



IUCLID 6 is developed by the European  
Chemicals Agency in association with the OECD



# What is IUCLID?



## International Uniform Chemical Information Database

- What
  - Stores and records chemical, product and use data in a structured format
  - Provides a User Interface and additional functionalities to manage data
  - Provides a means to exchange data (XML, i6z files, API)
- For Whom
  - Industry
  - Regulatory bodies (EU and non-EU)

*IUCLID is the essential tool for any organisation or individual that needs to record, store, submit, and exchange data on chemical substances*



# ECHA and IUCLID



# Chemicals legislations managed by ECHA



## REACH

Registration  
Evaluation  
Authorisation

All chemicals  
>1 tonne  
per annum



## CLP

Classification  
Labelling  
Packaging

All chemicals  
and mixtures  
UN-wide standards

Including Poison  
Centres format



## BPR

Biocides

Active substances  
and biocidal  
products

## PIC

Prior Informed  
Consent

Import/export of  
certain hazardous  
chemicals

Rotterdam  
Convention



Waste Framework  
directive

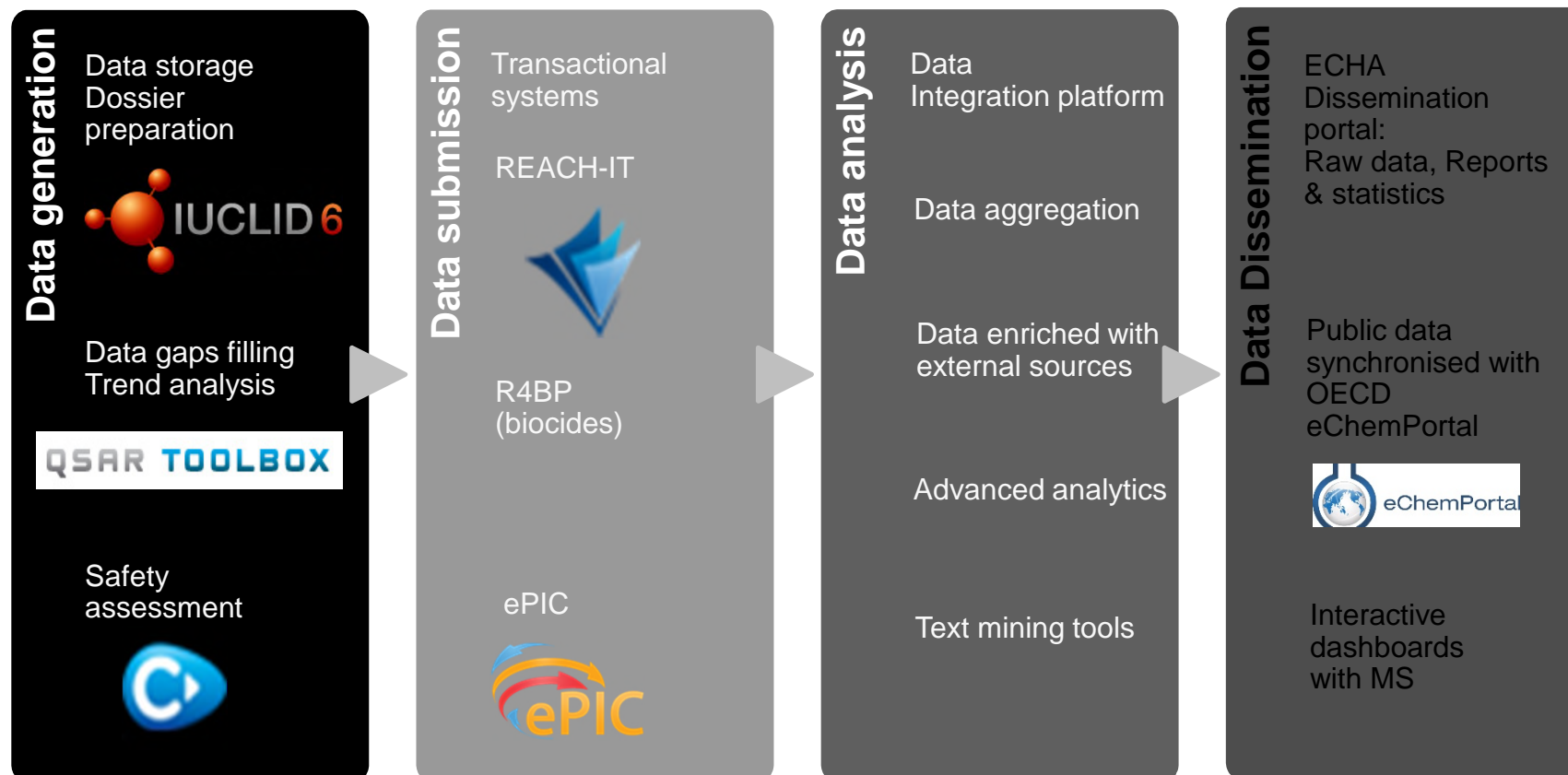


## Information on chemicals

Companies are required to collect or generate information on properties and uses of their chemicals, assess the risks and recommend safety measures.

