



18 November 2020

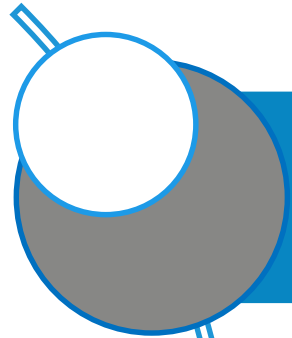
Ad Hoc Advisory Group meeting
on the Implementation
of the Transparency Regulation

Update on IUCLID implementation and hypercare

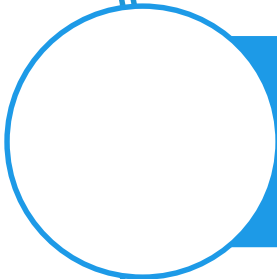
Jane Richardson and Karine Lheureux
EFSA

Trusted science for safe food

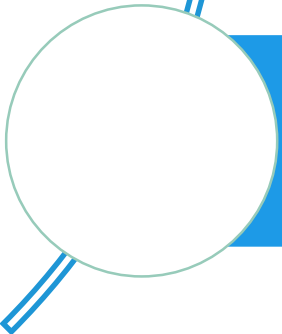




IUCLID 6.5 available



IUCLID HYPERCARE



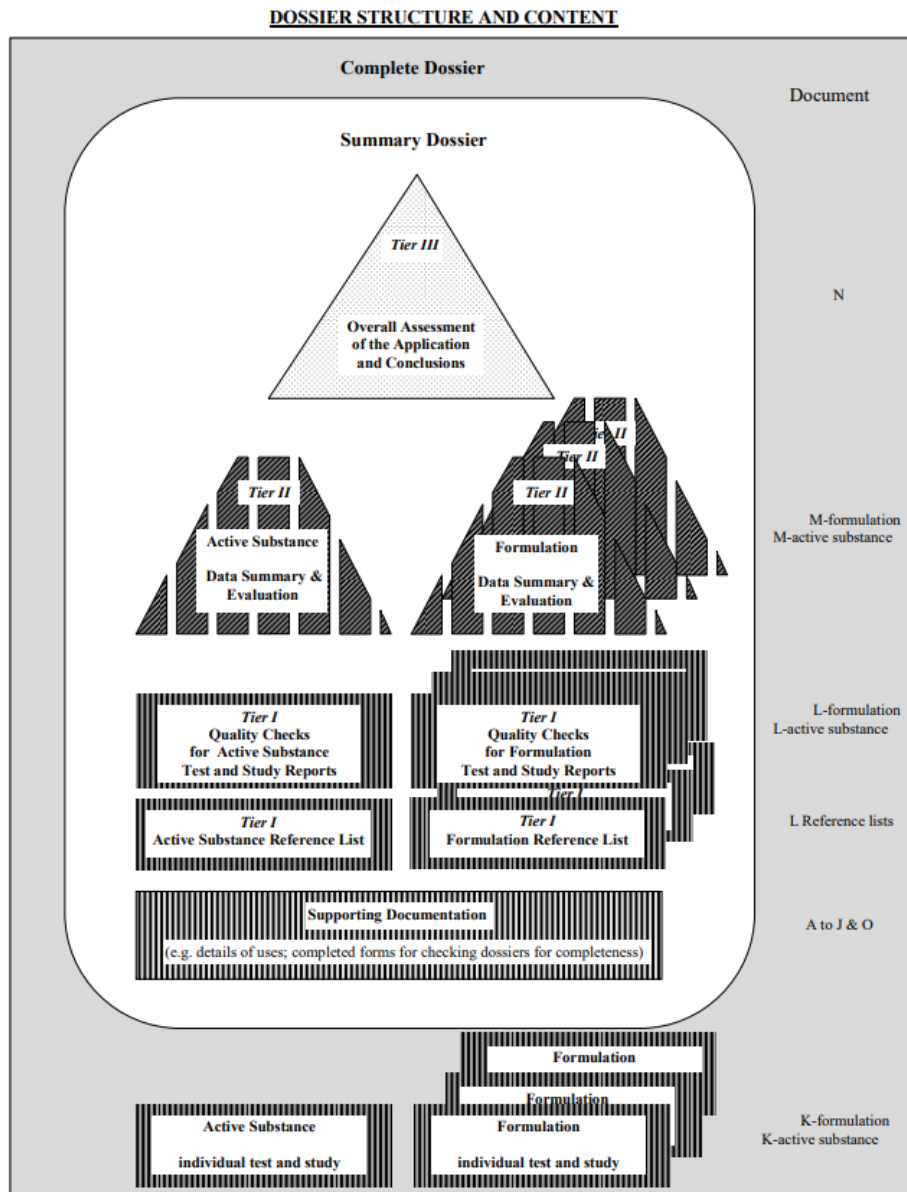
IUCLID training and supporting materials



