ABIM 2023 - WORKSHOP

# IUCLID Registration

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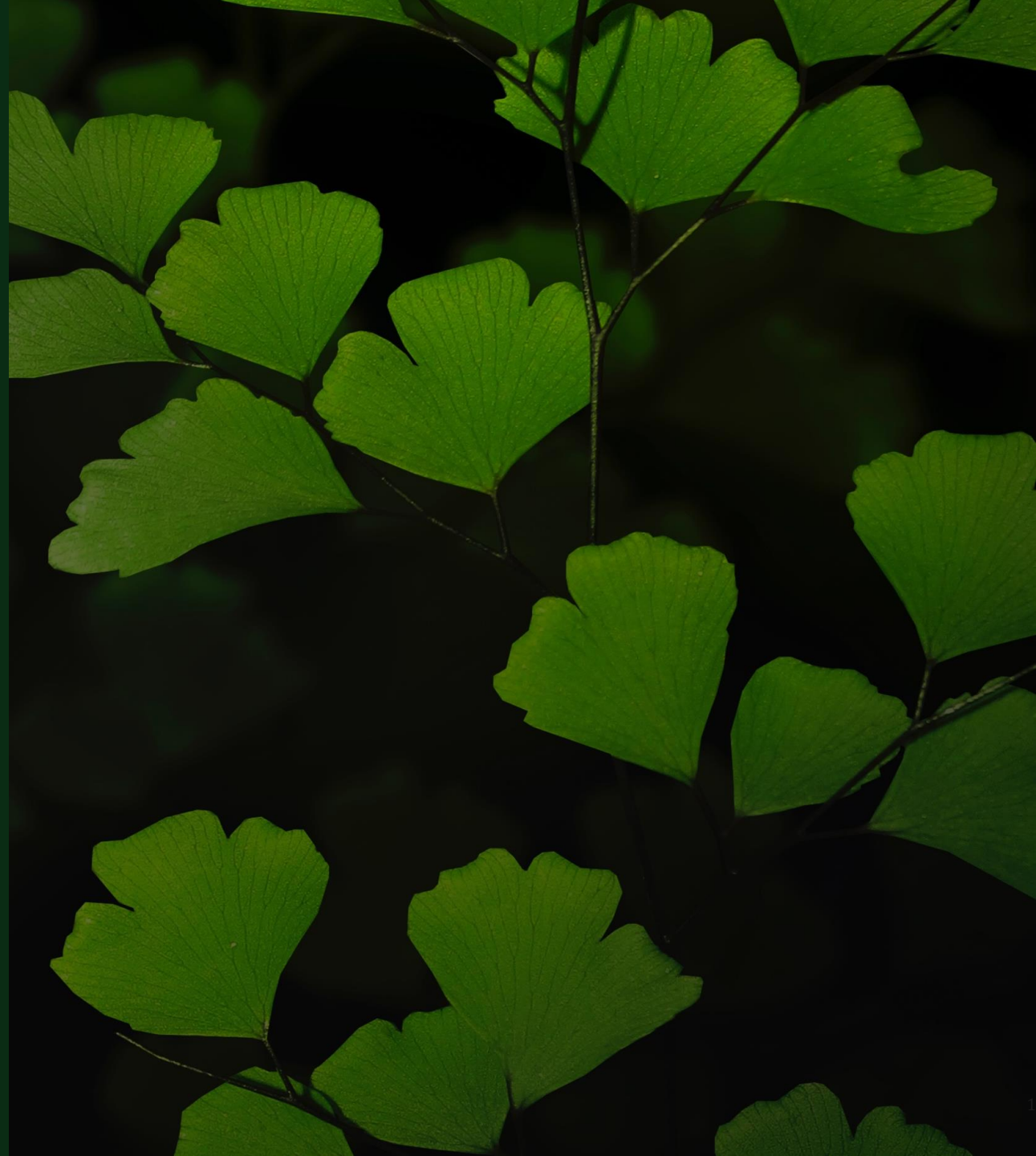
ERM, SUSTAINABLE PRODUCT & SUPPLY CHAIN

