6th November 2019

Introduction to the pilot and the components to be included

Jane Richardson

DATA Officer, EFSA

Trusted science for safe food

efsa
European Food Safety Authority

EFSA and ECHA

Bernhard Url @BUrl_EFSA · Apr 12

Bringing the cooperation with @EU_**ECHA** to the next level. **EFSA**-**ECHA** workshop in Helsinki: moving from joint activities to a strategic partnership.

EU ChemicalsAgency - ECHA @EU_ECHA · Apr 12

Together with @EFSA_EU's management team, we signed an agreement for using #IUCLID also for data related to #pesticides. We discussed further cooperation to improve risk assessment and research on chemical #substances. #SaferChemicals

Bernhard Url and Barbara Gallani

Survey of RMS: use of IUCLID for pesticides dossiers

- The survey was circulated to members of the EFSA Pesticide Steering Network in June 2019
- Responses were received from 17 organisations in 11 countries
- Most of the respondents use a file system and CADDY viewer to review pesticides dossiers. File and document management systems, digital archives and in-house systems are being used to store dossiers and create assessment reports.
- For organisations with more advanced systems other functionalities include dossier version management and assignment of study identifiers, managing commenting and confidentiality, tracking study evaluations.

EFSA Pesticides Steering Network Survey

Country	Organisation	IUCLID Users	Benefit IUCLID for PPP	In House System
Austria	Austrian Agency for Health and Food Safety	No	No	No
Denmark	Pesticider and Biocide Unit, Danish EPA	Yes	Yes	No
Finland	Finnish Safety and Chemicals Agency	Yes	Yes	No
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	Yes	No	Yes
Germany	German Environment Agency	Yes	Yes	Yes
Germany	German Federal Institute for Risk Assessment, BfR	Yes	No	Yes
Ireland	Department of Agriculture, Food and the Marine	Yes	Yes	No
Netherlands	Ctgb - Board for the authorisation of Plant Protection Product and Biocides	Yes	Yes	No
Norway	Norwegian Food Safety Authority	No	Yes	No
Poland	Bureau for Chemical Substances	Yes	Yes	No
Poland	Ministry of Agriculture and Rural Development	No	Yes	No
Portugal	DGAV - Direção Geral de Alimentação e Veterinária	Yes	Yes	Yes
Slovenia	Chemical Office of the R Slovenia	Yes	No	No
Spain	INIA - INSTITUTO NACIONAL DE INVESTIGACION Y TECNOLOGIA AGRARIA Y ALIMENTARIA	No	No	No
Spain	Ministerio de Sanidad, Consumo y Bienestar Social	Yes	No	Yes
Sweden	Swedish Chemicals Agency (KemI)	Yes	Yes	No
United Kingdom	Health and Safety Executive (CRD)	Yes	No (Updated information Yes)	No
		76%	**59%**	**30%**

Pilot Technical group

- Six member states (PT, FI, PL, DE, FR, AT)
- Two industry associations (ECPA, ECCA)
- European Chemicals Agency (ECHA)
- EFSA
- EC (observer)

Pilot objectives

- Engage stakeholders and better understand dossier processing steps
- Prove the suitability of IUCLID for pesticide dossiers
- Demonstrate that the use of structured data enhances the quality, clarity and usability of information included in dossiers with a focus on interoperability and information exchange
- Identify required adaptations for inclusion in future IUCLID releases
- Provide feedback on users' experience to support EFSA's decision for the implementation of the Transparency Regulation deliverables (March 2021 and onwards)

Proof of concept dossier

Adaptation, into IUCLID format, of a new active substance and renewal pesticide dossier (pilot phases I and II)

- Completion of administrative data
- Removal of confidential data and replacement with 'dummy data' and inclusion of confidentiality flags and justifications
- Upload of sanitised attachments with reference metadata
- Completion of all relevant OECD harmonised templates
- Use of existing templates for summary and evaluation information
- Testing validation assistant, reporting and filtering tools
- Recording issues and time taken for dossier preparation

