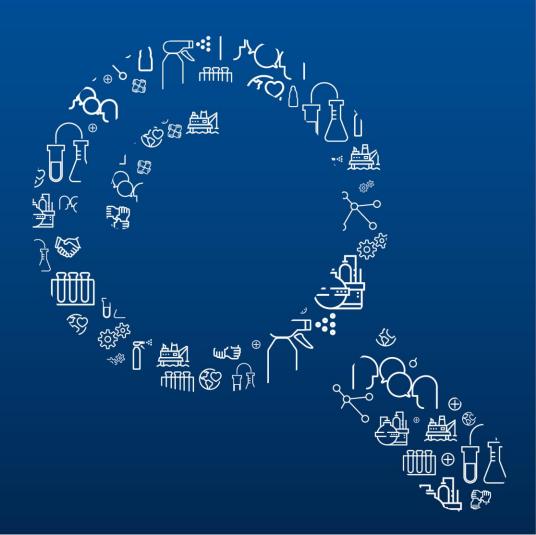


Overview

- Ways to prepare your notification
- New developments

Upcoming changes

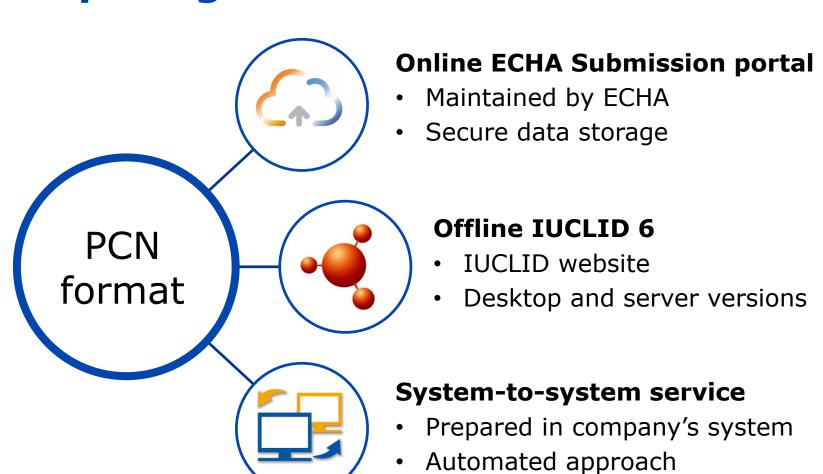
Ways to prepare your notification



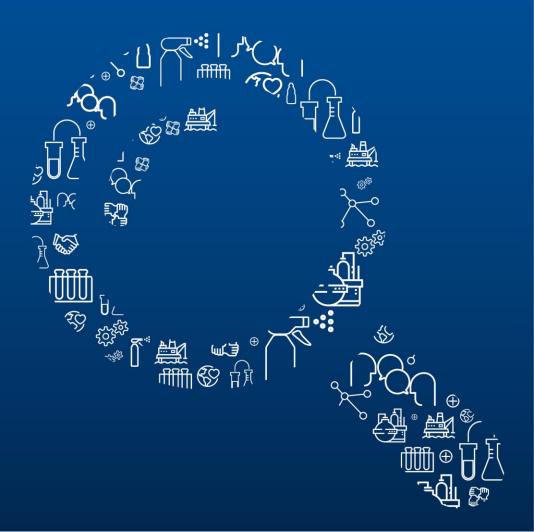




Preparing a PCN notification



New developments







2020 release plan

13 July 28 October 27 January 5 May Easier way to Possibility to Improvements Format in dataset provide expand changes classification market areas (IUCLID 6.5) view information in updates Adaptation to II amendment Support for Automatic displaying PCN calculation of labelling documents in information the dataset and dossier Cloning a view mixture dataset Navigation tree in a PCN Multi-lingual dossier fields available in dataset Visualisation view of submission history chart Improved document Update naming system-tosystem API to System-toreturn event system full log testing





Current approaches to PCN preparation

Dataset view

- 1. Substance datasets
- 2. Mixture in mixture dataset
- 3. Mixture dataset
- 4. Dossier header
- 5. Mixture composition
- 6. Product information