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
- IUCLID 6.5 webinar
<https://iuclid6.echa.europa.eu/it/webinars>
- 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>

From structured dossier to structured data



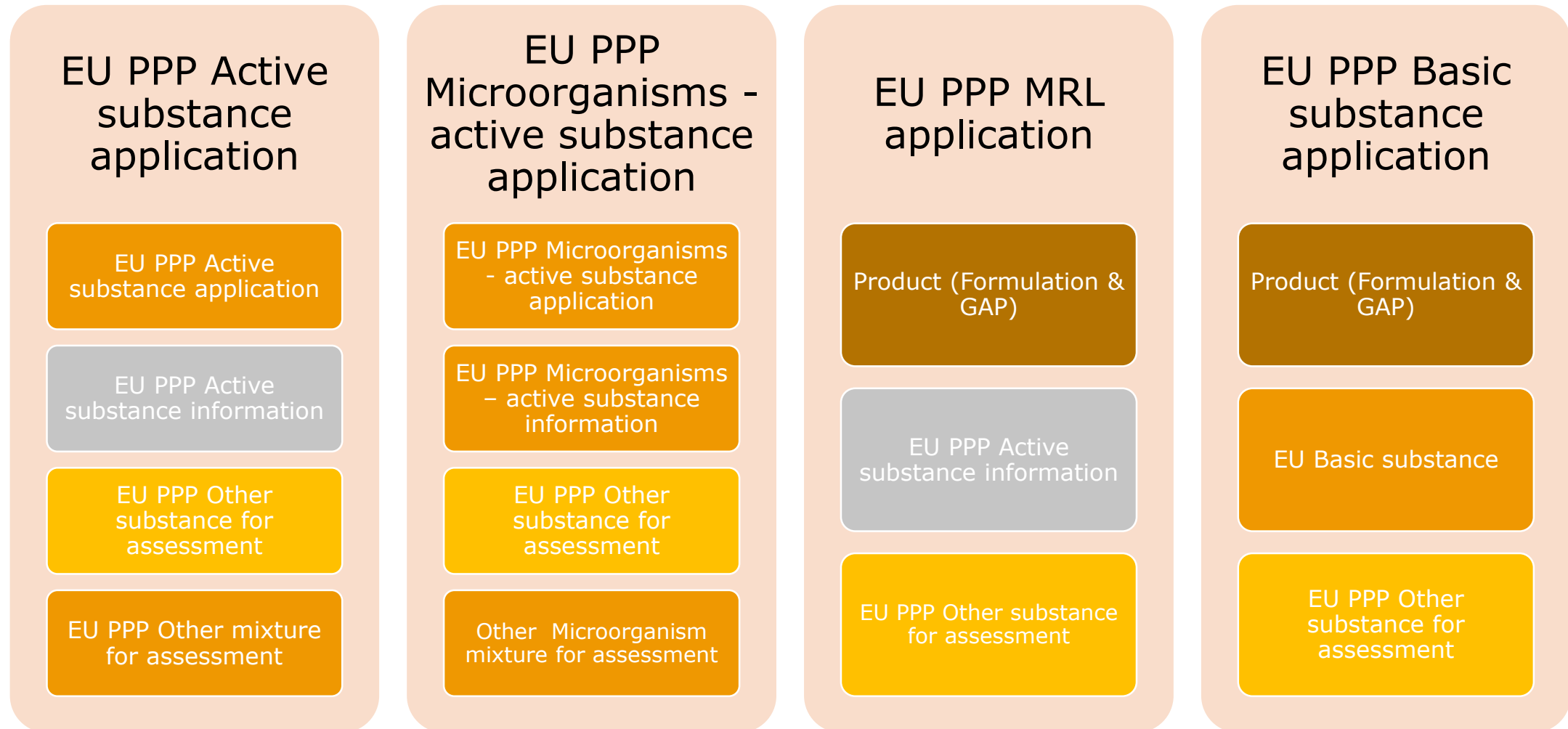
IUCLID Dossier



Active substance




Mixture




Easy creation of EU PPP Active substance application and EU PPP MRL application from the same dataset

- Clodinafop-propargyl 100 EC (TOPIK)
 - > 1 Identity of the plant protection product and applicant (5)
 - > 2 Physical, chemical and technical properties of the plant protection product (76)
 - > 3 Data on application (2)
 - > 4 Further information on the plant protection product (6)
 - > 5 Analytical methods (9)
 - 6 Efficacy data
 - > 7 Toxicological studies on the plant protection product (19)
 - > 8 Residues in or on treated products, food and feed
 - > 9 Fate and behaviour in the environment (11)
 - > 10 Ecotoxicological studies (36)
 - > 11 Literature data and change log
 - > 12 Classification and labelling (1)
 - 13 Summary and evaluation

7.1.2.1 Route of degradation in soil (soil photolysis)

 **Phototransformation in soil**
Last Modified:26/10/2020 12:01