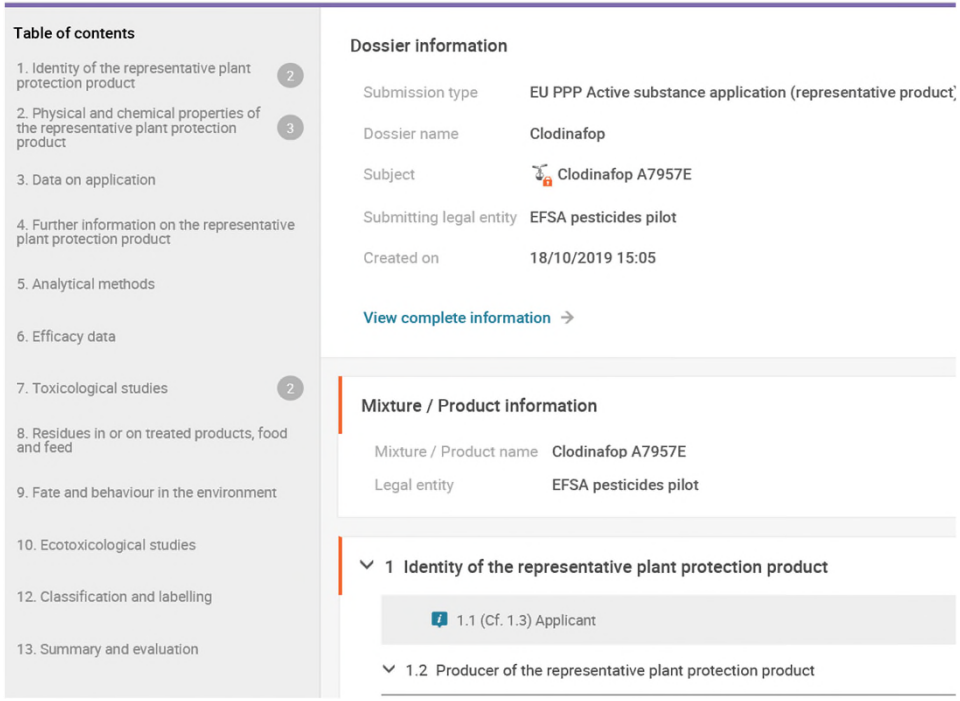
Role of applicant to be performed by EFSA's contractor: Contact finalisation in progress

IUCLID adaptations for pesticides

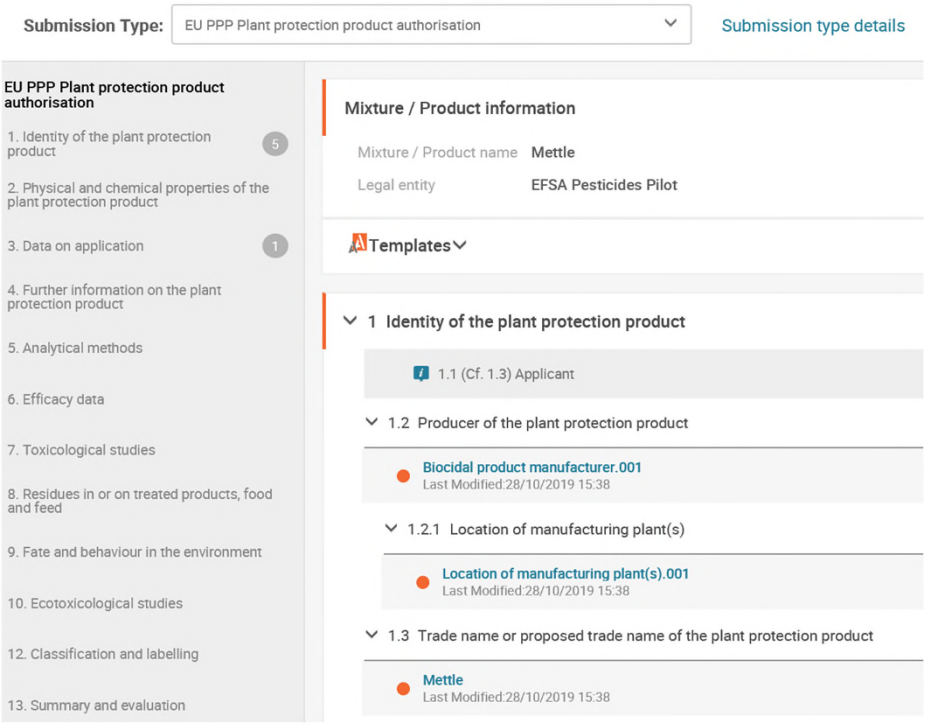
Submission types	Configuration of new submission types for Pesticides Active Substances and Pesticides Products, already included in IUCLID 6.4 – review needed
Format	Identify additional needs for structured information, in addition to the existing forms (e.g. OECD harmonised templates)
Validation assistant	Selection of existing rules, identification of new ones
Report generator	E.g. draft assessment report, List of studies, List of confidentiality claims
Other features / adaptations	E.g. use of IUCLID annotations, 'light dossier' concept to reduce the dossiers size, dossier comparison