Guided dossier tool

- 1. Dossier header
- 2. Mixture information
- 3. Create mixture in mixture
- 4. Create MiM components
- 5. Create substance(s)
- 6. Product information

Create > Validate > Submit





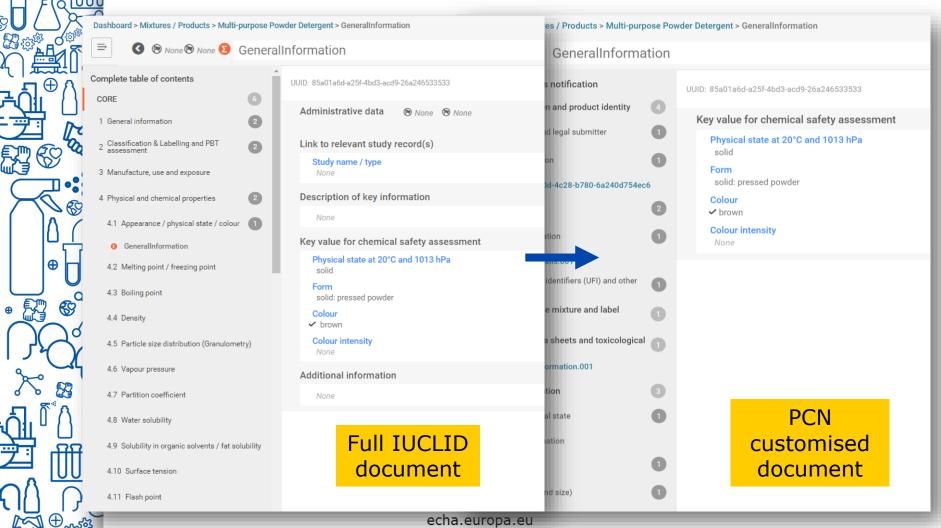
Use the customised dataset view

- IUCLID Cloud Services options
 - Guided dossier preparation mode
 - Dataset view mode: grouping information including separate elements (IUCLID documents) that can be combined in a IUCLID file (.i6z)
- Focus on improving the dataset view option only
 - Improving data preparation for all IUCLID users
 - Customised notification documents
 - Tutorial
 - Support material available
 - Monitoring feedback from users





Example: customised dataset







Use the validation assistant

- Will help you submit successfully
- Almost 120 rules implemented
 - Validation assistant rules (before submission)
 - Portal assistant rules (database check upon submission)
- List of validation rules <u>update</u> coming soon





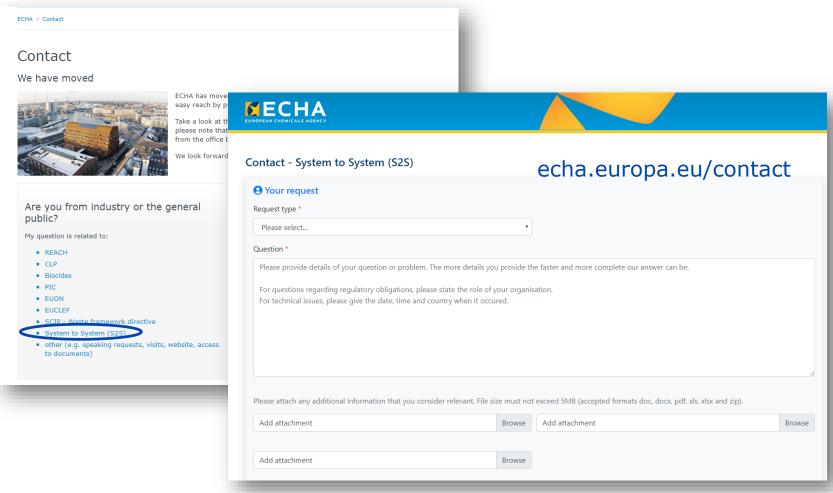


Use the ECHA tools to submit

- ECHA submission portal
 - Centralised and convenient tool for preparing, submitting and managing submissions
 - Supports multi-market submissions
- System-to-system service
 - Automatic transfer of notifications to the ECHA submission portal using the system approach
 - Possible to bulk submit
 - Submit a request to ECHA to access