All this information is submitted to ECHA

# Data dissemination



# IUCLID and data format standards



## Benefits of structuring the information in an electronic format

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- **Exchange** of data between different IT tools is facilitated
- Easier to **identify**, from a set of defined fields, what **key information** is expected to be submitted within a specific regulatory context
- Possibility to **format the data** automatically (e.g. assessment reports)
- **Search** possibilities are increased allowing data mining and prioritisation
- Existing data stored in a Harmonised Template can be processed in order to **prepare data submissions** to answer different regulatory requirements

# Optimal balance between different levels of information structure



## Structured information with the correct data types

E.g. numeric fields with relevant units, selection of phrases in pick-lists

Allows automated IT processing

## Free text fields

E.g. Details on test materials

For screening of the same information across dossiers

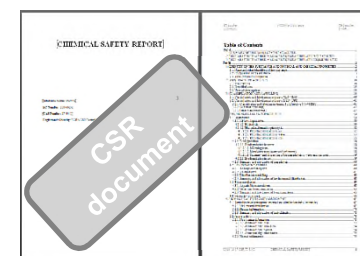
## Document / report

Chemical Safety Report

For assessment by the expert, advanced analysis

<b>Administration / exposure</b>	oral: gavage
Route of administration	oral: capsule
	oral: feed
oral: drinking water	oral: drinking water
	oral: unspecified
Type of inhalation exposure	inhalation: aerosol
Effect level	
	ca. 15 - mg/kg bw/day (actual dose received)

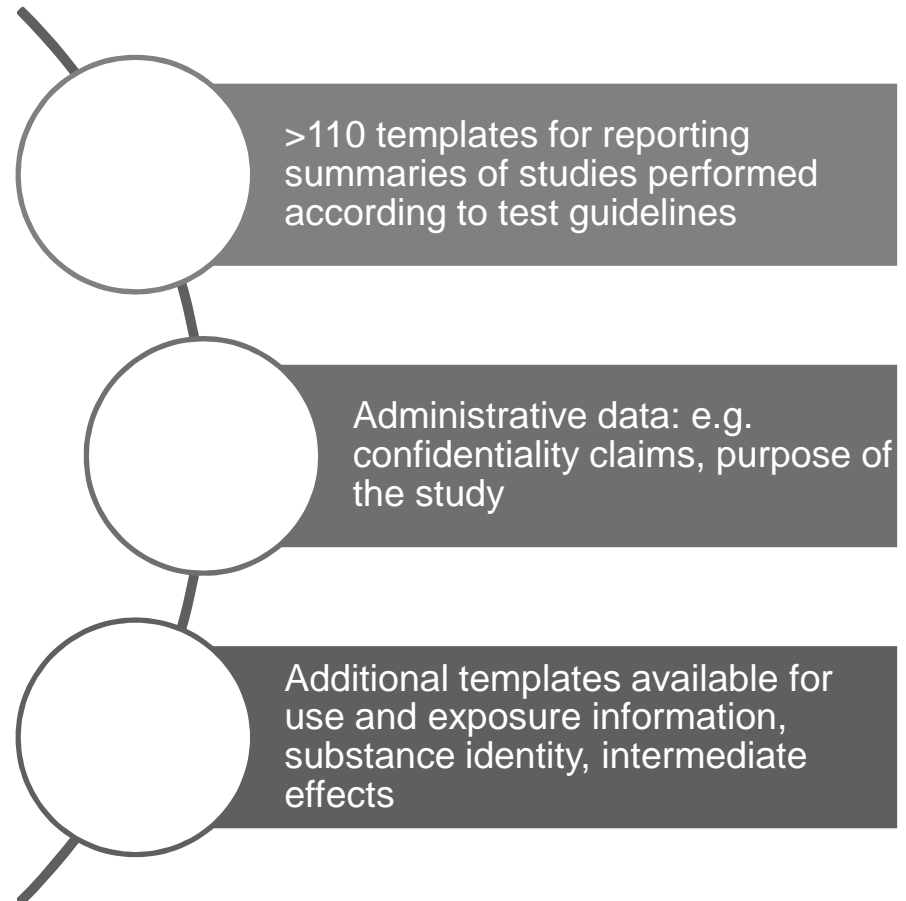
<b>Details on test material</b>
- Name of test material (as cited in study report):
- Molecular formula (if other than submission substance):
- Molecular weight (if other than submission substance):





<http://www.oecd.org/ehs/templates/>

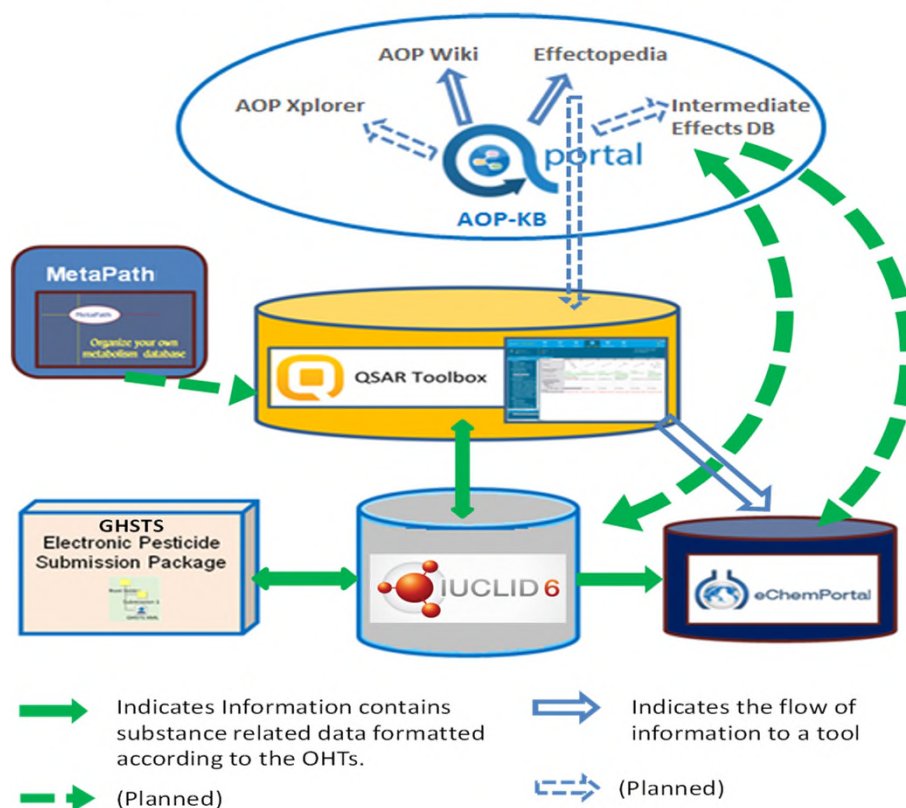
- Standard data formats for reporting information used for the risk assessment of chemicals
- By using these templates, governments and industry are easily able to electronically exchange test study summary information



