

Implementation of Annex VIII of CLP: Industry concerns

Cefic would like to acknowledge the efforts carried out by the Commission, ECHA and appointed bodies for the future implementation of Annex VIII on harmonizing the information requirements for notification to the Poison Centres for emergency response.

Cefic has been actively involved in the discussions and developments of the Guidance document, IT tools and Product Categorization System. We are also awaiting the launch of the workability study that the Commission is expected to carry out. At this point and after careful consideration, we believe it is vital to raise the following concerns. **Cefic and its members consider it will present a considerable challenge to comply with the timelines, as there are still too many questions open and because the submission tools are not yet ready to use for all types of mixtures and their different types of components. These unresolved issues cannot be ignored.**

Please find below our most important concerns for your consideration:

- **Workability study:** The Commission indicated in 2017 that they would carry out a workability study to evaluate several important issues raised by industry that would affect compliance. Mainly the change of the interpretation of industrial use, the ranges for notification included in Annex VIII, dealing with UVCBs and traceability of the UFI. The study has not yet started and the issues remain. We believe the study will demonstrate the need of amending the text of the Annex to make it workable. With only 18 months until the first notification deadline for consumer mixtures (practically all of the mixtures taking in account the Commission interpretation of industrial use at the moment) we believe it is impossible for the Commission to deliver results for a quality workability study and address and solve the highly important issues mentioned previously.
- **Distributors' role:** Cefic understands that the Commission has concluded that relabellers and rebranders, do not have any obligation according to Annex VIII of CLP and the REACH definitions of downstream users. However, the Commission needs to acknowledge the disadvantage that this will cause for importers and downstream users. There is no legal obligation for distributors to notify to the Appointed Bodies according to Annex VIII, even when the distributor is responsible for the placing on the market in a certain member state. In that case, it will be impossible to comply with the notification downstream in the new member state. These will result in non-compliance with the requirements from Annex VIII. Cefic would like to ask the Commission to consider how this major problem can be addressed.
- **IT tools**
 - **No decisions on the ECHA database, delay on the portal development:** During the last months Cefic has followed closely the CARACAL and ECHA Management Board discussions on the development of the notification portal in ECHA and the possibility of having a centralized database. Progress has been slow and the decision on the development of the database is still open. The Appointed Bodies of the Member states have now been presented with the question on the possibility to host their own

databases in case ECHA does not have a centralized one in place. Again, with such short timeframe Cefic considers it will be impossible for the companies to prepare for compliance with this amount of uncertainty remaining over basic features. The uncertainty on the centralized database should not result in a delay on the development of the central submission portal.

- **Delay on the release of version 1 of the PCN format:** The timelines proposed for the development of the PCN format and the delays the pilot projects have suffered make the proposed dates unrealistic for such a complex project. Industry will need to dedicate considerable resources to comply with Annex VIII; therefore, we cannot accept the use of overcomplicated tools. As the future users, we need to be provided with enough time to try out the tools. Moreover Company IT adaptations are needed to facilitate data extraction from their IT-systems, e.g. SAP as required for ECHA database. These tools have to be ready for notification purposes way ahead of the first deadline the 1st of January 2020.
- **Data Security:** The information to be submitted is in many cases Confidential Business Information. Cefic is concerned that the given timelines will not allow the member state authorities to implement on time the appropriate data protection standards safeguarding the intellectual properties and know-how of the European companies. Especially for downstream users (often SMEs) who formulate mixtures for professional or private use, the product know-how that absolutely demands protection lies in the formulations of their products. Confidential business information (CBI) must be strictly protected at all levels of the notification process, from reporting through central or national reporting portals to the transfer of relevant information to the poison information centres. We would like to ask the Commission to communicate regularly in a transparent manner on measures taken against internal and external unauthorized access including their effectiveness.
- **Member States unalignment:** Via our national associations, we are receiving information of some MS preparing to include national requirements. The exercise of harmonization will be completely futile if this happens. We would like to ask the Commission to convey this message to the MS and ensure alignment. However, we accept parallel national submission systems if no additional information is required, the PCN format can be used and when submission through the central portal are also accepted.

We would like to ask the Commission to take these comments into account. Cefic remains available for any question and clarification. We would be prepared to engage in further discussion.

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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of 29,000 large, medium and small chemical companies in Europe, which provide 1.2 million jobs and account for 14.7% of world chemicals production.