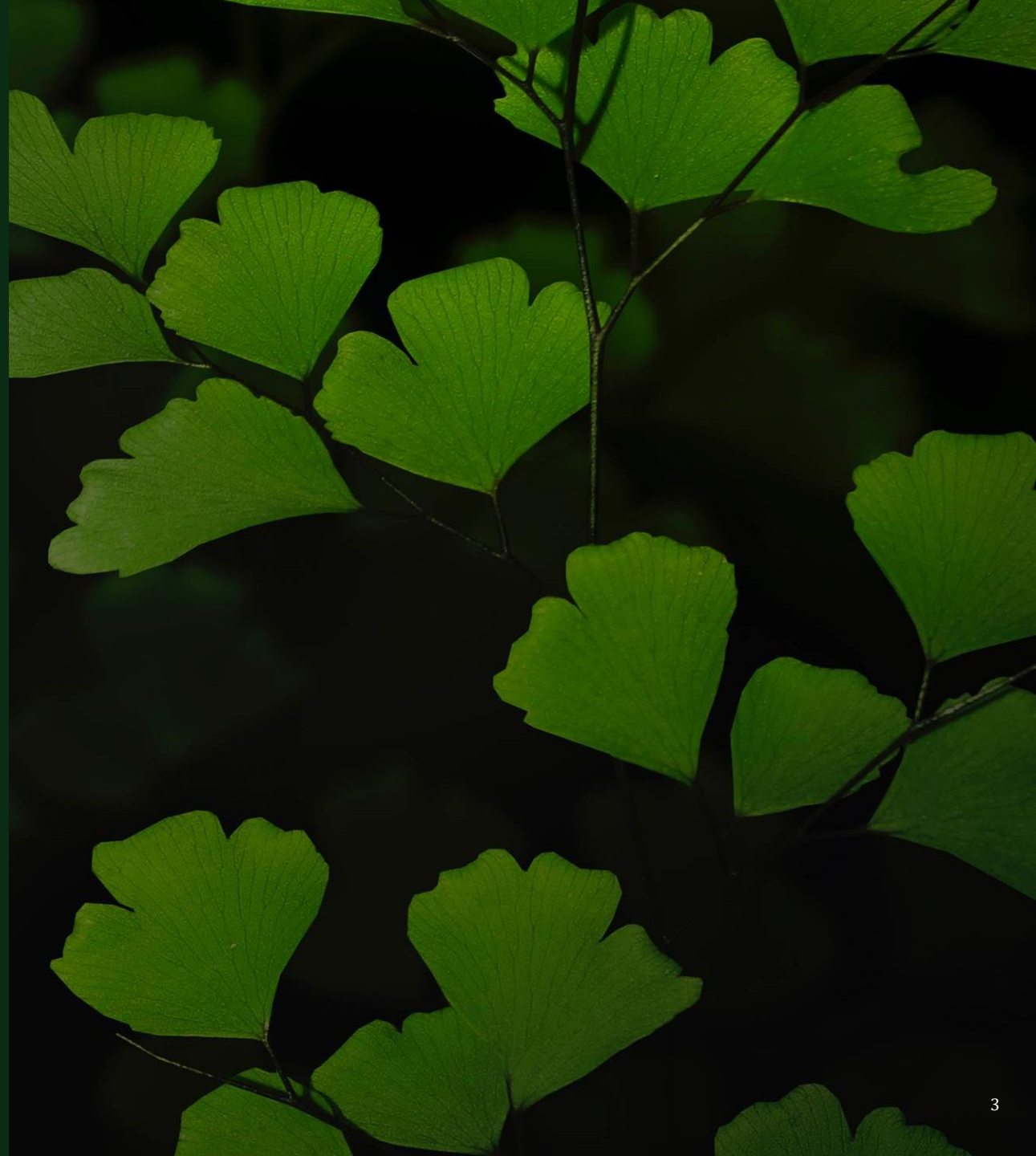
Sustainability is our business



# Agenda

1. About ERM
2. Recap about IUCLID
3. Pre-submission phase
4. How does that work?
5. Two options for managing an IUCLID project
6. Post-submission phase
7. IUCLID Integration Platform IIP project
8. Q&A

# About ERM



# Sustainability is our business

## We are the world's largest pure play sustainability consultancy

Founded in 1971, we are the largest advisory firm in the world focusing solely on sustainability, offering unparalleled depth and breadth of expertise.