# Tools to support chemical management at the OECD level



## Interlinkage of tools developed to support chemical management in a regulatory context



02006R1907 — EN — 11.10.2016 — 031.001 — 1

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**►► REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
of 18 December 2006  
concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC  
(Text with EEA relevance)   
(OJ L 396, 30.12.2006, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Council Regulation (EC) No 1354/2007 of 15 November 2007	L 304	1	22.11.2007
►M2	Commission Regulation (EC) No 987/2008 of 8 October 2008	L 268	14	9.10.2008
►M3	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008	L 353	1	31.12.2008

**Article 111**

**Formats and software for submission of information to the Agency**

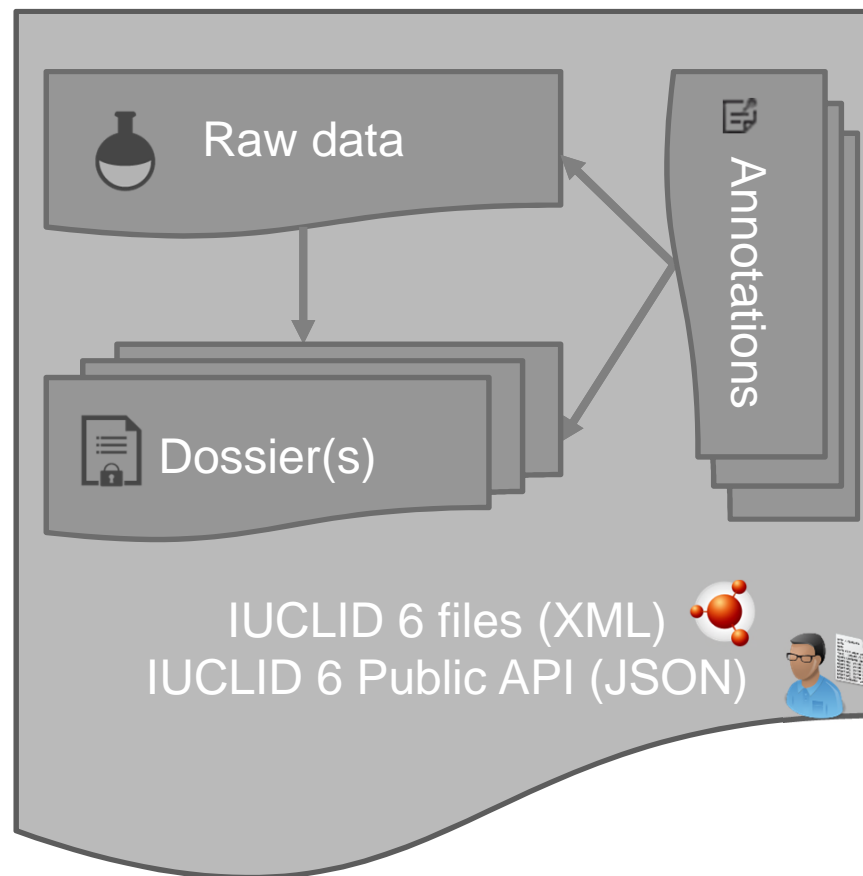
The Agency shall specify formats and make them available free of charge, and software packages and make them available on its website for any submissions to the Agency. Member States, manufacturers, importers, distributors or downstream users shall use these formats and packages in their submissions to the Agency pursuant to this Regulation. In particular, the Agency shall make available software tools to facilitate the submission of all information relating to substances registered in accordance with Article 12(1).

For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation.

