EFSA IUCLID pilot on Pesticides dossiers

Outcome of phase 1

Identification of useful IUCLID features and improvements

IUCLID 6 is developed by the European Chemicals Agency in association with the OECD

Content

Presentation prepared taking into account the feedback gathered in the Issue List

- Dossier preparation and submission
  - Validation assistant
  - Light dossier
  - Submission portal (new)
  - Large IUCLID Cloud instance
  - Identification of new studies in renewal dossiers

- Assessment
  - Report generator
  - Annotations
  - Filtering (including sanitised documents)
  - Aggregation

- Integration with 3rd party systems

- Miscellaneous

Dossier preparation and submission

- Validation assistant
- Light dossier
- Submission portal (new)

Validation assistant

- Validation assistant possibilities presented during the pilot
- Ongoing investigation on reusable rules
- Technical adaptations started to make the rules reusable for mixtures
- New rules started to be proposed, cf. ‘Validation (assistant, rules)’ category from the Issue Tracking file
- Set of rules to be defined for the go-live

Light dossier

PPPIUCLID_I250

- Issue with the (repeated) transfers of the PoC dossier during the Pilot phase
  - Dossier rapidly reached 500 MB as all studies attachments were added
  - All dossier updates were > 500 MB

- Problems
  - Longer time to export the dossier (e.g. from the contractor's server)
  - Transfer between users have to be done using specific download servers
  - Longer time to import the dossier (e.g. to the EFSA instance)

- Proposed solution
  - Re-implement the light dossier concept available in IUCLID 5 but abandoned in IUCLID 6
  - Seamless transfer of dossiers in ECHA Cloud environment (from Industry instance to the submission portal and the central IUCLID instance)

Submission portal

Objective: ECHA Submission portal supports the submission of PPP dossiers and submitter can view the status of the submission (PPPIUCLID_I150)

- Proposal:
  - Adapt ECHA Submission portal to allow the submission of IUCLID dossiers with PPP specific submission types
  - Validation rules should run automatically and potential failures/warnings should be reported back to the submitter or made available to relevant Authority
  - Metadata can be extracted in order to be able to display status information about the submission
  - Successfully submitted PPP dossiers should be routed to the central EFSA Main IUCLID instance, accessible by Member States and the Commission

Large IUCLID Cloud instance

Objective: The central EFSA Main IUCLID instance supports the needs of EFSA and RMS users

- Proposal
  - Instance Based Security could be enabled: only specific users having access to specific annotations (if needed)
  - Enterprise-grade database: database that supports large number of dossiers and concurrent connections
  - Restricted access through secured channels (IPSec via EFSA network)

Renewal dossiers

Identification of new studies

- During the pilot a need emerged to have a clear indication of the new studies provided and the ones becoming obsolete

- Proposal (format change)
  - Creation of a new ‘log’ document
  - Optional document relevant only for ‘renewal’
  - Link to Endpoint study records available in the dataset
  - Indication whether the study is new or obsolete

This log document would have to be filled-in per dataset though (solution to be further analysed)

Assessment

- Report generator
- Annotations
- Filtering (including sanitised documents)
- Aggregation

Report generator

Report templates

Report templates

Three different categories to be considered

1. DAR and RAR
2. Existing report templates to be reused
3. New report templates

(1) Draft / renewal Assessment Report (DAR / RAR)

Objective: help the rapporteur Member State generate the first draft(s) of the D/RAR (PPPIUCLID_I106a)

- Targeted objectives for the end of the year
  - Hazard-related sections to be generated in priority (as most of the format is already available)
  - Split the report in agreed sub-parts
  - Include rapporteur MS's conclusions from annotations
  - Provide a draft report that can be used as starting point for Member States
- Ultimate goal
  - Enter all necessary information in IUCLID (data edition happens there)
  - Generate the final DAR (for review)
- Limitations can come from
  - the level to which the dossiers are filled-in from March 2021
  - the attempt to reuse existing report templates fragment
- Prerequisites
  - we use the DAR template from the Commission
  - we assume a great overlap between the DAR and RAR templates

Not in the MVP

(2) Existing report templates to be reused

- Identified reports
  - List of annotations
  - List of attachments
  - Literature references (references list)
- Adaptations needed to make them work for PPP dossiers
- Coverage of additional documents included in PPP dossiers
- Discussions and agreement on the content
  - consensus should be reached among all users
  - if not, a new report will have to be developed (hopefully reusing relevant report templates fragments) = cf. category 3

(3) New report templates to be developed

- Identified reports
  - Confidentiality claims list
  - List of studies / endpoints (PPPIUCLID_I239, PPPIUCLID_I29a)
  - List of linked metabolites?