**We shape a sustainable future with the world's leading organizations**

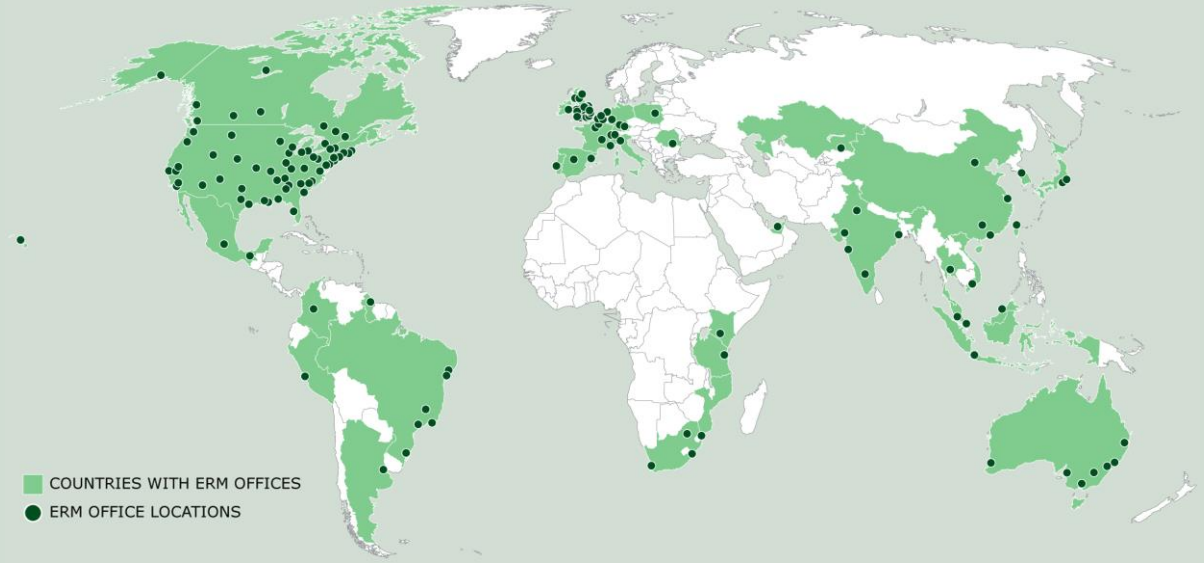
Our purpose guides everything we do. We create a better future by helping the world's biggest brands address today's sustainability imperatives.

**We are the recognized market leader in sustainability services**

Numerous industry benchmarks attest to our market leadership and the majority of our work is sole-sourced, reflecting trusted partnerships we build with our clients.

ERM OVERVIEW

| | | |
|---|---|---|
| 8000+<br>Professionals | 40<br>Countries & territories | **Climate change consulting Leader**<br>Verdantix Green Quadrant 2023 |
| 150+<br>Offices | 50+<br>Years of experience | #1<br>Sustainability service provider – HFS 2022 |




We partner with…

70%
of Fortune 100

55%
of Fortune 500

# Recap about IUCLID

# Reminders about IUCLID

The **Transparency Regulation Reg (EU) 2019/1381** amended the General Food Law by introducing new requirements in the pre-submission phase and submission application procedure, such as:

- possibility to request for general pre-submission advice;
- obligation to notify information related to studies commissioned or carried out to support an application;
- submission of the application dossier using IUCLID format, including non-confidential version of the dossier;
- public disclosure of non-confidential version of all information submitted in support of the application and related confidentiality decision-making process;
- public consultation on submitted application dossiers.

**SANCO/10181/2013** - Guidance document for Applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013

"*On or after 27 March 2021 (…), applications must be submitted electronically through a central submission system using the* ***IUCLID (International Uniform Chemical Information Database)*** *software*".

**SANTE/10182/2021** - Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure

# Pre-submission phase

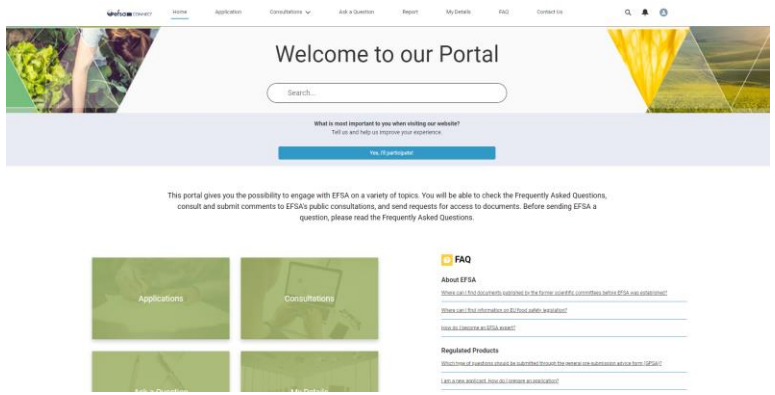
# Pre-submission phase

EFSA Portal

1. **Registration**: In order to initiate a pre-submission activity, applicant, laboratory/ testing facility and third party (including outside EU) shall first register in EFSA Connect ;
2. **Pre-application identification**: Applicants shall request a pre-application identification (Pre-App ID), which links all submission activities undertaken to support a future application of an active substance dossier;
3. **Study notification**: ALL studies launched after 27 March 2021 (including non EU studies and efficacy trials) should be notified, attributed with a unique study identification (NoS ID).

