



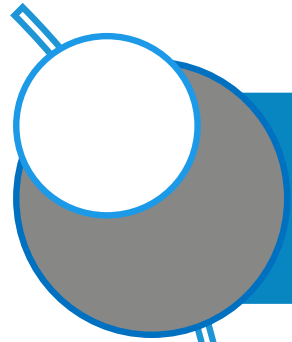
Expert Group on General Food Law
16 November 2020

Update on IUCLID implementation and hypercare

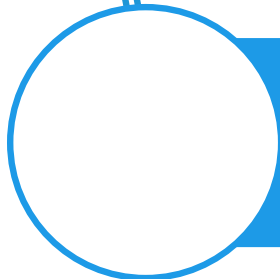
Jane Richardson and Karine Lheureux
EFSA

Trusted science for safe food

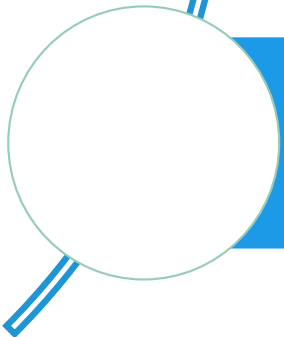




IUCLID 6.5 available



IUCLID HYPERCARE



IUCLID training and supporting materials

IUCLID 6.5

- 28/10/2020 **IUCLID 6.5** is available
- Version includes Minimum Viable Product to be used for dossier building and submission of all EFSA PPP submissions

- Several **submission types**
 - New & renewal Active Substance
 - Micro-organisms
 - Basic substance
 - MRL



- Documentation for IUCLID 6.5 available on the IUCLID 6 website 6
<https://iuclid6.echa.europa.eu/it/home>
- Documentation on EFSA Technical group IUCLID for PESTICIDES
<https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation>

Submission Type: EU PPP Active substance information



1. Identity of the active substance	8
2. Physical and chemical properties of the active substance	72
3. Further information on the active substance	8
4. Analytical methods	56
5. Toxicological and metabolism studies on the active substance	93
6. Residues in or on treated products, food and feed	61
7. Fate and behaviour in the environment	56
8. Ecotoxicological studies on the active substance	93
10. Classification and labelling of the active substance	3
11. Summary and evaluation	11

Table of content

- 6 Residues in or on treated products, food and feed (12)
- 6.1 Storage stability of residues (3)
- 6.2 Metabolism, distribution and expression of residues (3)
 - 6.2.1 Metabolism of residues in plants and in rotational crops (2)
 - Metabolism of residues in plants and in rotational crops.001
 - Metabolism of residues in plants and in rotational crops.002
 - 6.2.2 Metabolism of residues in livestock (1)
 - 6.3 Magnitude of residue trials (1)

View Dossiers

UUID: e1067a6c-ad1a-408e-a1bd-b6b190d05166

Administrative data

None None

Endpoint
None

Type of information
None

Adequacy of study
None

Robust study summary

Used for classification

Used for SDS

Study period
None

Reliability
None

Rationale for reliability incl. deficiencies
None

Data waiving
None

Justification for data waiving
None

Justification for type of information

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View Dossiers Go to search

UUID: 92c1bbe0-1a2b-4627-a831-e90c6120c639 Hide empty

Administrative data

None None

Description of key information

None

Primary crops

#.	Cro...	Co...	Tre...	Ap...	DAT	L

Rotational crops

#.	Crop gr...	Comm...	PBI	Link

Additional information

None

Attached background material

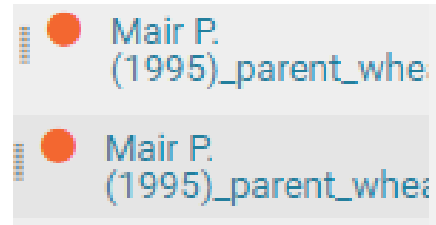
#.	Attached document	Remarks

Attached (sanitised) documents for publication

None

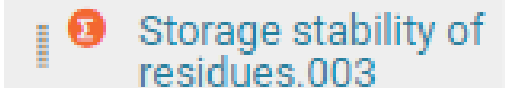
■ **Study records:**

- Attached pdf documents (full & sanitized)
- Structure template when available (e.g. OECD harmonised templates (OHT))



