

6th November 2019

Introduction to the pilot and the components to be included

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Trusted science for safe food

EFSA and ECHA



Bernhard Url @BUrI_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.

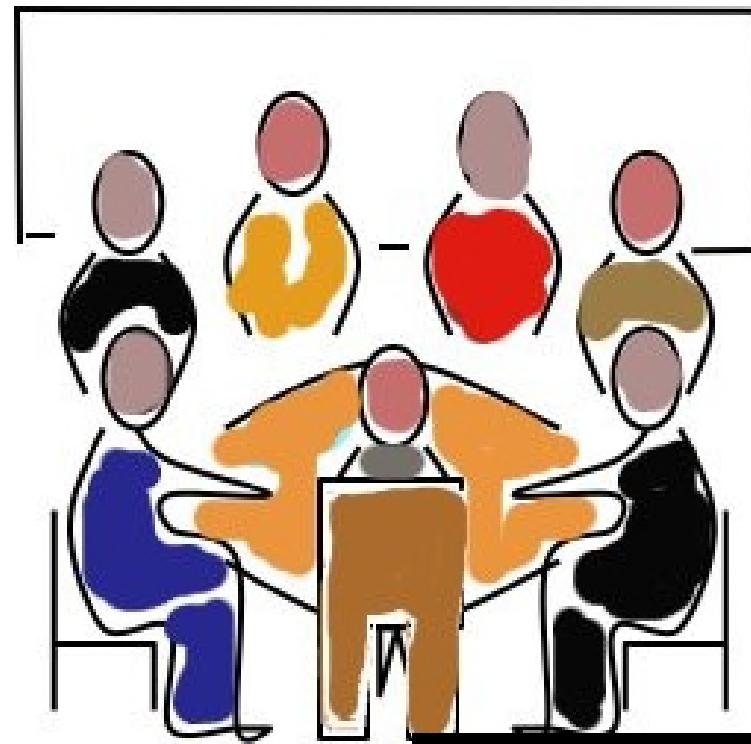
EFSA Pesticides Steering Network Survey



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)



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- 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)

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)

Table of contents

- 1. Identity of the representative plant protection product
- 2. Physical and chemical properties of the representative plant protection product
- 3. Data on application
- 4. Further information on the representative plant protection product
- 5. Analytical methods
- 6. Efficacy data
- 7. Toxicological studies
- 8. Residues in or on treated products, food and feed
- 9. Fate and behaviour in the environment
- 10. Ecotoxicological studies
- 12. Classification and labelling
- 13. Summary and evaluation

Dossier information

Submission type	EU PPP Active substance application (representative product)
Dossier name	Clodinafop
Subject	Clodinafop A7957E
Submitting legal entity	EFSA pesticides pilot
Created on	18/10/2019 15:05

[View complete information](#)

Mixture / Product information

Mixture / Product name	Clodinafop A7957E
Legal entity	EFSA pesticides pilot

1 Identity of the representative plant protection product

- 1.1 (Cf. 1.3) Applicant
- 1.2 Producer of the representative plant protection product

EU PPP Plant protection product authorisation

Submission Type: EU PPP Plant protection product authorisation [Submission type details](#)

EU PPP Plant protection product authorisation

- 1. Identity of the plant protection product
- 2. Physical and chemical properties of the plant protection product
- 3. Data on application
- 4. Further information on the plant protection product
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Mixture / Product information

Mixture / Product name	Mettle
Legal entity	EFSA Pesticides Pilot

Templates

1 Identity of the plant protection product

- 1.1 (Cf. 1.3) Applicant
- 1.2 Producer of the plant protection product
 - Biocidal product manufacturer.001
Last Modified: 28/10/2019 15:38
 - 1.2.1 Location of manufacturing plant(s)
 - Location of manufacturing plant(s).001
Last Modified: 28/10/2019 15:38
- 1.3 Trade name or proposed trade name of the plant protection product
 - Mettle
Last Modified: 28/10/2019 15:38

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 . <ul style="list-style-type: none">○ 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 in 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.