- New report templates can be developed as long as they do not require the development of complex logic, advanced formatting and do not include a large number of fields

- Existing output formats can be used

- Process for prioritising new report templates
  1. Report of the need to the PPP group
  2. Agreement on content and usefulness
  3. Technical analysis by the IUCLID team
  4. Decision on prioritisation for development

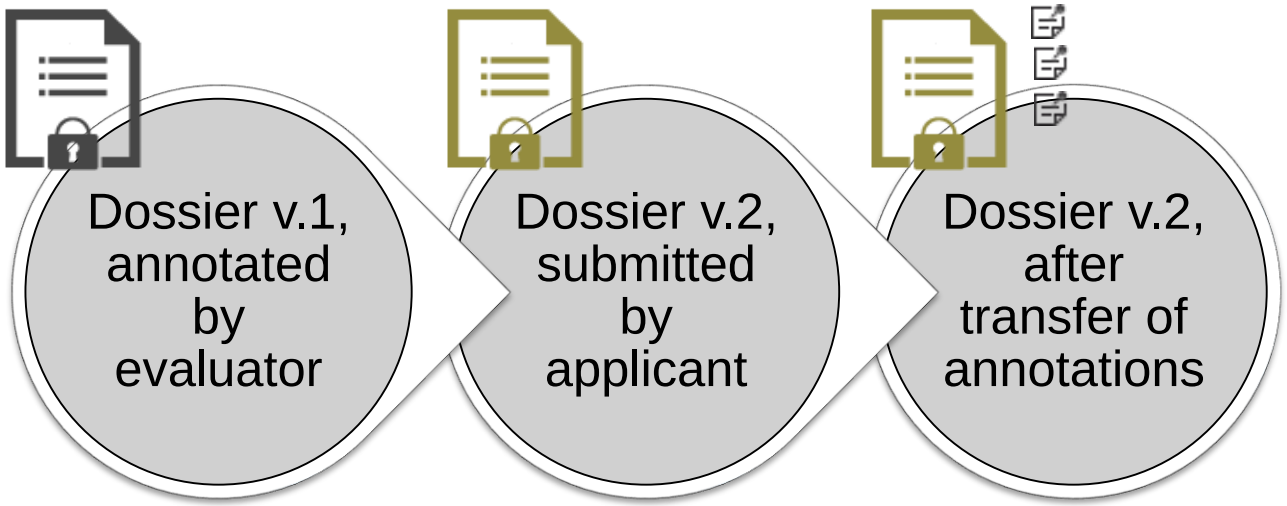
Report templates can also be built by third parties (with ECHA support if needed)

Not in the MVP

Annotations

Annotations transfer

PPPIUCLID_I106, PPPIUCLID_I242, PPPIUCLID_I242a



- Upon dossier import, the system could automatically identify the previous version and transfer (**or copy**) the annotations to the dossier update
- **Users should be informed about the fact that they are working on the latest version of the dossier or not**