Submission types in IUCLID 6.4.2.1

EU PPP Active substance application (representative product)



EU PPP Plant protection product authorisation



Format: Summary and Evaluation

ENDPOINT_SUMMARY

- Based on the current biocides dossier format
- Possible use of existing templates, excel formats?
- Collection on-going

Table 1: WoE for T-mediated adversity

• Thyroid histological changes (follicular dilatation, FC hyperplasia and FC adenoma) observed in two species (mouse and rat) in the **carcinogenesis studies** (study ID x and y) and considered adverse (intermediate and high doses).
• The two carcinogenesis studies were conducted at the **MTD**. ○ Based on survival, body weight, food consumption, clinical chemistry and clinical signs
• The proliferative effect was confirmed by an increase in cell proliferation observed in a short study (up to 28 days) and lower dose (time & dose concordance).
• Additional target organ toxicity was observed in the adrenal, kidney (only mouse) and liver at the same doses (**relevant for consideration on potential non-endocrine MOA**)
• For the liver, changes were mainly characterized by panlobular hypertrophy, hepatocellular necrosis, fatty change and hepatocellular neoplasm. Considered adverse and observed in multiple studies also of shorter duration (**likely lead toxic effect**)

Table 2: WoE for T-mediated endocrine activity

• TPO in vitro investigation negative
• Decrease in THs in the mouse was observed in studies of shorter duration (14 and 28 days) and at lower doses (35 and 350 mg/kg/day).
• Decrease in THs in the rat was observed is a study of shorter duration (14 days) and dose tested of 700 mg/kg bw per day.
• Increase at week 16 only in TSH (measured in rat and mouse) were observed in mouse.

Validation assistant

REACH rules for OHTs & Generic Substance Identification

A reference substance must be linked in the substance identification

At least one endpoint study record indicated as a key study, with the 'Endpoint' selection 'in vitro gene mutation study in bacteria' must be provided

'Critical effects observed', 'Lowest effective dose/conc.', 'System', 'Organ' and 'Treatment related' must be provided

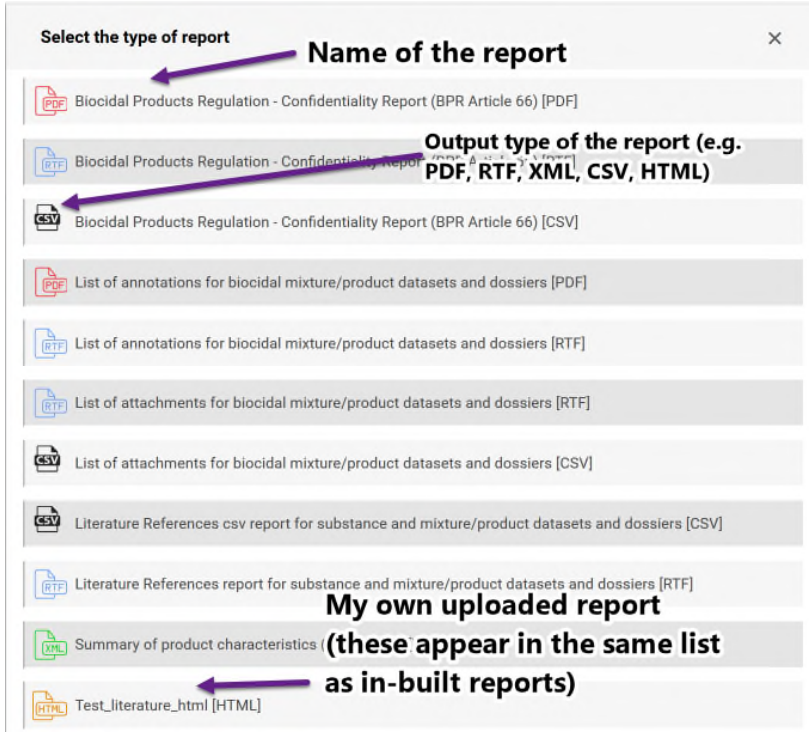
'Materials and methods' is not complete. For each study marked as 'key study' the 'Type of method' must be provided

