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ECHA Poison Centres Submission Portal online - Workability Issues remain

As announced by ECHA (see also <u>EMO Newsflash 05/19</u>), version 1.0 of the <u>ECHA Submission Portal</u> for Poison Centres Notifications went online on 24 April 2019 and is accessible to industry users via the <u>ECHA Poison Centres website</u> (see also <u>press release</u>). National authorities have a separate access through the ECHA Remote access portal.

In version 1.0 of the Submission Portal for industry, users can search, create, validate and submit a PCN dossier online. Dossiers are created and validated using the guided dossier preparation tool in the IUCLID Cloud. A number of <u>validation rules</u> are applied to ensure the dossier is complete and to warn the user of possible inconsistencies.



Version 1.0 of the Submission Portal is equipped with the basic functionalities for creating, validating and submitting dossiers. Further functionalities shall be introduced with the upcoming versions of the Submission Portal. To this, ECHA has scheduled an intermediate release in July 2019 (version 1.5) and a second release of the Submission Portal in November 2019 (version 2.0). According to the versions overview provided by ECHA, the strongly requested system-to-system integration for industry users shall be part of the intermediate version 1.5.

Supporting material helping users with the preparation and submission of the dossiers **is available on the ECHA Poison Centres website**. The material includes inter alia

- a guide to dossier preparation and submission
- an overview of Poison Centre Notification (PCN) languages as require by each Member State
- an <u>overview (current snapshot) of Member State intentions in relation to implementation</u> of Annex VIII to the CLP Regulation

- a <u>notification example</u> (IUCLID dossier) for a product containing a Mixture in Mixture (MiM), covering multiple markets and different languages
- a <u>notification preview generated</u> by the IUCLID PCN wizard

Although the workability issues are still being discussed, the decision to amend the current Annex VIII is still pending (Member States should discuss modification proposals in July apparently) and the requested postponement of applicability dates is being seriously considered by DG GROW (a decision is expected in the coming weeks, in parallel further meetings of the industry with European Commission officials are in planning), the EMO secretariat strongly recommends mortar manufacturers to already get acquainted with the creation of the dossiers, without actually submitting them, as the amendments regarding the workability issues may have an impact on the final format/information.



To familiarise with the process in a safe manner, ECHA provides users access to IUCLID Cloud Trial, a test version of the online guided dossier preparation tool. To access the IUCLID (trial) cloud, users must have or create an ECHA account (see also guide how to create an ECHA Account).

The practical work on trial dossiers is expected to provide valuable insight in the process as well as the type and level of detail of information required. This insight is considered to be valuable even in case the final preparation and submission is foreseen with external system-to-system integrated software tools. After all, irrespective of how the information is submitted, the work always starts with collecting and preparing (integrating) the data for submission. Another reason to start familiarising is that while we are confident the applicability dates will be postponed, we do not know if the European Commission will follow the recommendation to postpone the dates by at least 12 months or decide for a shorter delay.

1 the PCN example, provided in i6z format is compatible with the release of IUCLID 6.3, available on the IUCLID 6 website

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