REACH rules for OHTs & Generic Substance Identification

A reference substance must be linked in the substance identification

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

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

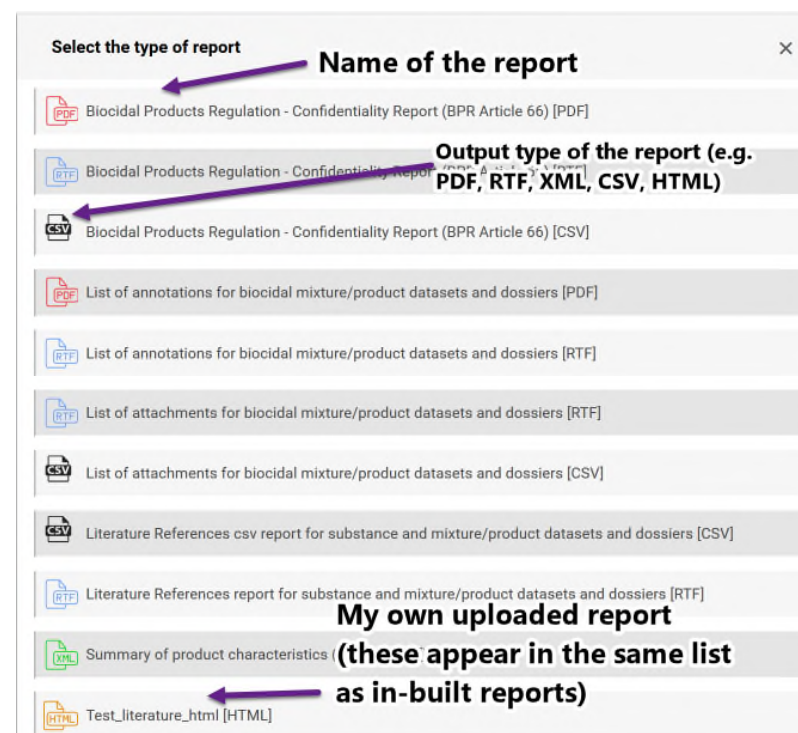
The CAS number for the reference substance information is of an invalid format

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

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



The screenshot shows a web interface titled "Select the type of report" with a close button (X) in the top right corner. It displays a list of report options, each with a file icon and a description. Annotations with arrows point to specific elements:

- An arrow points to the "Name of the report" header.
- An arrow points to the "Output type of the report (e.g. PDF, RTF, XML, CSV, HTML)" column.
- An arrow points to the "My own uploaded report (these appear in the same list as in-built reports)" section.

Select the type of report	
	Name of the report
	Biocidal Products Regulation - Confidentiality Report (BPR Article 66) [PDF]
	Biocidal Products Regulation - Confidentiality Report (BPR Article 66) [RTF]
	Biocidal Products Regulation - Confidentiality Report (BPR Article 66) [CSV]
	List of annotations for biocidal mixture/product datasets and dossiers [PDF]
	List of annotations for biocidal mixture/product datasets and dossiers [RTF]
	List of attachments for biocidal mixture/product datasets and dossiers [RTF]
	List of attachments for biocidal mixture/product datasets and dossiers [CSV]
	Literature References csv report for substance and mixture/product datasets and dossiers [CSV]
	Literature References report for substance and mixture/product datasets and dossiers [RTF]
	Summary of product characteristics [XML]
	Test_literature_html [HTML]

Annotation

Limit test
None

Test material
Test material information
None
Specific details on test material used for the study
None
Specific details on test material used for the study (confidential)
None

Test animals
Species
mouse
Strain
None
Sex
None
Details on test animals and environmental conditions
None

Administration / exposure
Route of administration
None
Vehicle
None
Details on oral exposure
None
Doses
None
No. of animals per sex per dose
None
Control animals
None
Details on study design
None