■ **Summary records (Endpoint summaries)**

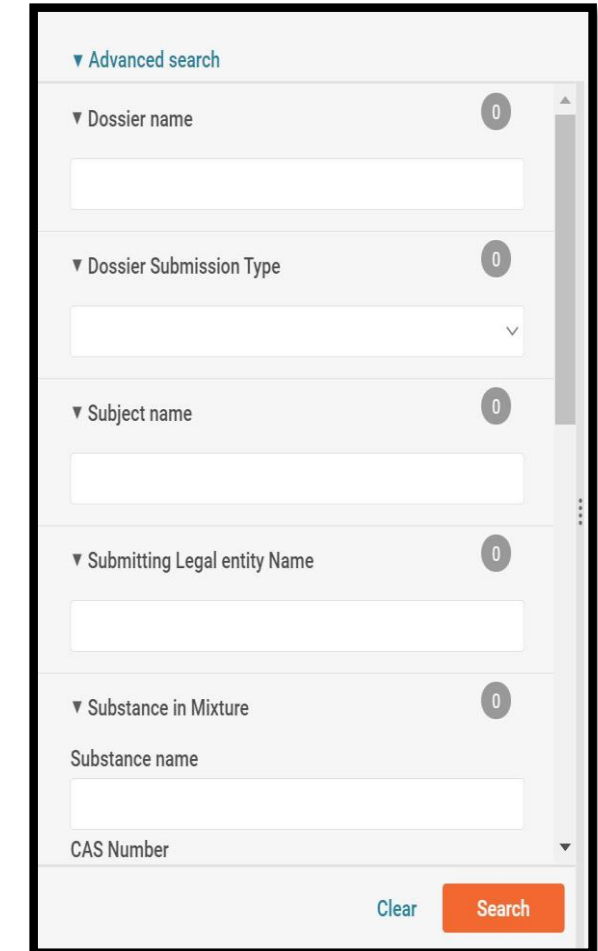
- Reuse of the existing (e.g. tox)
- Creation of new templates based on the LOEP (e.g. residues)



■ **Harmonisation** based on current terminologies:

- Use of picklist (e.g. EPPO codes, food classification Reg 396/2005)
- One similar structure for the GAP table in all dossiers

- **Validation assistant** rules and configuration
 - Check presence of a required document (depending on submission type)
 - Quality check for in document completeness (simple rules)
 - **Create PDF** from data in each component of the dossier (full dossier in development)
 - **Search** for entities and documents (e.g. search dossiers, advanced search)
 - **Comparison** of the versions of the dossiers
 - Filtering of **confidential** information
 - **Dissemination** preview
 - Commenting (to send comments to applicants)
 - Annotations (to be further developed)
- (more in Annex)



The screenshot shows the 'Advanced search' interface in IUCLID. It features a vertical list of search criteria, each with a dropdown arrow, a search field, and a circular counter with the number '0'. The criteria are: 'Dossier name', 'Dossier Submission Type', 'Subject name', 'Submitting Legal entity Name', and 'Substance in Mixture'. The 'Substance in Mixture' section includes a 'Substance name' field and a 'CAS Number' dropdown. At the bottom right, there are 'Clear' and 'Search' buttons.



- Submission area for applicants
- Automated file checks
- Submission report



- Secure access to Agency instance of IUCLID*
- Agency view and entity search
- Notifications (e.g. dossier received)
- Requires VPN for access (EC collecting nomination for MSs)



Generate report

- Study and Reference literature lists
- Assessment reports
- Reports aggregating information from repeated documents (e.g. GAP and 5 batch analysis)

- TIMELINE: NOV 2020 – NOV 2021
- HYPERCARE team: APDESK, PESTICIDE, DATA, ECHA, EC
- Objectives:
 - Targeted support to MSs and applicants
 - Deliver a IUCLID Hypercare programme for early submitters of renewal active substances + few MRL submissions
 - Around 15 substances with extended legal deadline July-August 2021
 - Develop and extend IT technical knowledge of IUCLID for MSs and applicants
 - Use this IUCLID Hypercare programme to refine EFSA help desk support, EFSA IUCLID training materials, IUCLID implementation (link to IUCLID release schedule)

- WHO
 - “applicants” are owners of the selected applications for renewal of active substance and are **active participants**
 - The lead Rapporteur Member States are **active participants**
 - Co-RMS and observer MS are **observers**
 - ECHA, EFSA, EC