 **Keller, A. (1993) (summary)**
Last Modified:26/10/2020 12:01

Endpoint studies (OHTs)

OECD format to describe experimental results
Relevant picklists for PPP (e.g. EPPO codes, food classification Reg 396/2005)
Includes link to a Literature reference entity

Summaries

Conclude on the available evidence for a data requirement
Ongoing work to align with LOEP (Document N2)

New transparency regulation requirements

- Need to link bibliographic data with a GLP study report and an endpoint study record
- Need to distinguish between original and sanitized reports for publication of 'admissible' dossiers
- Need to identify studies reported in the Notification of Studies Database

General information

Reference Type

study report

Title*

Leaching behaviour of clodafop-propargyl and its metabolites

Author

A Gurney

Year

2001

Bibliographic source

None

Testing facility

None

Report no.

Mod01ag01

Study sponsor

None

Study no.

None

Report date

None

Remarks

None


Attached documents

IDD0000138411.pdf

Attached (sanitised) documents for publication

None

Other study identifier(s) [+ New item](#)

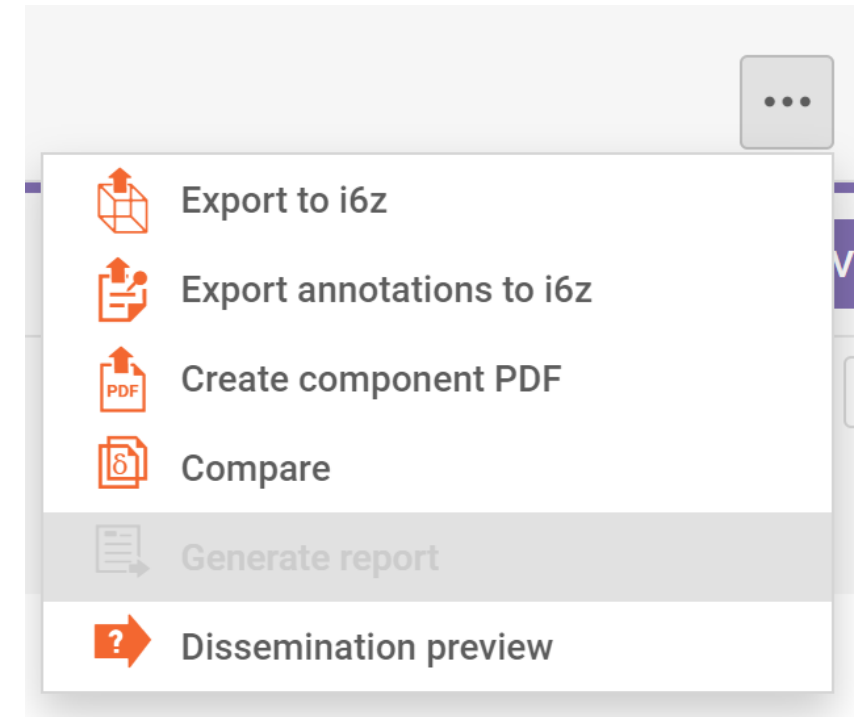
#...	Study ID	Remarks	Action
1	EFSA-2020-0000348	NOS_ID	