Note: an applicant can share a “relationship” with a third party, “on behalf of”.

For more details, see the User guide for pre-application ID, the Webinar on notification of studies and its User guide.




User Guide
Pre-application ID
Last update: 14 September 2023

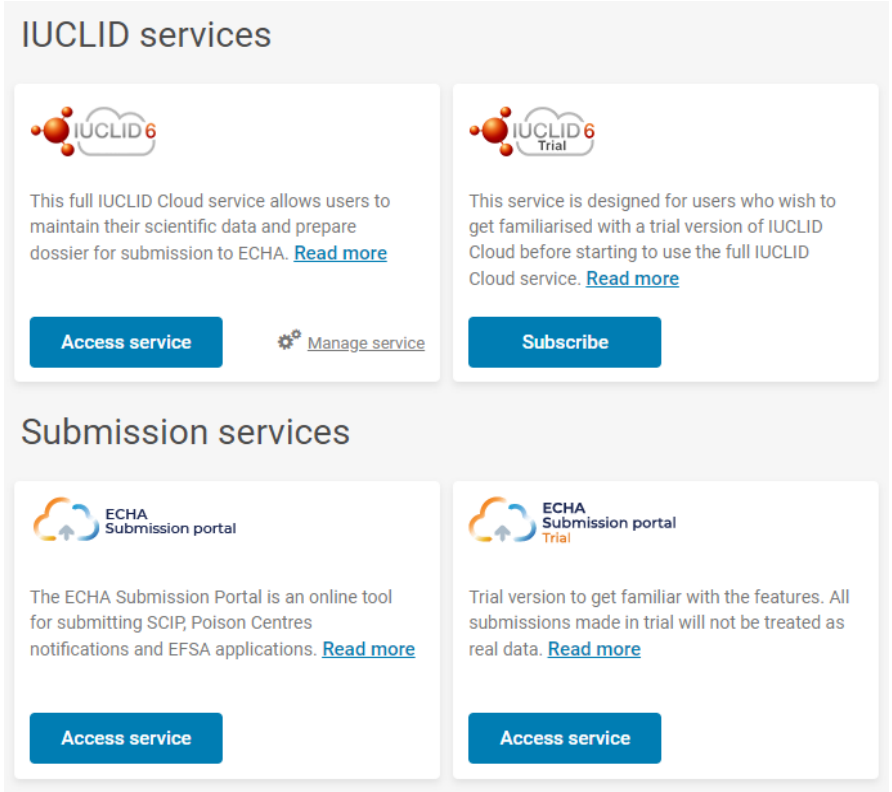
# Pre-submission phase

ECHA Cloud

1. **Registration**: In order to initiate a submission activity, applicant, and third party shall first register and create a Legal Entity in the ECHA Cloud;
2. If a third party is mandated to do the submission for an applicant, the legal entity of the third party should be assigned as a **foreign account** to the applicant legal entity.

For more details, see:

- ECHA Cloud Services support: see FAQ
- How to create a personal ECHA account
- How to create a legal entity
- How to create users in a Legal Entity (company) as a Legal Entity Manager
- How to assign roles and include a foreign account to a legal entity.



# How does that work?

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IUCLID inputs

Currently: **IUCLID 6 version 7.0.7**.

Two main IUCLID releases are made per year, in April and in October. The planned releases are published. An historic track record and update of release notes is available.

For details, see the IUCLID user manual.

For software requirements support, see ECHA FAQ.

After EFSA/RMS confidentiality assessment and validation, the dossiers are published.