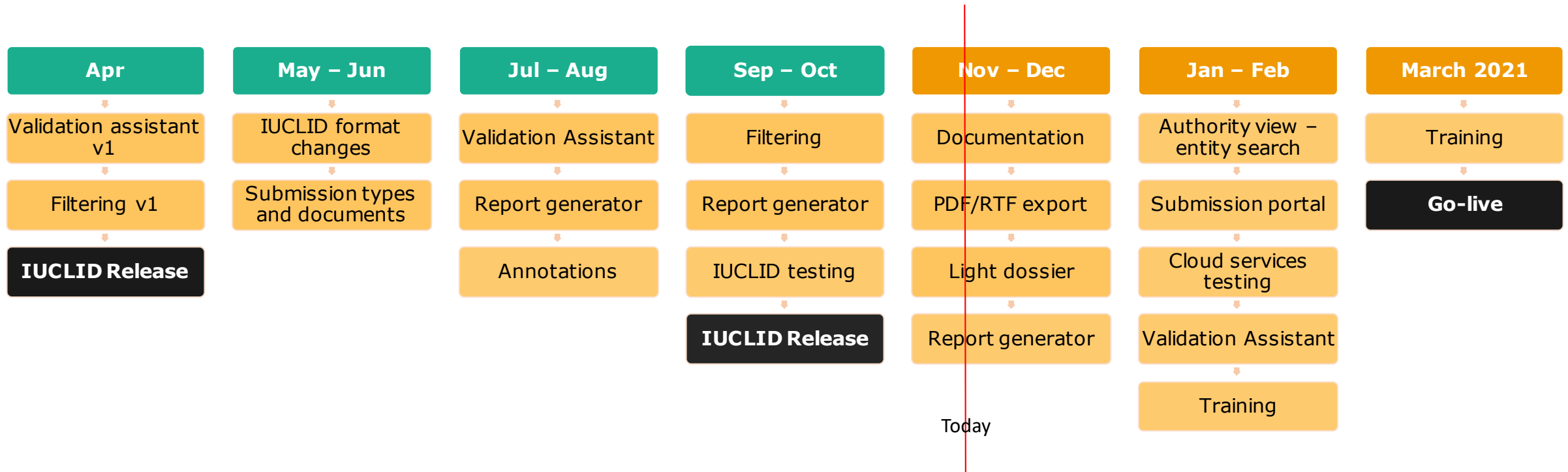
- HOW
 - Creation of a new **EFSA Pesticide Steering Network sub-group**
 - Kick-off meeting end of November 2020
 - Biweekly tele-meeting - specific topics, IUCLID format
 - Example: data on residues, specific OHT
 - Every 6-weeks tele-meeting – generic topics, IUCLID feature
 - Example: annotation, validation assistant, reporting
 - 2 tele-meetings dedicated to MRL + prioritised **training materials on MRL**
 - Planning of topics discussed in tele-meetings (biweekly, monthly) is **established in advance**

The IUCLID training plan includes:

- Analysis of **existing IUCLID training material**
- Setting up of an inventory to catalogue and provide public access to old and new material
- Establish a **platform** (e.g. a **knowledge management platform/portal**) publicly available granting easy access to the available training material, the schedule of upcoming trainings and provide the possibility to express interest/register
- A lot of material already available:
 - IUCLID website <https://iuclid6.echa.europa.eu/documentation>)
 - IUCLID youtube channel
<https://www.youtube.com/playlist?list=PLOPGDACSD6qyDkdXwPua1Fjb5bJksY75k>

- Making available **technical documentation** to support applicants in preparing pesticides dossiers in IUCLID and scientists (risk assessors) in evaluating the information submitted
- The technical documentation will include user manuals, quick guides, fact sheets...
- Documentation will be provided **for all PPP submission types** and will be tailored to different user groups (i.e. RMS, applicants, EFSA staff, etc)
- A **modular approach** will be adopted in order to:
 - Ensure consistency in completing a IUCLID document in the same way for all submission types
 - Increase efficiency in making material available

IUCLID Milestones



ECHA [webinar](#) on IUCLID 6.5

EFSA [webinar](#) on Transparency Regulation

EFSA [Technical group](#) on IUCLID for PESTICIDES

- ANNEX

■ Renewal active substances

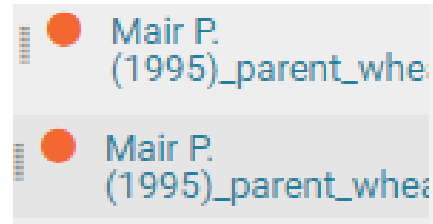
	SUBSTANCE	APPLICANT	RMS	CO-RMS
1	Azadirachtin (Margosa extract)	Mitsui; Trifolio; Sipcam Oxon	DE	ES
2	6-Benzyladenine	Fine Agrochemicals Limited, Sumitomo, Globachem (taskforce)	SE	NL
3	Flutriafol	FMC CHEMICAL	SK	UK
4	Quinmerac	BASF; ADAMA	EE	FI
5	1-Decanol	Drexel Chemical Company	PL	IT
6	Lime sulphur (calcium polysulphid)	Polisenio; Tessenderlo	CZ	NL
7	Sintofen (aka Cintofen)	ASUR Plant Breeding SAS	CZ	FR
8	Hexythiazox	Nisso Chemical Europe; JDDA	FI	SE
9	Dodine	Arysta LifeScience; Certiplant	ES	DE
10	Prosulfuron*	Syngenta Crop Protection	FR	SK
11	Isoxaben	Dow AgroSciences	AT	FI
12	Tembotrione	Bayer CropScience AG	AT	FR
13	Zinc phosphide	frunol delicia GmbH, Detia Freyberg GmbH (taskforce)	AT	DE
14	Aluminium sulphate	BIOFA AG	NL	CZ

