health effects - and are no more than 10% of the mixture. These include terms such as 'fragrances' or 'colouring agents', and are accepted assuming compliance with the stipulations in Article 24 of CLP: proving that an International Union of Pure and Applied Chemistry (IUPAC) name would commercially harm the business, particularly its intellectual property.

Changes to scope

The consultation found that calls relating to industrial products are a small percentage of those received by poison centres. As such, a limited information requirement has been proposed for submission of industrial products to a poison centre (i.e. products that are intended to be used solely on an industrial site). This submission requires the inclusion of product composition already specified in the SDS, but to be eligible a 24 hour telephone number must be supplied which can provide detailed additional product information in the case of an emergency. This has the potential to greatly reduce the volume and cost of submissions a business may need to undertake. However, organisations will need to ensure they their systems are robust enough to deliver round the clock expert advice when required.

Removal of the 30 day 'grace period'

All products, regardless of submission dates, must be registered **before** being placed on the market. This seems to counter the 30 day grace period countries have in place for registration after a product is placed on the market. This will require companies to have full knowledge of the legislation in their intended market and to factor in achieving compliance within their timescales.

Changes to submission format:

There is a wide range of submission formats used across Member States, requiring submissions in several formats and adding additional cost to industry. The draft proposes to harmonise submission in XML format, which will be supplied by the European Commission. Additionally, it will be possible for a single submission to be made for a group of similar mixtures that have the same hazards, and whose constituents fall within the same concentration levels. This is anticipated to significantly reduce the volume of individual submissions and the burden to industry, particularly for products of a very similar nature that have a variety of trade names within a single market.

Reducing the cost of compliance

These new requirements are being implemented step wise to reduce the effects on industry and will be implemented depending on the intended use of the mixture. These new amends are applicable to importers and downstream users from:

- 2019 for consumer products (destined for use by consumers).
- 2020 for professional products (destined for professional users but not used at industrial sites).
- 2023 for industrial products (used at industrial sites only).

It has also been proposed that submissions provided before these amendments come into force will remain valid until the 1st January 2025 unless there has been a significant change in formulation, product identifier or classification of the mixture.

If ratified, the Commission's amendments to CLP will dramatically change the requirements for companies' product submissions to Member State poison centres. The changes will have the potential to accelerate submissions while reducing the cost of poison centre compliance; however they also increase the enforcement of the legislation, and present a higher risk of fines or product removal for non-compliant companies. As always, a comprehensive understanding of how best to

meet corporate responsibility will be key to maintaining business continuity and securing commercial success.

It is important to appreciate that the current amendments found on the Commission's website are only a draft and subject to change. After the consultation stage, the NCEC will provide more information on ratified changes to help chemical companies maintain compliance and secure the greatest value from the new regulatory landscape.

For more information on how to comply with current regulations in every region in Europe download NCEC's poison centre compliance resource pack at http://the-ncec.com/Poison-centre-information-pack or contact Larissa Silver at larissa.silver@ricardo.com. For more first-look analysis on regulations and how they will impact your business follow the NCEC on LinkedIn and twitter

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