Manuals provide the regulatory frameworks and requirements to prepare an application for:

- Active substances, including natural substances (plant extracts, pheromones, …)
- Microbials
- MRLs
- Basic substances

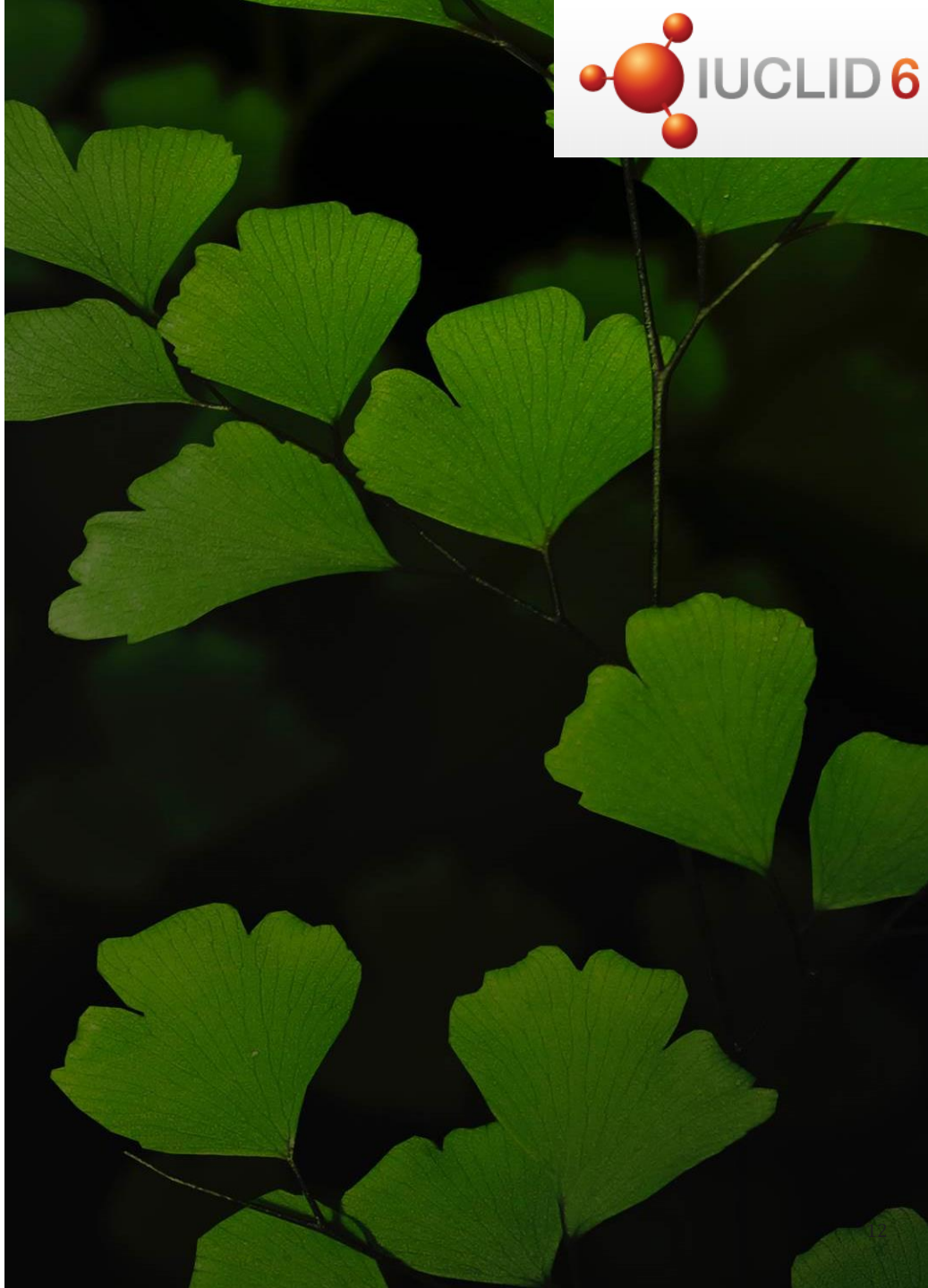
# How does that work ?

Confidentiality

For details, see dedicated link on the EFSA website, User guide on confidentiality and the Filter rules.