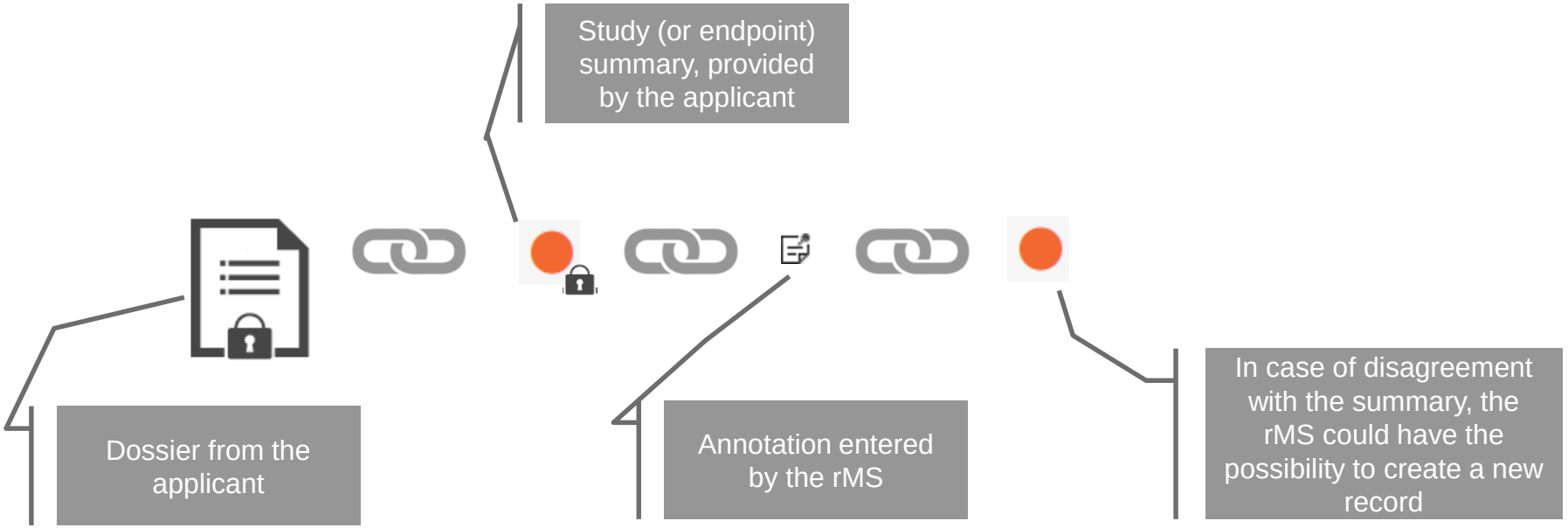
Annotations

Extension to provide alternative summary (PPPIUCLID_I106b)

Not in the MVP

- Relevant for the cases when values in the dossier provided by the applicant are different from those validated by regulators

- Proposal
  - Investigate the possibility to create an alternative summary record that is linked to an Annotation made for the summary record submitted by the applicant



Annotations

Additional improvements

- In the context of the transition from the Classic user interface to the new (web-based) one, several improvements are planned around annotations:
  - Export annotations from a dossier in order to share them with another user who has the same dossier in another database (IUCVI-12081)
  - Provide possibility to add attachments to annotations (IUCVI-12729)
  - Provide possibility to see annotations modification history (IUCVI-14525)

Annotations

Review of the format

- Inclusion of conditional formatting (PPPIUCLID_I121)
- Purpose of the status flag: should an annotation even be locked when an assessment is concluded? (PPPIUCLID_I122b)
- Basic and Dataset data (PPPIUCLID_I122c)

We could start with a simplification of the format to cover needs identified during the pilot

Aggregation and filtering

Aggregation

PPPIUCLID_I113

- The aggregation tool is available to be used
- It has been tested successfully on mixture-dossiers
- It can play a role in the case of multiple submissions as part of a renewal dossier to merge data to facilitate the assessment

Potential role to be confirmed in the next weeks while finalising the pilot phase

Filtering

PPPIUCLID_I241

- Tool adapted to mixture-dossiers during the pilot

- Planned to be used
  - to remove confidential information from submitted dossiers before they can be shared to the public
  - to support the preparation of a publishable version of the RAR

- Filtering configuration to be developed

Filtering

Attachments to be made public (e.g. sanitised reports)

- Different solutions available
  1. Public or confidential flag added at the attachment level
  2. Addition in all relevant documents of a repeatable field to store attachments declared, by the applicant, to be publishable

- Option (2) seems to be the best approach as the risk to mix public and confidential attachments is reduced and validation / filtering rules are easier to apply

- In parallel, a proposal emerged to enhance the current literature references by the addition of attachment fields (one for standard attachments, one for publishable attachments)
  - This represents the added value to store only once a study report that could eventually contribute to several endpoints

Integration with 3rd party systems

Integration with 3rd party systems

Objective: Improved support for integration with 3rd party systems

- Proposal
  - Improve documentation on how to build IUCLID (.i6z) files (based on the received feedback)
  - Improve documentation on the IUCLID Public REST API and IUCLID Extension Module API (based on the received feedback)
  - Clarify characteristics of HTML text handled by the IUCLID rich-text editor and potentially apply some kind of validation (format, allowed syntax check) on rich-text field content