System to system: new contact form







Test before submitting

- Use the isolated test environment
 - Different test scenarios possible supporting full validation
 - No interference with other users
 - Manually
 - <u>System-to-system</u>: use test run identifier
- Help make sure that:
 - Only real dossiers are dispatched to appointed bodies
 - Clean and accurate reporting is available



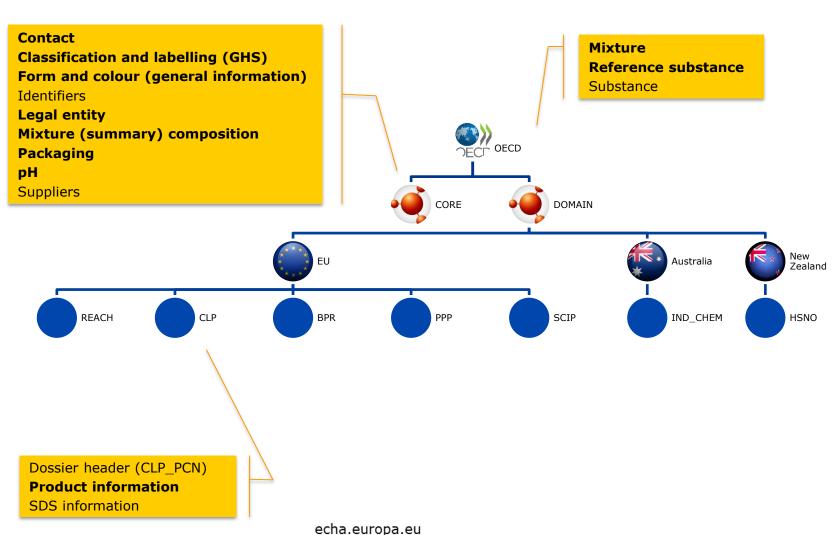
Upcoming

Changes planned for October 2020





IUCLID 6 format used worldwide







What you can expect

- New justification for update: 'expansion of market area'
- Updated European product categorisation system
- New packaging type 'cartridge'
- Justification when pH is not relevant
- 'Standard formula' indicator
- 'Interchangeable component' indicator
- 'Generic product identifier' changed to 'Generic component identifier'







Get ready for new IUCLID format

- Update of the IUCLID format is now documented on the <u>IUCLID website</u>
- Subset of the IUCLID format relevant to poison centre notifications is published on the <u>Poison centres website</u>

Finalising format changes (April / May) Implementing the format in IUCLID test version (June / July) Publishing the final draft format, incl.

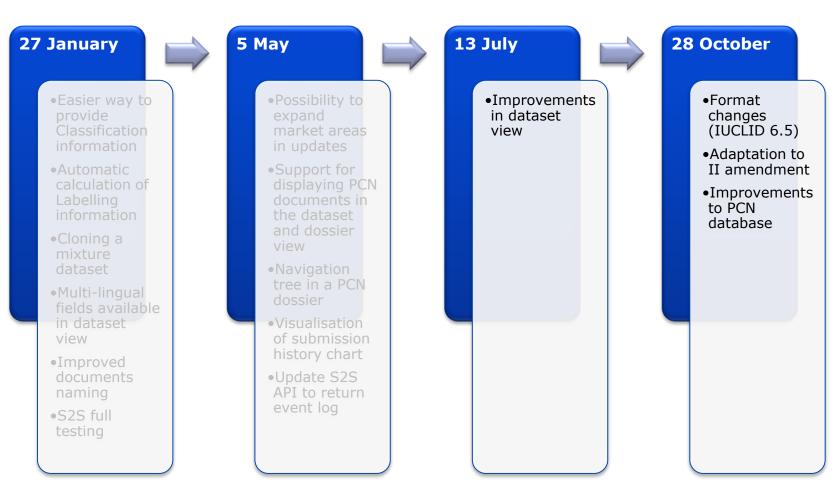
XSDs
(June / July)

Publishing IUCLID 6.5 (28 October)





Next steps in 2020







Take home

- Start using the dataset view
- Use the test environment to test submissions
- Prepare for IUCLID format change in October





Thank you!

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