Current ERM process is:

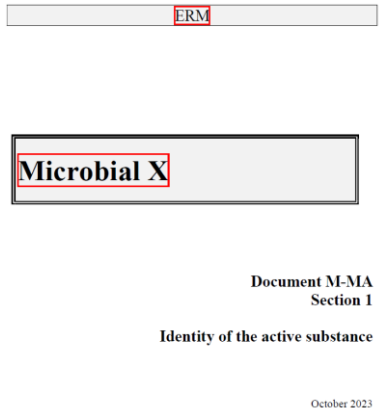
1. Mark the documents and create the corresponding justification files
2. Peer-review the marked documents and justification files at least once
3. Create redacted versions of the documents
4. Double check the redaction was applied
5. Attach in IUCLID
6. Download redacted documents from IUCLID and check the redaction is still in place
7. Select the CBI flag and add the justification in the justification box



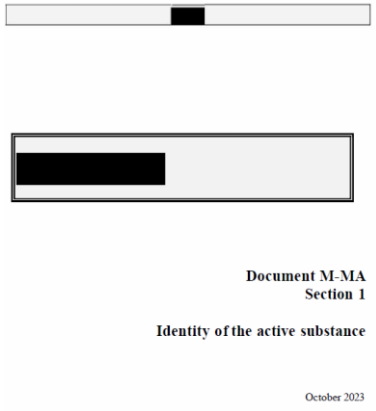
# How does that work ?

Confidentiality

## Marked version




## Redacted / Sanitized version




## Documents attachment in IUCLID

Attachments + New item Import file

| # | Attachment type | Attached confidential document | Attached (sanitised) document for publication |
|---|---|---|---|
| 1 | full study report | Redaction example_Marked.pdf | Redaction example_Redacted.pdf |

Confidentiality

CBI

Justification

Insert existing templates

PERSONAL DATA
The Applicant request confidential treatment for information contained in or related to study report that qualifies as personal data within the meaning of the Article 3(1) of Regulation (EU) 2018/1725 by its very nature.

I. CATEGORY OF PERSONAL DATA → The information concerned covers the following information in an unpublished document:
a) name(s) of (a) natural person(s) involved in testing on vertebrate animals as referred to in Article 39(e)(2) of Regulation (EC) No 178/2002; and/or
b) names and addresses of testing facilities involved in testing on vertebrate animals

II. IDENTIFICATION OF THE INFORMATION
Electronic page No. Description of sanitised information
1 Testing facility name

CONFIDENTIAL BUSINESS INFORMATION (CBI)
I. IDENTIFICATION OF THE RELEVANT ITEM → II. LEGAL BASIS →

3187/32768

Use restricted to selected regulatory programmes

EU: PPP

## Confidentiality flag in IUCLID

# Two options for managing an IUCLID project

# Two options for managing an IUCLID project

Option A: Preparation of a traditional dossier according to EU Table of contents (SANCO/10181/2013)

- Preparation of documents outside IUCLID, e.g. Administrative documents, docs J and M, Appendices E & I, PRIMo, etc., and uploading these to IUCLID
- Sanitisation of documents, which are then uploaded to IUCLID

See crosswalks from the EU Table of Contents for PPP and microbial PPP dossiers to IUCLID.

**Advantages**

- Familiarity with existing templates that are easy to adapt depending on the requirements of the submission
- Extensive team of technical experts and IUCLID trained in this approach; likewise, RMS and review body familiarity
- Ease for Applicant / Consultant to review technical content within M-CA/P documents
- No need to rely on IUCLID report generator, where reports may contain errors, e.g., table numbering, study data being switched around *(improved at each new IUCLID release)*

**Disadvantages**

- Using M-documents to facilitate IUCLID input can mean that time used to prepare these could be used to input directly into IUCLID
- Copy/paste from M-docs can lead to formatting issues, i.e. tables
- The datapoints in IUCLID do not necessarily align with those under SANCO/10181/2013, and some sections in IUCLID do not allow for input in these sections (context can be lost), whereas document preparation outside of IUCLID can provide extra context

# Two options for managing an IUCLID project

Option B: Preparation using IUCLID's functionalities to prepare a dossier

- Directly inputting data from study reports and using IUCLID Report generator to generate documents
- Sanitisation of K-documents, which are then uploaded to IUCLID

**Advantages**

- Improved efficiency and time – study input can start as soon as reports are available, no need of Docs-M preparation *(some intermediate study summaries may be needed)*
- Making use of IUCLID's automated functionalities, e.g. automatically redacted generated reports, no more need for document L as IUCLID report generator has rendered this obsolete, other CSV-outputs to manage data, i.e. study notification list