OVERVIEW

- IUCLID Hypercare Programme (NOV 2020 – NOV 2021)
- IUCLID Helpdesk: queries to be sent to APDESK
<http://www.efsa.europa.eu/en/applications/askaquestion>
- IUCLID Training & Documentation (NOV 2020 – OCT 2022)
- IUCLID Technical Group IUCLID (NOV 2019 – JUNE 2021)

■ Study records:

- Attached pdf documents (full & sanitized)
- Structure template when available (e.g. OECD harmonised templates (OHT))



■ Summary records (Endpoint summaries)

- Reuse of the existing (e.g. tox)
- Creation of new templates based on the LOEP (e.g. residues)



■ Harmonisation based on current terminologies:

- Use of picklist (e.g. EPPO codes, food classification Reg 396/2005)
- One similar structure for the GAP table in all dossiers

- IUCLID has a plugin which enables applicants to simulate which information from their pesticides dossiers is likely to be removed before publication and which information will be made publicly available
- The Dissemination preview allows applicants to use it while they are preparing their submissions in IUCLID
- Applicants can prepare dossiers that can be published without revealing business-confidential information
 - It is strongly recommended to use the tool before submitting a dossier, to simulate which information will be published
 - The tool also produces a report, listing for all information whether it was removed or left in the filtered dossier

IUCLID feature: Dissemination preview 2/2

Literature Reference	Ostrinil®: Determination of shelf life	Literature reference / General information / Reference Type	Published	ebd9f700-3390-490d-8a8a-4382d63aa410/fcde97b5-8c1e-4884-b81d-1e862d6cbfc3
Literature Reference	Ostrinil®: Determination of shelf life	Literature reference / General information / Title	Flagged confidential / Not published	ebd9f700-3390-490d-8a8a-4382d63aa410/fcde97b5-8c1e-4884-b81d-1e862d6cbfc3 LITERATURE.GeneralInfo.Name
Literature Reference	Ostrinil®: Determination of shelf life	Literature reference / General information / Author	Flagged confidential / Not published	ebd9f700-3390-490d-8a8a-4382d63aa410/fcde97b5-8c1e-4884-b81d-1e862d6cbfc3 LITERATURE.GeneralInfo.Author
Literature Reference	Ostrinil®: Determination of shelf life	Literature reference / General information / Year	Published	ebd9f700-3390-490d-8a8a-4382d63aa410/fcde97b5-8c1e-4884-b81d-1e862d6cbfc3 LITERATURE.GeneralInfo.ReferenceYear
Literature Reference	Ostrinil®: Determination of shelf life	Literature reference / General information / Testing facility	Not published	ebd9f700-3390-490d-8a8a-4382d63aa410/fcde97b5-8c1e-4884-b81d-1e862d6cbfc3 LITERATURE.GeneralInfo.TestLab
Literature Reference	Ostrinil®: Determination of shelf life	Literature reference / General information / Study sponsor	Published	ebd9f700-3390-490d-8a8a-4382d63aa410/fcde97b5-8c1e-4884-b81d-1e862d6cbfc3 LITERATURE.GeneralInfo.CompanyOwner
Literature Reference	Ostrinil®: Determination of shelf life	Literature reference / General information / Study no.	Published	ebd9f700-3390-490d-8a8a-4382d63aa410/fcde97b5-8c1e-4884-b81d-1e862d6cbfc3 LITERATURE.GeneralInfo.CompanyOwnerStudyNo
Literature Reference	Ostrinil®: Determination of shelf life	Literature reference / General information / Report date	Published	ebd9f700-3390-490d-8a8a-4382d63aa410/fcde97b5-8c1e-4884-b81d-1e862d6cbfc3 LITERATURE.GeneralInfo.ReportDate

- The Dissemination preview works on dossiers and not datasets

- The output is an excel sheet

- Tutorial available: <https://www.youtube.com/watch?reload=9&v=m pS1g4RIG68>