# IUCLID 6 data layers



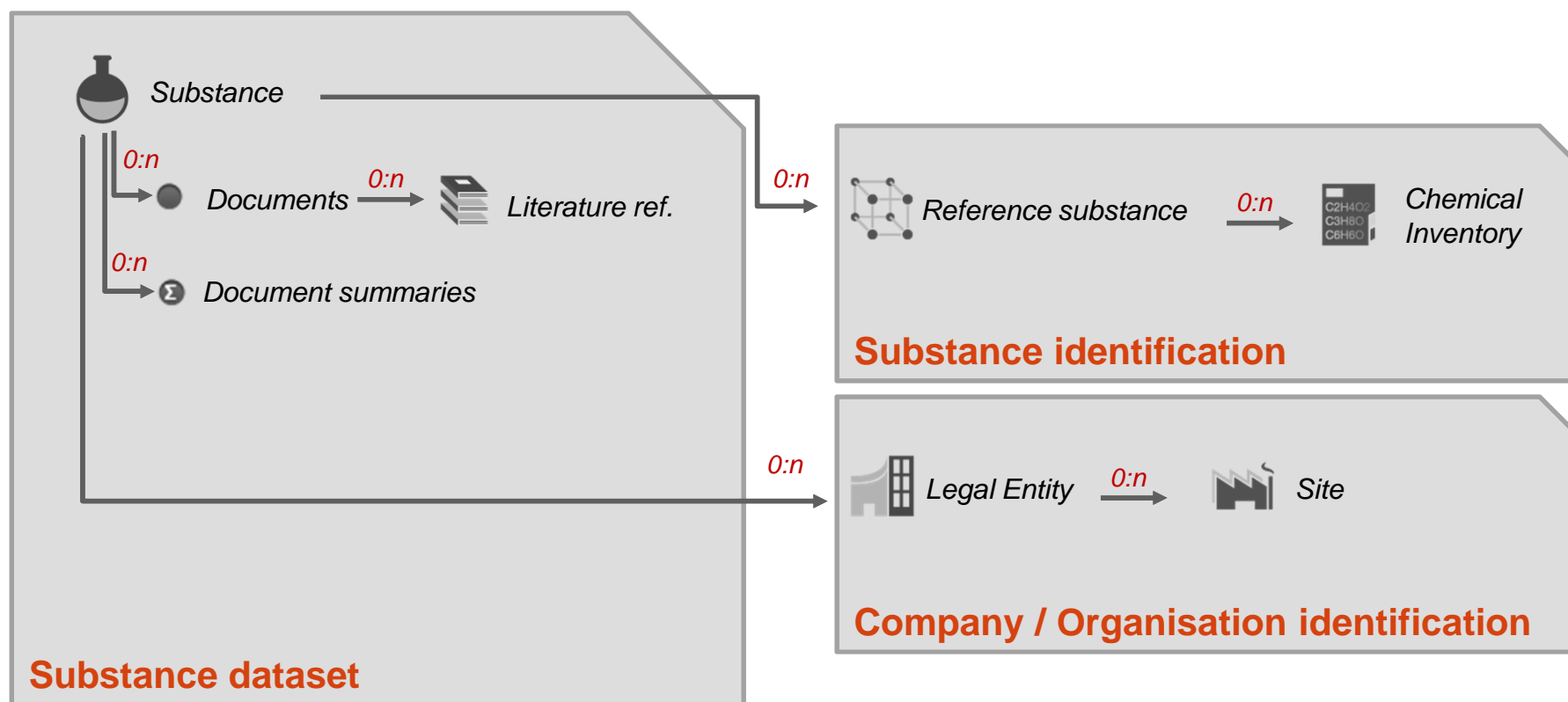
- Data entry and management at the raw data layer (e.g. in substances or mixtures)
- Data submission at the dossier layer (creation of snapshots of relevant information)
- Comments can be added in annotations
- Exchange is done using the .i6z format (package of .i6d files in XML) or the IUCLID 6 Public API (JSON)



# IUCLID entities (type of information)



## Main entities and relationships (Substance)



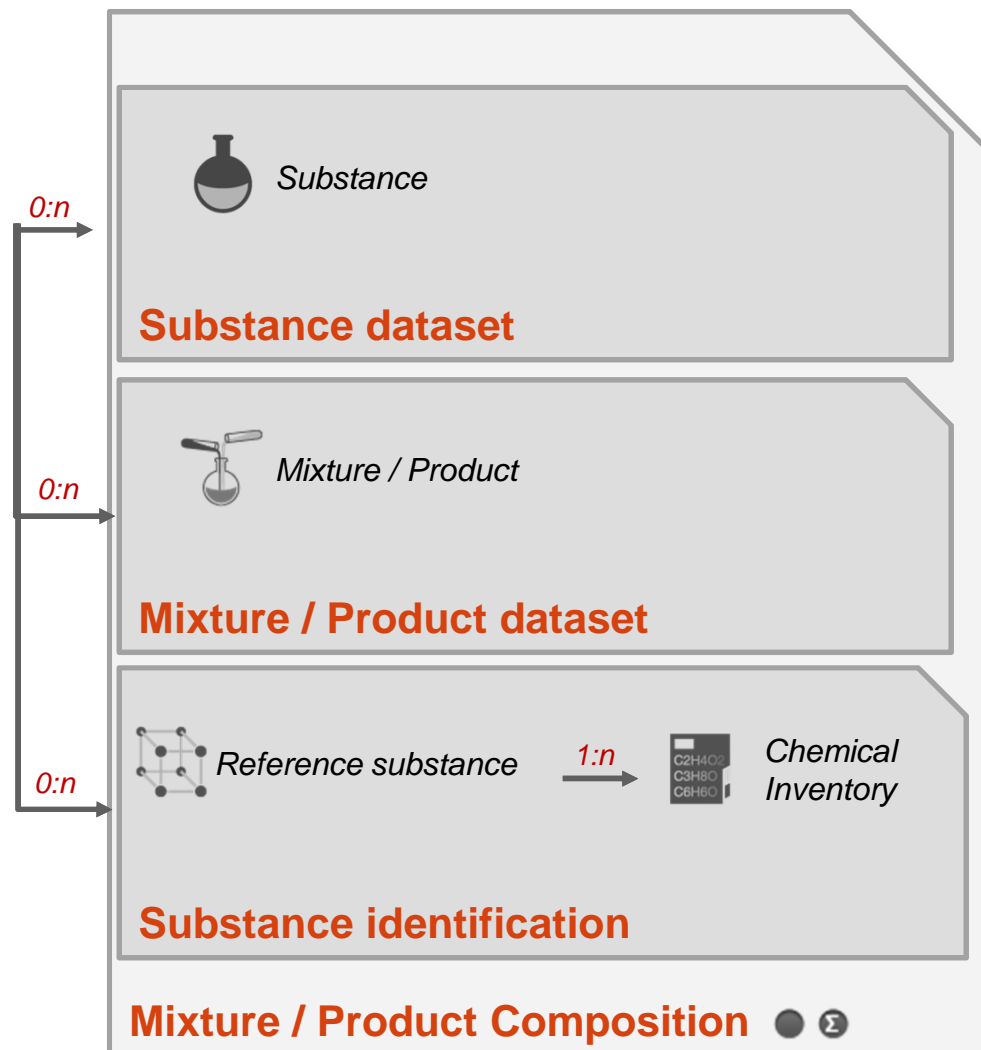
Attachments can be added to all entities and documents