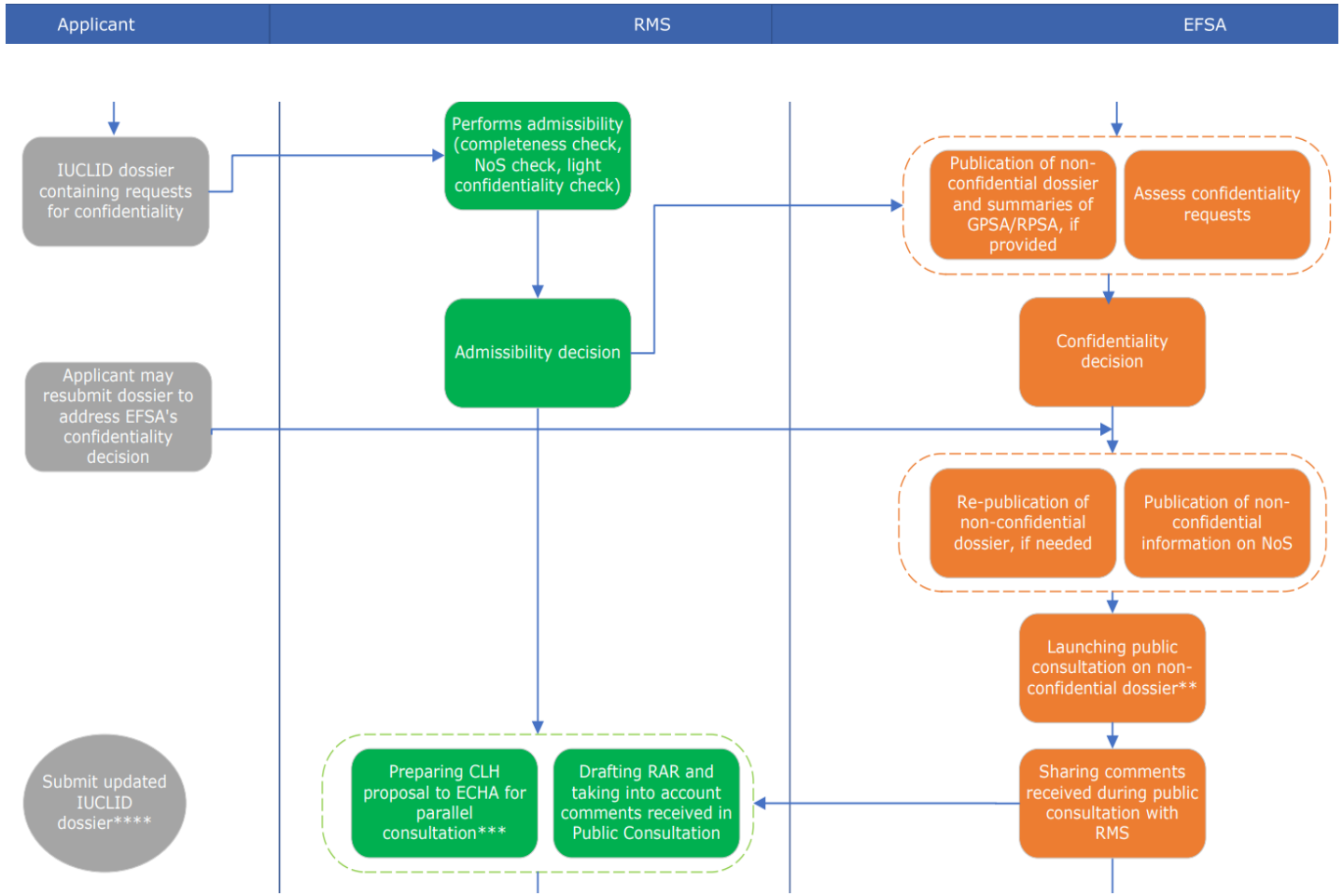
**Disadvantages**

- Early stage for this approach
- Applicant / Consultant technical review process modified to automated documents
- Although improved at each new release, the generation via IUCLID report generator still requires re-work of exported documents
- Additional documents, e.g. risk assessments, MSS/DER composer, PRIMo are still required
- Some RMS still request dossier documents acc. to SANCO/10181/2013.

# Post-submission phase

# Post-submission

For details, see the general overview of application procedure for approval or for renewal of (new) active substances.