The CAS number for the reference substance information is of an invalid format

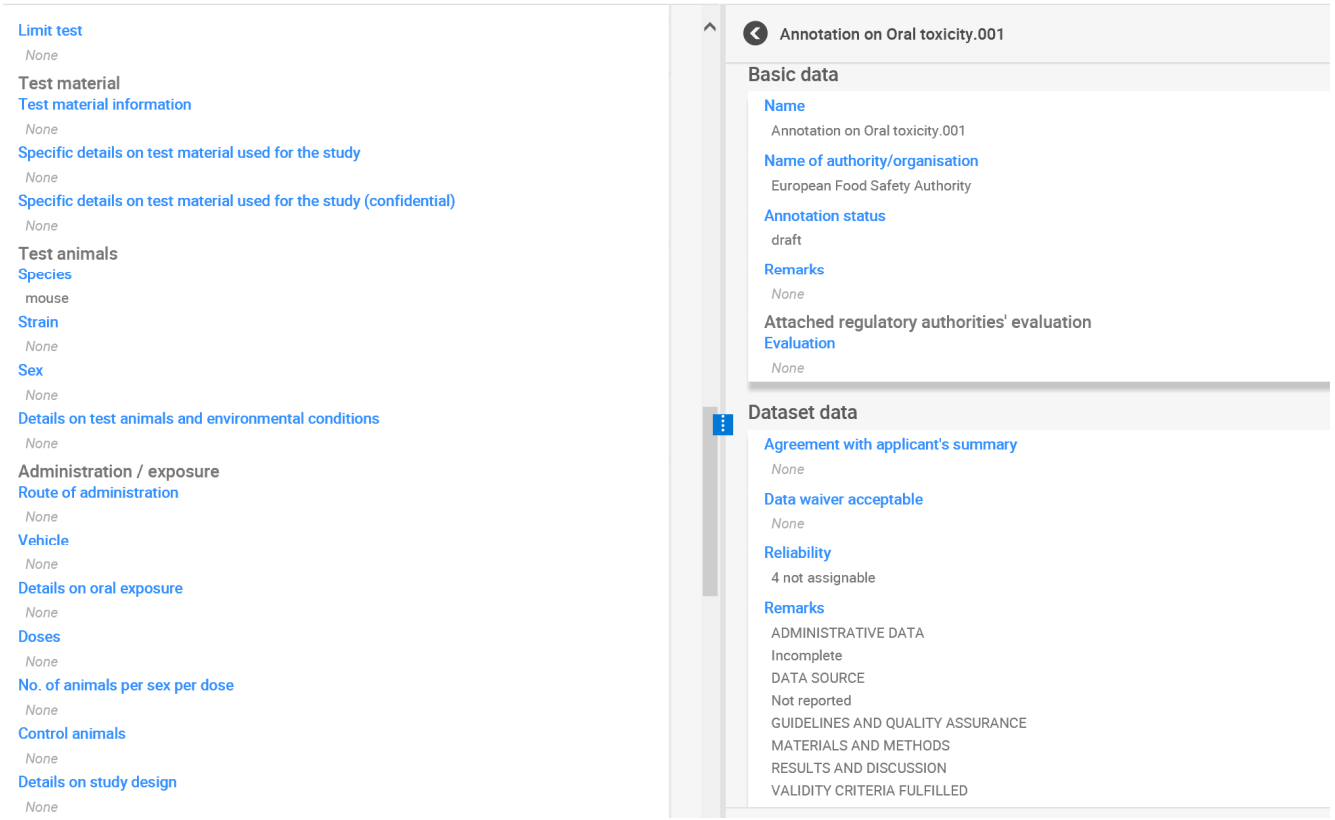
For a substance, the molecular formula, molecular weight and structural formula of the reference substance must be indicated