Annotations can be linked to all entities and documents

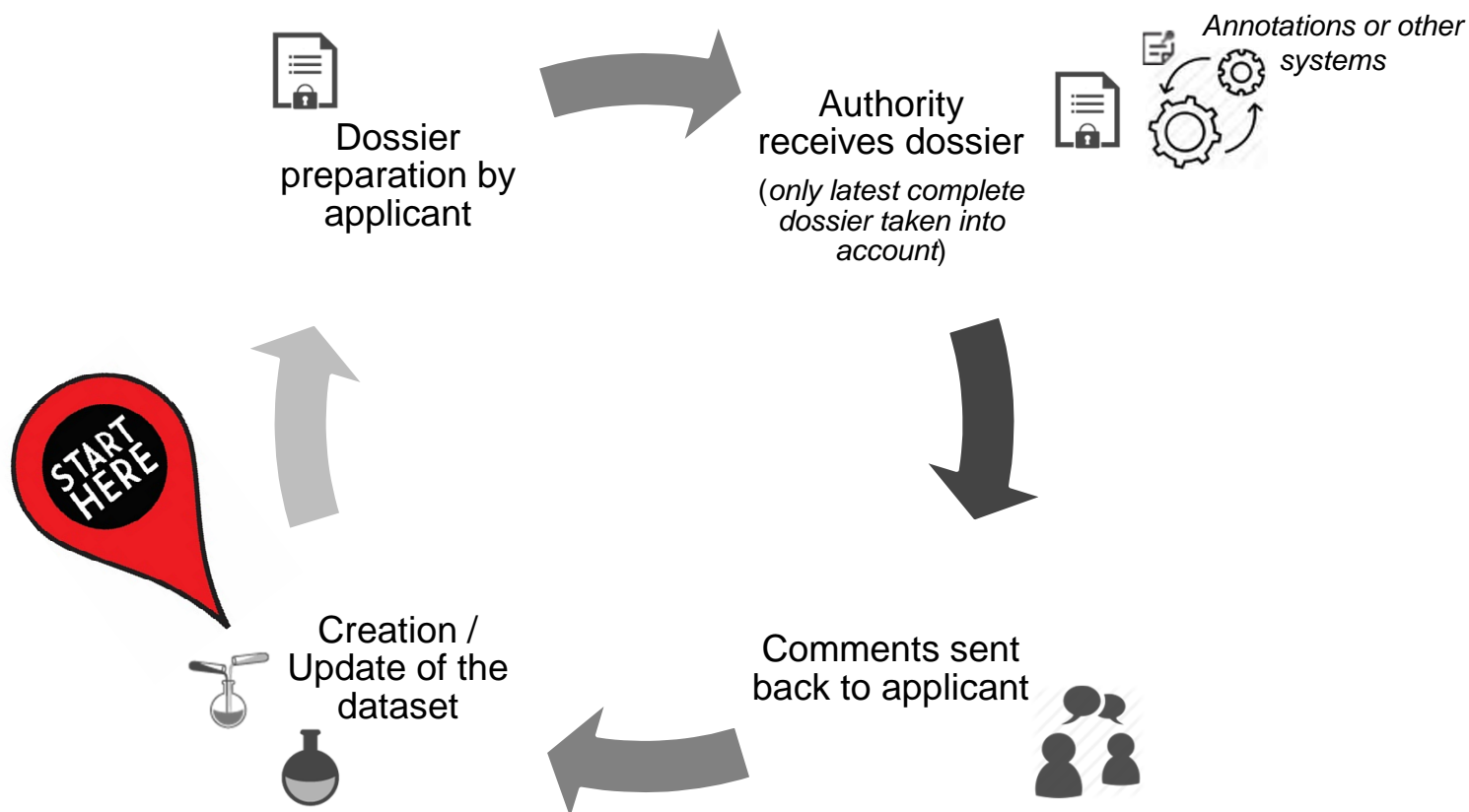
# IUCLID entities (type of information)



## Mixture / Product



# IUCLID and regulatory data submission



# IUCLID configuration possibilities



# Customisation possibilities in IUCLID



## OECD report

- IUCLID offers to regulatory bodies and industry a key application to record, store, maintain and exchange data on chemicals
- IUCLID is currently used in a variety of countries and regulatory contexts
- Main elements to the customisation of IUCLID described in this document:
  - the IUCLID format
  - IUCLID's features and add-ons (e.g. validation, reporting)
  - the integration of other systems with IUCLID

<https://www.oecd.org/chemicalsafety/risk-assessment/customisation-opportunities-of-iuclid-for-the-management-of-chemical-data.pdf>