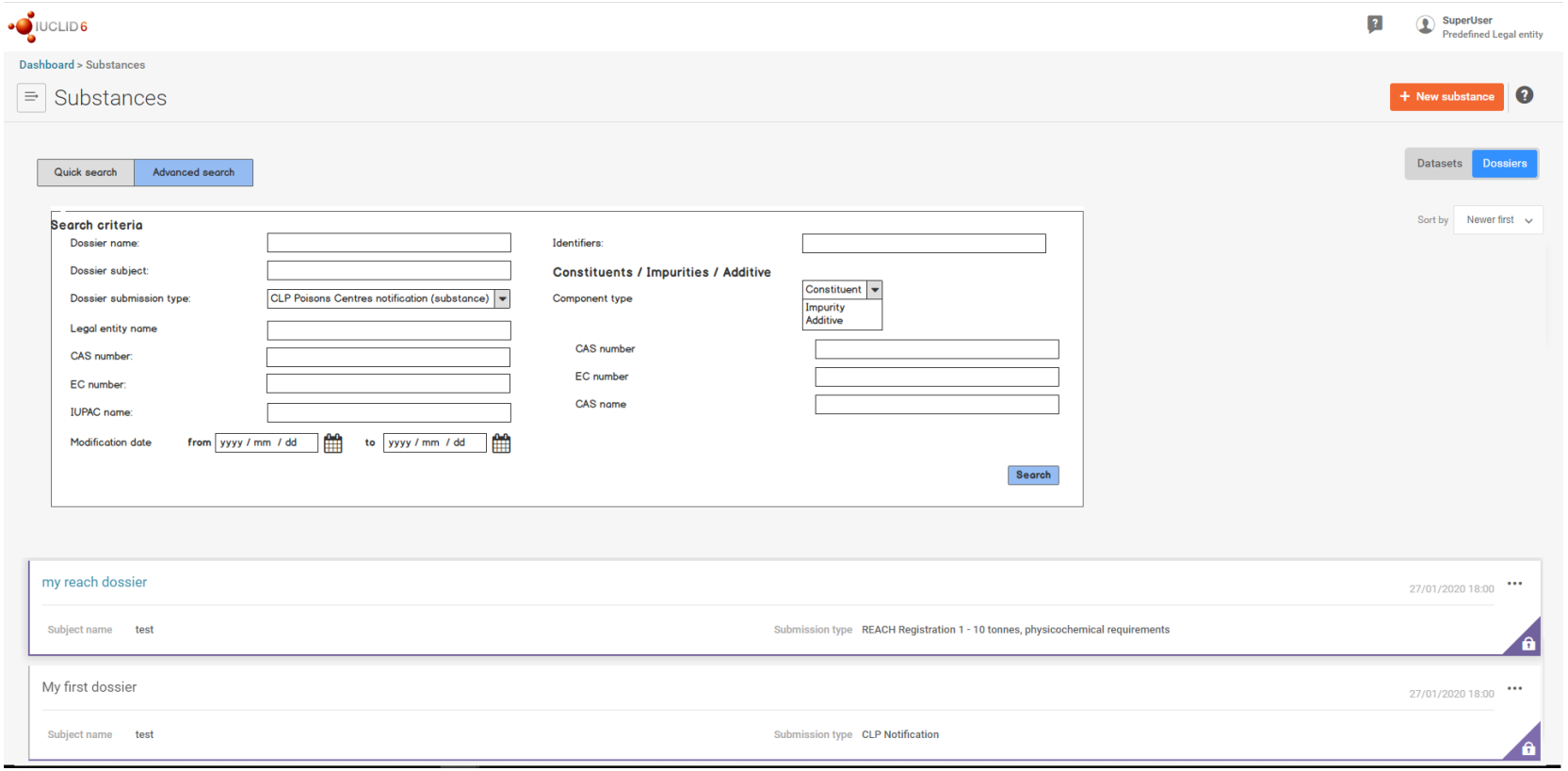
Miscellaneous

(but still important ☺)

Other improvements

Search

- Search by document UUID (PPPIUCLID_I109), by lit. ref. (PPPIUCLID_I29d) (PPPIUCLID_I324)