PUBLISHED

e.g. ENDPOINT_STUDY_RECORD DermalAbsorption
MaterialsAndMethods TestMaterials
SpecificDetailsOnTestMaterialUsedForTheStudy

UNLESS-CONF

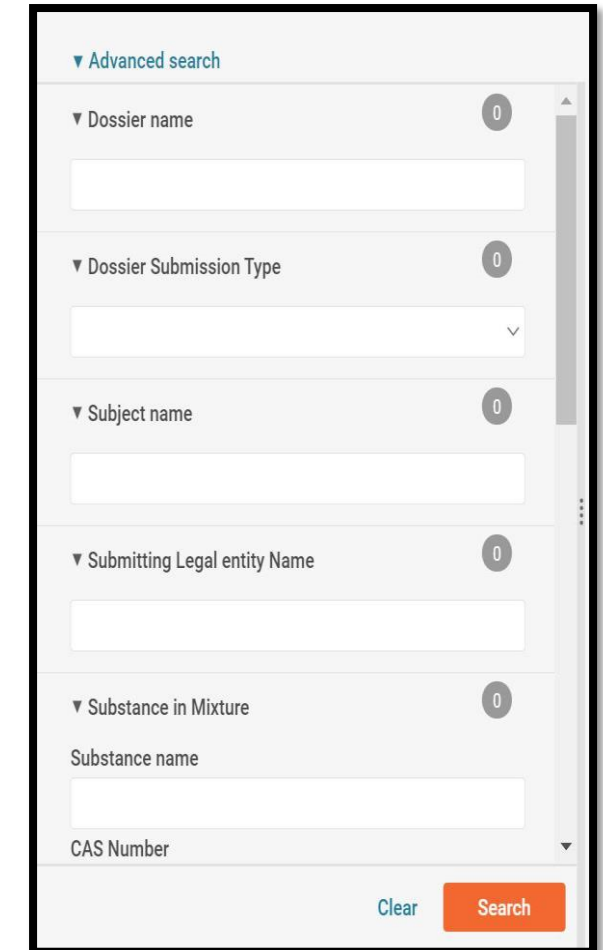
e.g. ENDPOINT_STUDY_RECORD AcuteToxicityDermal
ResultsAndDiscussion
AnyOtherInformationOnResultsInclTables OtherInformation



<https://www.youtube.com/watch?v=mpS1g4RIG68>

Consultation version of dissemination preview available
[Use google form to provide feedback](#)

- **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 showing '0' results. The criteria are: Dossier name, Dossier Submission Type, Subject name, Submitting Legal entity Name, and Substance in Mixture. The Substance in Mixture section includes fields for Substance name and CAS Number. At the bottom right, there are 'Clear' and 'Search' buttons.

- Submission area for applicants in preparation
- Automated file checks (e.g. file is in IUCLID format)
- Submission report



Applicant

Submission services



The ECHA Submission Portal is an online tool for submitting SCIP and Poison Centres notifications.