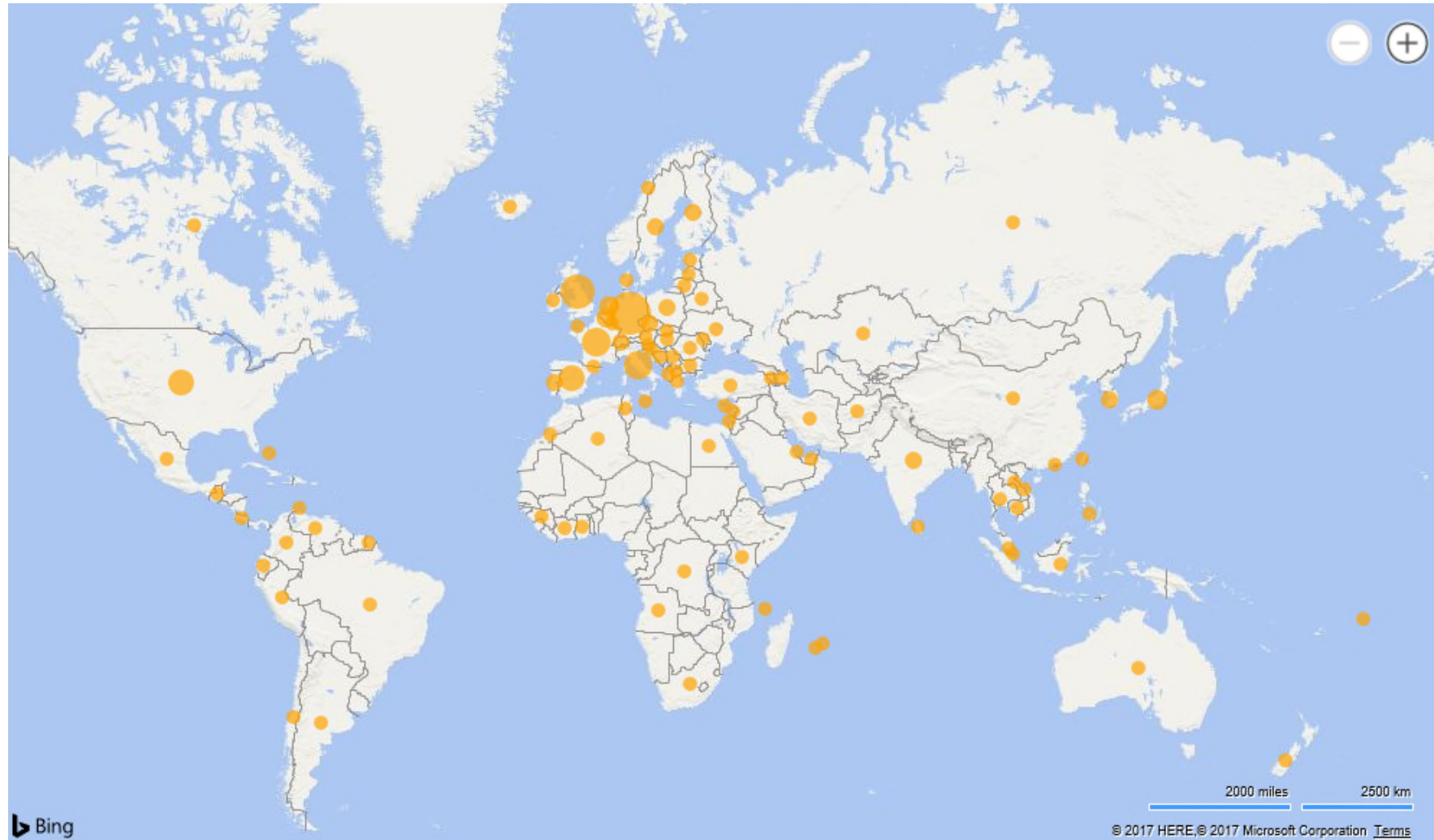
# IUCLID - International activities

Cooperation on IUCLID (activity in 2018/2019)



- |                        |                          |               |               |
|------------------------|--------------------------|---------------|---------------|
| • EU (incl. EFSA, JRC) | • Envir. & Health Canada | • Japan       | • South Korea |
| • NICNAS, Australia    | • Turkey                 | • Mexico      | • US EPA      |
|                        | • Israel                 | • New Zealand | • Brazil      |
|                        |                          | • Taiwan      |               |

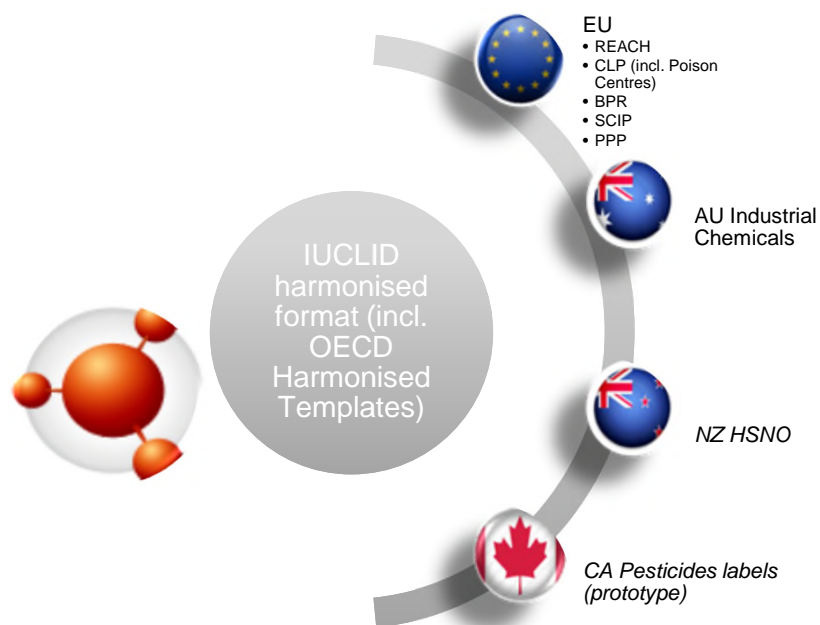
# From where IUCLID 6 is downloaded?