Screenshot extract of the application procedure for renewal

# IUCLID Integration Platform IIP project

# IUCLID Integration Platform IIP project

**Project sponsor:** CropLife Europe

**IIP core team:** Syngenta, BASF, Bayer, Corteva

**IIP extended team:** European consultancies involved with IUCLID

**Scope**: optimizing IUCLID:

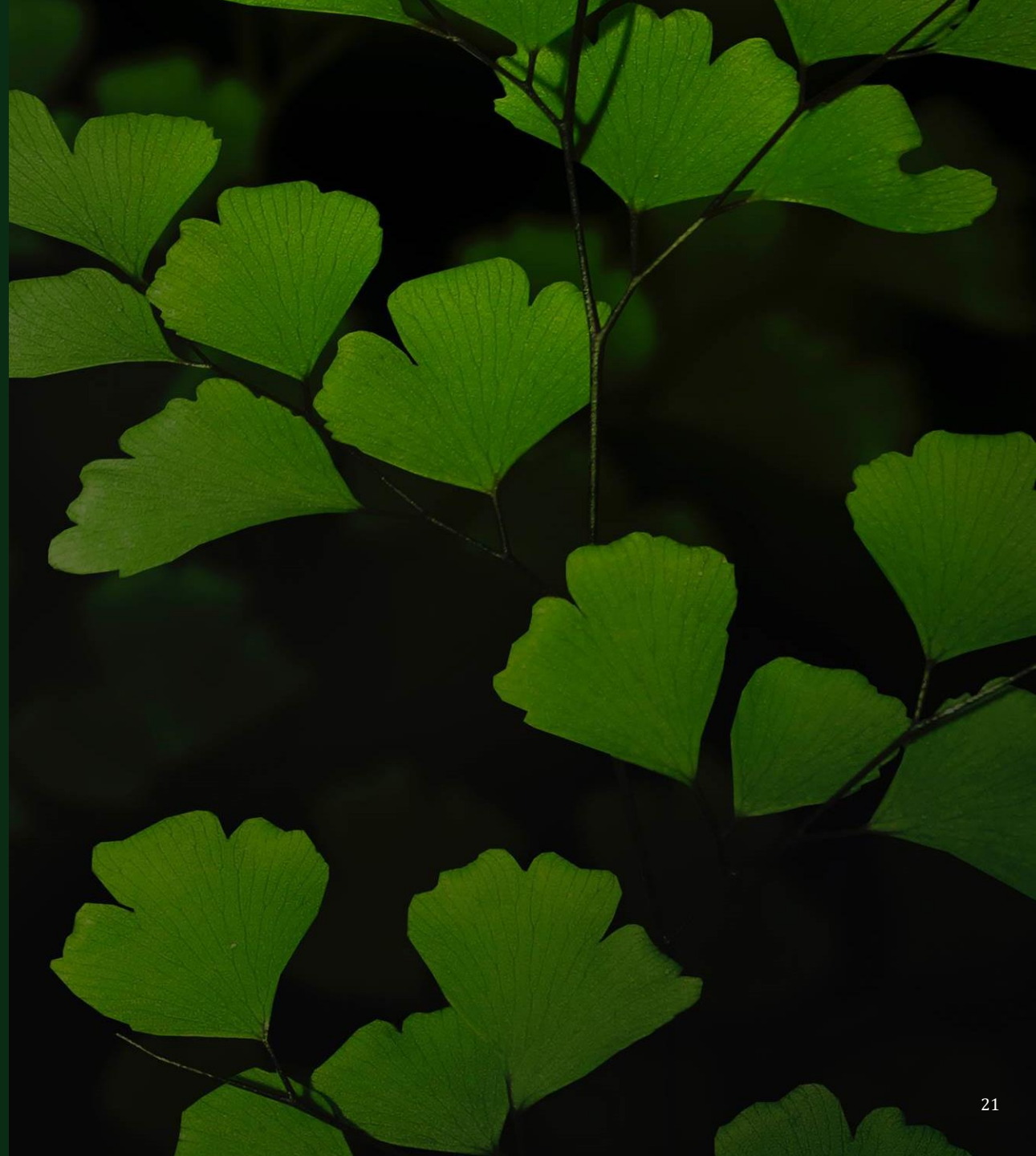
- Enable efficiency gains in data import / data entry
- Provide additional functionality relevant for applicants
- Find solution patterns that are triggered by a specific issue throughout the IUCLID format

**Duration**: Q2/2023 – Q1/2025

**Current status**: 90+ requirements collected, refined and categorized. IIP vision developed to drive further refinement and agile software development

**More information**: https://esubmission.croplifeeurope.eu/iip/

# Q&A



# Thank you

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**EFSA**
**ECHA**

**Let's meet in our booth #51 !**