[Access service](#)

**Agency instance of
IUCLID**

- Large database – contains all EU PPP dossier submissions
- Agency view and entity search
- Notifications (e.g. dossier received)
- Requires VPN for access



RMS evaluator



EFSA reviewer



Super user

Secure VPN connection

**Agency instance of
IUCLID**



- 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

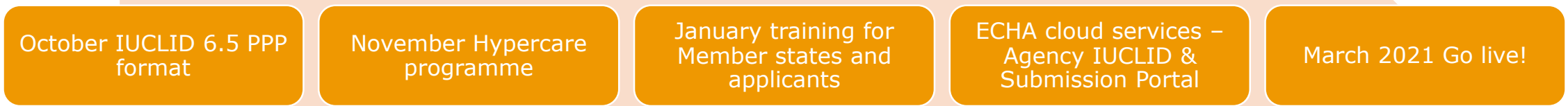
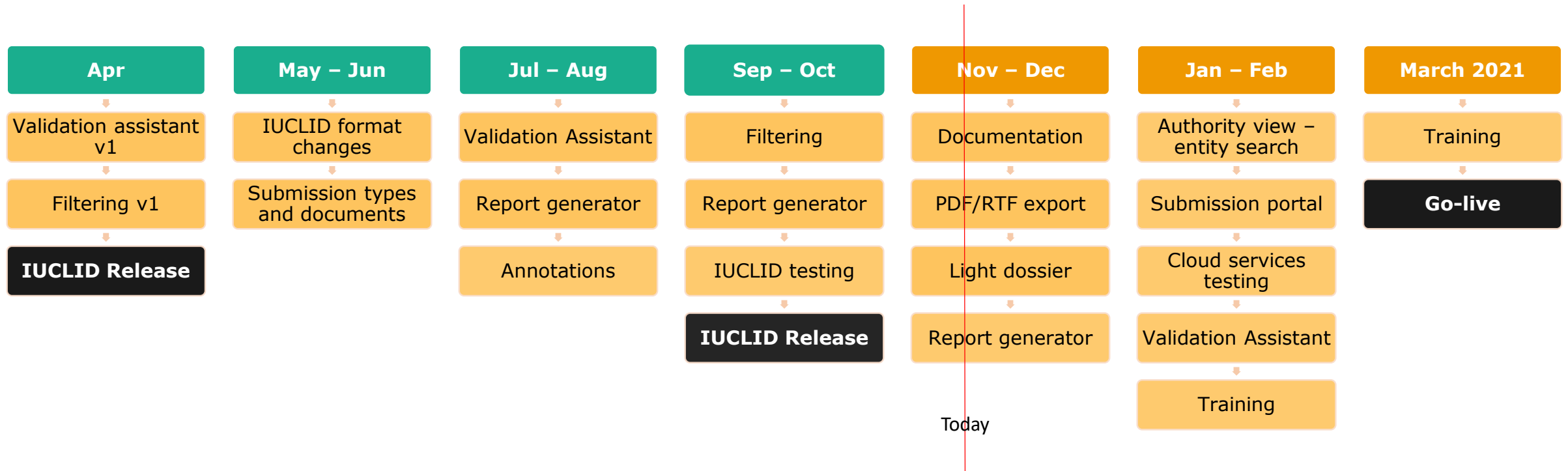
- Creation of a new **EFSA Pesticide Steering Network sub-group**
- Kick-off meeting end of November 2020
- Biweekly tele-meeting - specific topics, IUCLID format
 - Example: data on residues, specific OHT
- Every 6-weeks tele-meeting – generic topics, IUCLID feature
 - Example: annotation, validation 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 (17/11/2020)

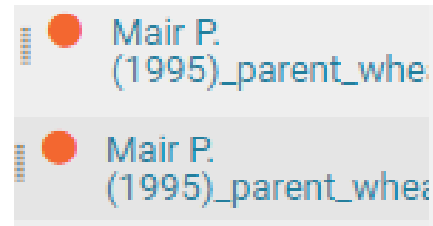
	SUBSTANCE	APPLICANT	RMS	CO-RMS
1	Azadirachtin (Margosa extract)	Mitsui; Trifolio; Sipcam Oxon	DE	ES
2	6-Benzyladenine	Fine Agrochemicals Limited, Sumitomo, Globachem (taskforce)	SE	NL
3	Quinmerac	BASF; ADAMA	EE	FI
4	1-Decanol	Drexel Chemical Company	PL	IT
5	Lime sulphur (calcium polysulphid)	Polisenio;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