# IUCLID 6 format



## IUCLID 6.4 format











## Format configuration possibilities

- Re-use of existing forms, including OECD harmonised templates
- Definition of submission types (e.g. corresponding to information requirements)
- Propose updates to existing forms
- Creation of new forms to cover additional data needs

# IUCLID 6 configuration and customisation



IUCLID module	What can be customized?	How?	By who?
<b>Definition providers</b>	Documents Table of Content (submission / dossier types)	ITEM	
<b>Validation</b>	Rules and scenario parameters Rule scenarios	Java code Configuration file	 
<b>Filtering</b>	Filtering rule set for a legislation	Configuration file	 
<b>Reporting</b>	Report templates	Template in DocBook and FreeMarker format	
<b>Help System</b>	Content of the Help System for a specific legislation	Content to be integrated by ECHA	
<b>Web services and IUCLID extension</b>	Build your own IUCLID client or extension and reuse / extend IUCLID functionalities using web services	Code	

# IUCLID Product management



## Adaptations for pesticides – IUCLID configuration

**DRAFT**

Format	Reuse existing format for a pilot phase and plan first adaptations and extensions for <b>October 2020</b>
Submission types	Pesticides Active Substances (+ Pesticides Products), already for <b>October 2019</b>
Validation rules	Focus on Admissibility / Completeness Check in two steps: <b>April</b> and <b>October 2020</b>
Reports	Draft assessment report List of studies List of confidentiality claims - <b>2020</b>
Filtering rules	Preparation of filtered dossiers for publication of the Dossier Summary ( <b>April 2020</b> )

# Pesticides dossier structure



reference  
substances  
(constituents,  
impurities...)



active  
substance



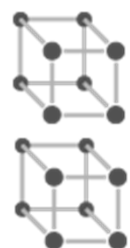
Pesticide product or  
representative  
product



substances  
are linked in  
mixture /  
product  
composition



Pesticides dossier  
is created based on  
a product dataset  
or representative  
product  
dataset



other  
substance(s),  
if needed



The main component of a Pesticides dossier is always a mixture/product. All substances data are linked in the composition section of the (representative) product.

# Pesticides submissions



## Substance datasets



EU PPP Active substance information

EU PPP Microorganisms

EU PPP Other substance for assessment

EU PPP Basic information (substance)

function: active substance

## Mixture/product datasets



EU PPP Active substance application (representative product)

EU PPP Plant protection product authorisation

relevant to  
dossier  
creation



# Identification of relevant features of IUCLID



Possible enhancements for EFSA (and IUCLID users) needs

**DRAFT**

- Improvement of the IUCLID **Annotations** to support the commenting phase by RMS and EFSA
- Analysis of the '**light**' **dossier** approach as an alternative to incremental updates: the aim is to reduce the size of dossiers updates by removing already submitted attachments
- Use of the **comparison** report to support the future renewal process; proposal of alternatives for old cases: previous information as an attachment, new information in the new format
- IUCLID related tools
  - Text analytics
  - Data extractor
  - Provider agent to the eChemPortal

# IUCLID distributions

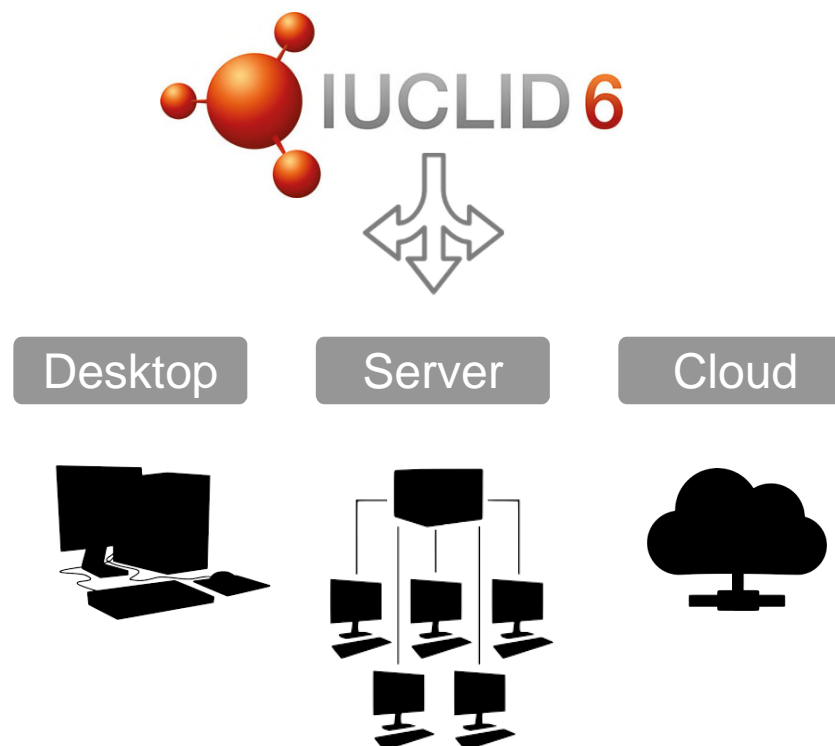
(and which one to use during the pilot)



# IUCLID distributions



- One IUCLID software, different ways of distributing it
  - Desktop: for single user, on his/her own computer
  - Server: hosted on a server, shared with multiple users
  - Cloud: ECHA Cloud Services, hosted by ECHA, for REACH and CLP users