Annotation on Oral toxicity.001

Basic data

Name
Annotation on Oral toxicity.001

Name of authority/organisation
European Food Safety Authority

Annotation status
draft

Remarks
None

Attached regulatory authorities' evaluation
Evaluation
None

Dataset data

Agreement with applicant's summary
None

Data waiver acceptable
None

Reliability
4 not assignable

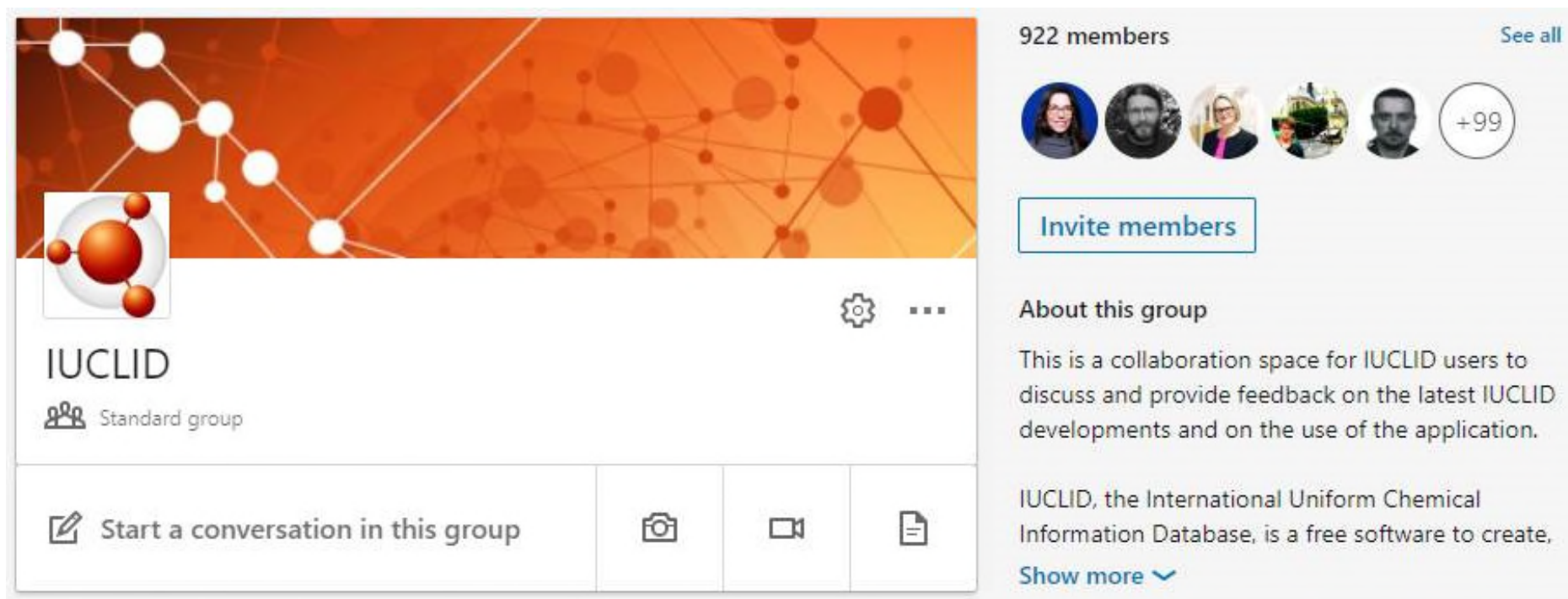
Remarks
ADMINISTRATIVE DATA
Incomplete
DATA SOURCE
Not reported
GUIDELINES AND QUALITY ASSURANCE
MATERIALS AND METHODS
RESULTS AND DISCUSSION
VALIDITY CRITERIA FULFILLED

- 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



The screenshot shows the LinkedIn group page for IUCLID. The header features a large orange banner with a molecular network pattern. Below the banner is the group's profile picture, which is a circular icon with a molecular structure. The group name "IUCLID" is displayed, followed by the text "Standard group". To the right of the name are settings and more options icons. Below the name is a row of four buttons: "Start a conversation in this group", "Add photo", "Add video", and "Add document". On the right side of the page, it shows "922 members" with a "See all" link. Below this is a row of five member profile pictures and a "+99" button. A blue "Invite members" button is located below the member list. The "About this group" section describes the group as a collaboration space for IUCLID users to discuss and provide feedback on the latest IUCLID developments and on the use of the application. It also mentions that IUCLID, the International Uniform Chemical Information Database, is a free software to create. A "Show more" link is provided at the bottom of the about section.

IUCLID

Standard group

Start a conversation in this group

922 members [See all](#)

[Invite members](#)

About this group

This is a collaboration space for IUCLID users to discuss and provide feedback on the latest IUCLID developments and on the use of the application.

IUCLID, the International Uniform Chemical Information Database, is a free software to create.

[Show more](#)

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