Report generator

- Once entered in IUCLID, the data can be extracted and presented in different ways in different formats (.csv, .html, .rtf, .xml)
- Using the report generator
- Example of reports that could be developed: draft assessment report, list of studies, list of confidentiality claims



Annotation



- All comments and assessment related to one substance/product in one place
- Possibility to share comments (annotations) with other users
  - In the same database
  - Or by exporting the annotations

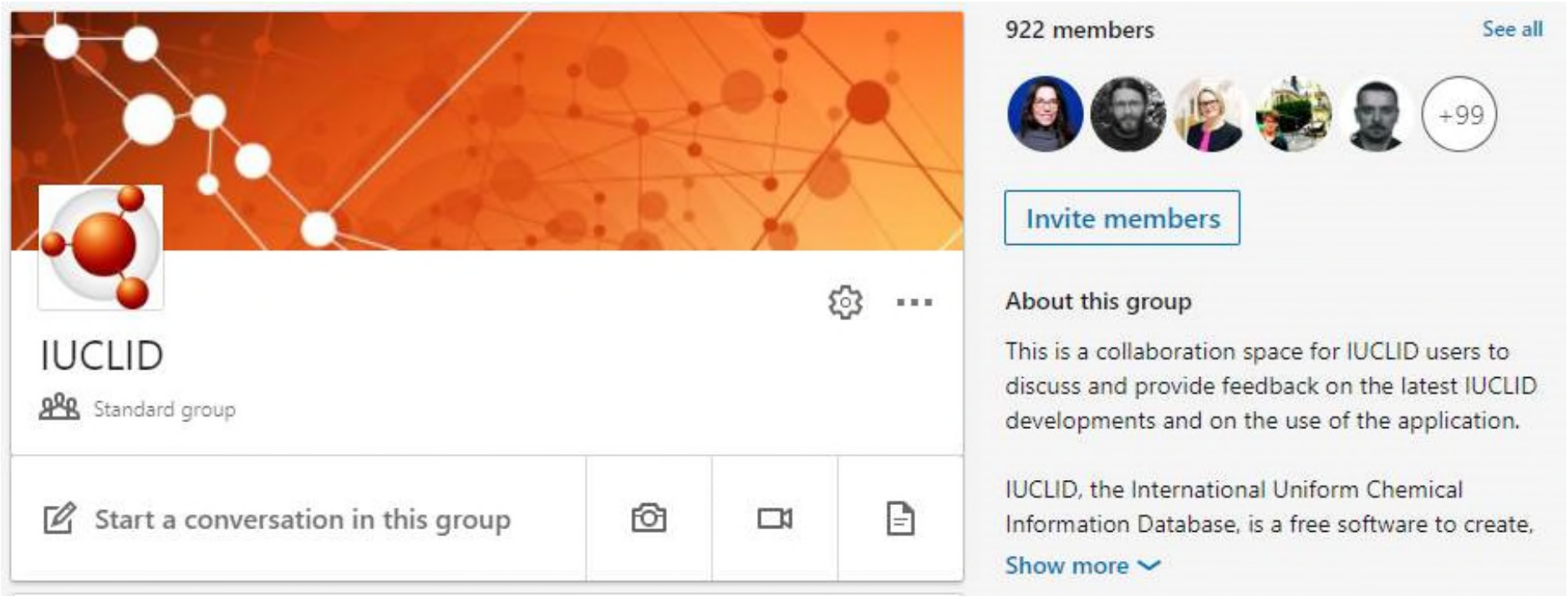
Goals for the meeting

1. Get to know each other

2. Shared understanding of dossier processing steps to prepare a detailed plan and timing for the pilot activities

3. Identify training needs for IUCLID features to allow their testing during pilot phase

Meet other IUCLID users



https://www.linkedin.com/groups/12043483/