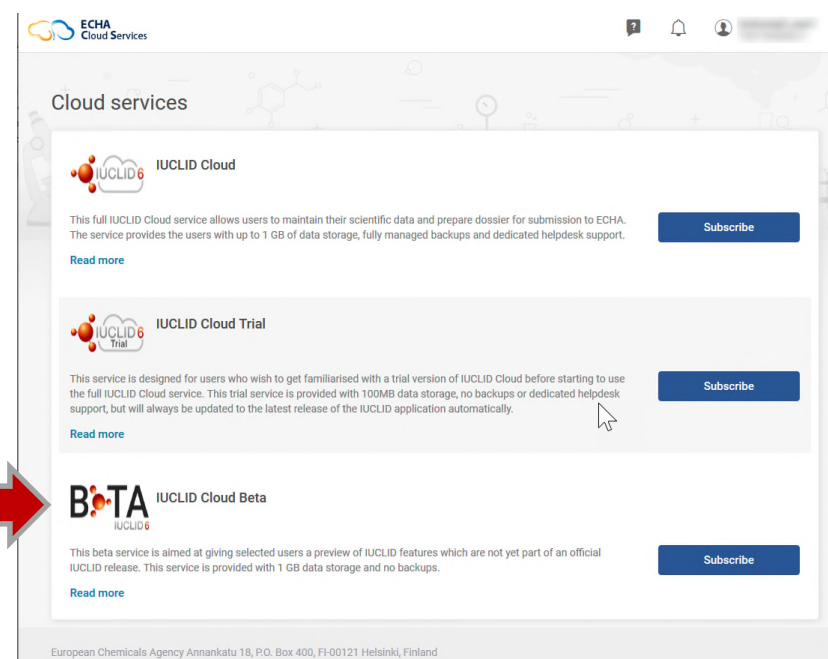


# IUCLID distributions



## Beta Cloud service to be used during the pilot

- Why IUCLID Cloud beta?
  - No installation required
  - Always access to the latest version (if relevant improvements are included in newer versions)
  - Test accounts created for the members of the group
  - ECHA and EFSA can support the pilot members
- We propose to share one account within an organisation (credentials available)
- Confidential data can be used but password would have to be changed, account sharing (?)



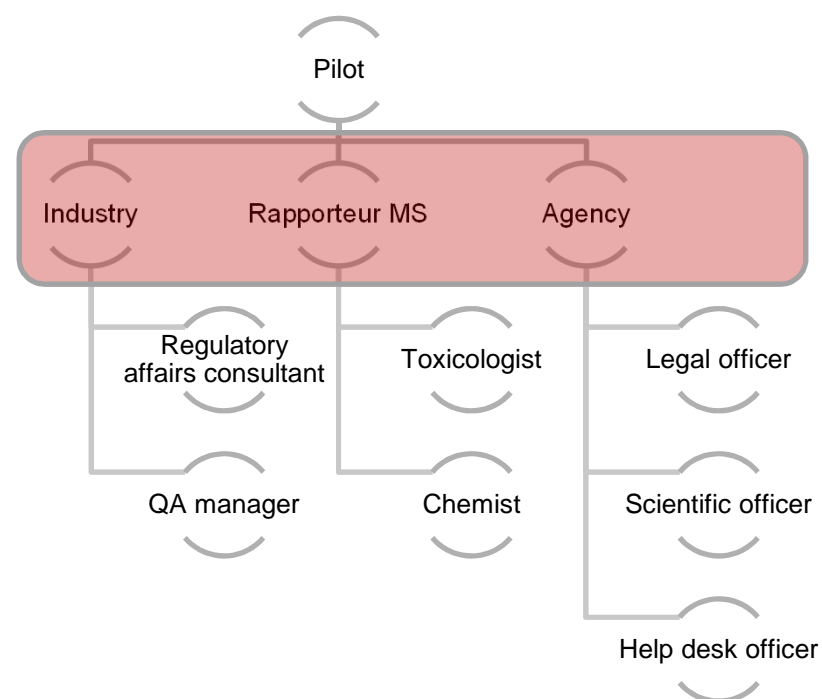
*Other distributions of IUCLID can be used as well*

# Access Management



## Need to define Legal Entities and users

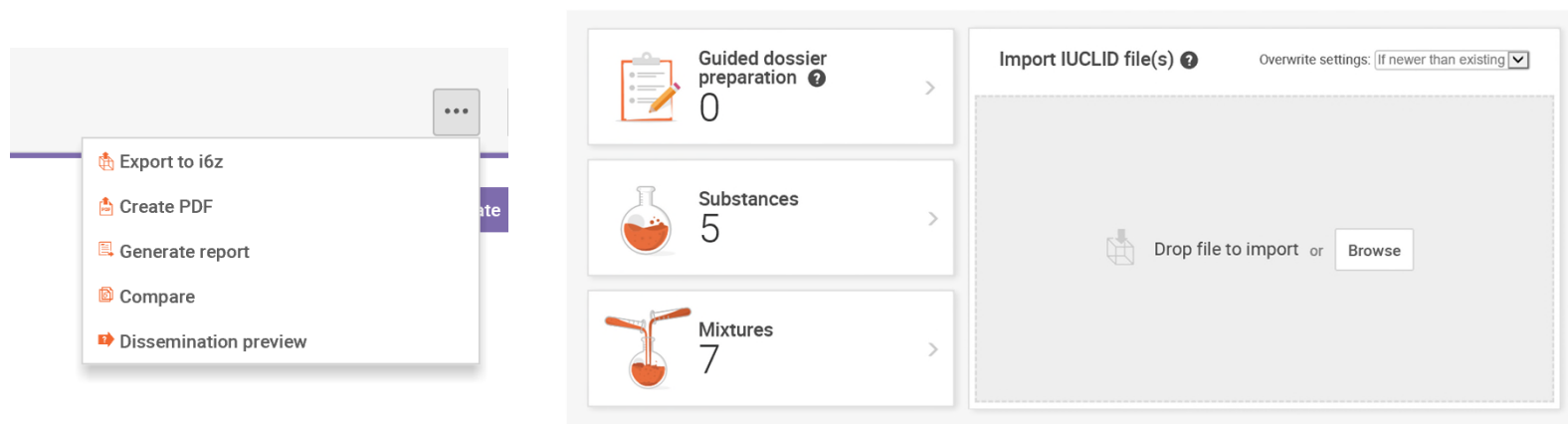
- Beta instances: accounts are created and shared within each organisation (Industry, Member States, EFSA)
- A 'special' instance will be created to be made available to regulatory authorities (shared between EFSA and RMSs): 'EFSA central database'



# Exchange via Submission of dossiers



- Semi-manual process to be used via EFSA DMS
  - Export from organisation's instance
  - Upload to EFSA shared drive
  - Import to EFSA instance
- Pilot to identify suitable solutions for the future





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