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Current experience of the Belgian Poison Centre with the new product notification requirements implementing article 45

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Objective

According to Annex VIII of article 45 of the CLP regulation the industry will have to submit product notifications via ECHA. That obligation will be effective on January the 1st of 2021 for consumer and professional products and on January the 1st of 2024 for industrial products. ECHA decided to use the IUCLID format. The aim is to identify the major problems that the IUCLID format entails for appointed bodies.

Methods

We present the current experience of the Belgian Poison Centre (appointed body for Belgium).

Results

Originally, the idea was to notify products in one XML file. This idea was left in 2017, when ECHA decided to use the IUCLID format. This format was originally developed to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances (REACH), not to notify products. This has as a consequence that future modifications in the IUCLID format due to changes in REACH, may also have repercussions on product notifications. IUCLID dossiers are extremely complex to read. They contain one primary XML, which describes all other XML's included in the dossier. Those XML's define single entities (a substance, a mixture, a legal entity, etc.) that are interconnected with each other.

At this moment, different mixtures have to be declared separately by the submitter. As a result, appointed bodies will receive multiple notifications for one commercial product containing multiple components, each with a different mixture. There is currently no way to merge automatically these different mixtures into one commercial product.

The IUCLID format is a dynamic format, resulting in a recurrent development cost for the appointed bodies to be able to support the changes in the IUCLID format, which can also result in changes in the structure of the databases of the appointed bodies (and poison centres).

The rigorous security requirements imposed by ECHA, are a major concern. Additionally, the expected amount of notifications will have a big impact on the systems of the poison centres and on the way of searching for a specific product.

Conclusion

The choice for the IUCLID format to submit product notifications involves many problems. It is important to achieve a result, acceptable for both ECHA, appointed bodies and poison centres.

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