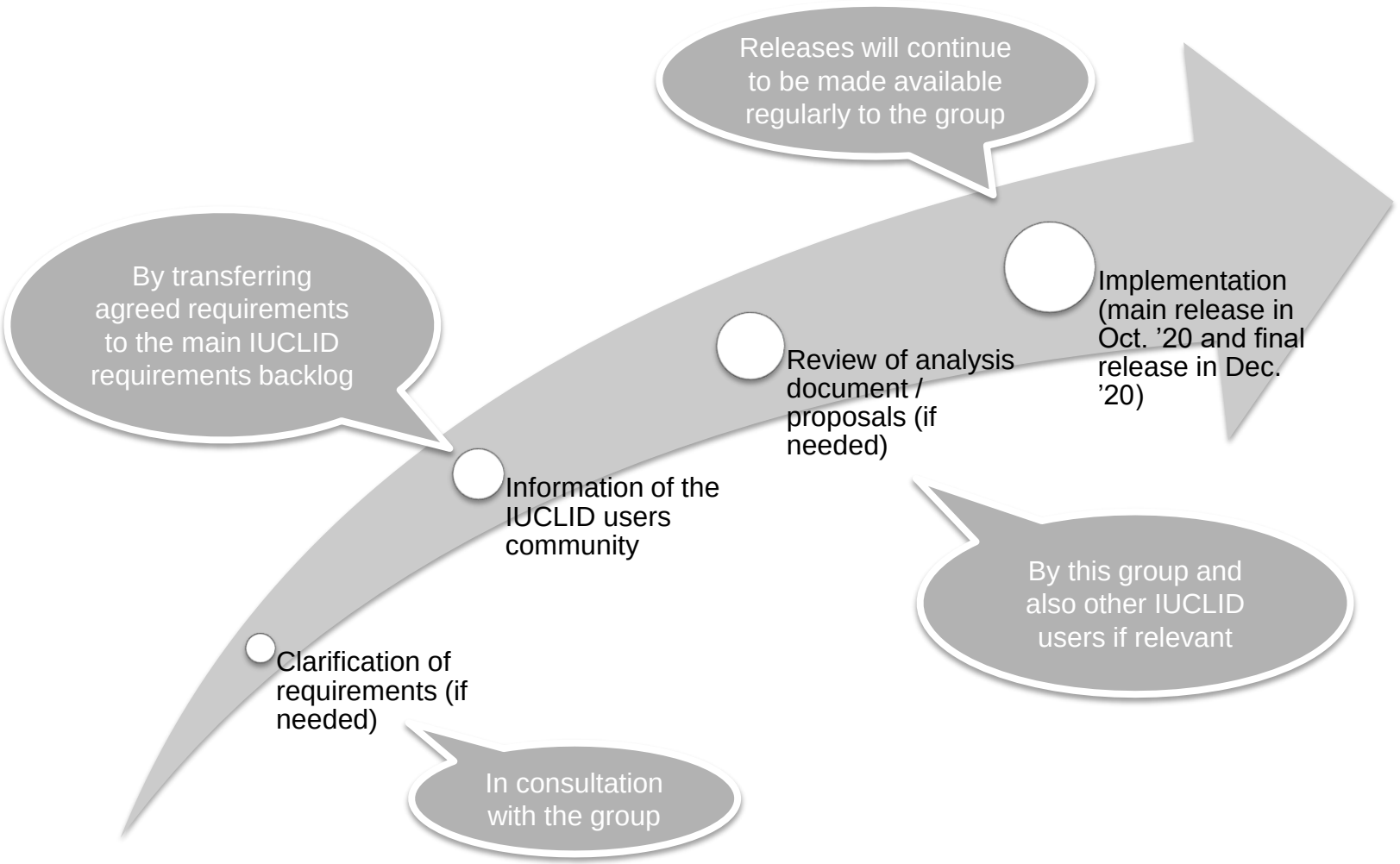


Other improvements

- Search by document UUID (PPPIUCLID_I109), by lit. ref. (PPPIUCLID_I29d) (PPPIUCLID_I324)
- Printing full dossiers – create PDF (including components) (PPPIUCLID_I116, PPPIUCLID_I53)
- Easier access to the Active Substance dataset (from the generic product)
- Displaying only latest dossier (PPPIUCLID_I323): to make sure evaluators are informed when a new version is available in the database

Next steps

Next steps


Releases will continue to be made available regularly to the group
By transferring agreed requirements to the main IUCLID requirements backlog
Implementation (main release in Oct. ’20 and final release in Dec. ’20)
Review of analysis document / proposals (if needed)
Information of the IUCLID users community
By this group and also other IUCLID users if relevant
Clarification of requirements (if needed)
In consultation with the group

Thank you!

ECHA
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IUCLID 6 is developed by the European Chemicals Agency in association with the OECD