ECHA's DWD IT tools user group

Introduction to the IUCLID DWD template

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Role and tasks for the DWD IT tools user group

Role of the DWD IT tools user group

→ Overall, to provide **informal, non-binding** technical advice

→ To actively contribute to the development of DWD application process IT tools:

1. Task 1: The **IUCLID-based format** that applicants will use for preparing their notifications of intention and applications to ECHA
2. Task 2: The **validation rules** that will be available for applicants to use to check whether their dossiers contain the necessary information
3. Task 3: The **filtering rules** that will be available to verify the information that will be published by ECHA
4. Task 4: The **application portal** that applicants will use to submit their applications

How the DWD IT tools user group will work

- → Periodic meetings (online) to discuss new tasks
- → Follow-up meetings (online) to check-up on progress, address open issues, answer questions
- → Review activities and testing will mostly take place outside the meeting dates
- → A common working area will be provided by ECHA, to e.g.
  - Store presentations and meeting recordings
  - Store files intended for review by the members (e.g. IUCLID documents specifications)
  - **NB.** we aim for transparency, so members can see each others commons, to jointly learn more and limit duplication (so avoid sharing confidential information!)

2023 Work Plan of the IT tools user group

→ Of the 4 tasks (IT tools), only the first version of the IUCLID template will be available for review in 2023 → Focus in 2023 will be on the IUCLID template

→ In 2024, as a minimum, we aim to have available for members' review:

- The second, improved version of the IUCLID template
- The validation rules, at least for the DWD notification template
- The filtering rules for the DWD application template
- The first version of the application portal

→ More detail on the workload/plan for 2024 will be provided later in 2023

Introduction to the information requirements for applicants under the DWD

Tasks of ECHA and RAC in Article 11 of the DWD

→ **Role of ECHA**:

1. Collect MS notifications of national positive lists and provisions by 12 July 2021 (Art. 11(3))
2. Generate first EUPLs (Art. 11(3))
3. Propose expiry dates for each entry in the first EUPLs (Art. 11(4))
4. Set up a system to accept and process applications from industry and MSCAs requesting changes to the EUPLs (Art. 11(5))

→ **Role of RAC**:

1. Issue an opinion on any application submitted to ECHA (Art. 11(6))

Implementing legislation and timelines

Legal act	Short description of content of legal act	Commission's intended adoption date
1.IA	Methodologies for testing and accepting starting substances, compositions & constituents into the EU positive lists	**By 12 Jan 2024**
2.IA	First EU positive lists of starting substances, compositions and constituents (including transitional provisions)	**By 12 Jan 2024**
3.DA	Procedure for the application process to include or remove an entry from an EU positive list	**By 12 Jan 2024**

Status of draft legal acts and relation to current IUCLID DWD template

- → ECHA concluded drafting of legal acts in early May 2023
- → Drafts to be presented/discussed with Member States on 16 June (DWD Expert Group meeting in Brussels)
- → Then Inter-service consultation and review by COM's Legal Service
- → Later in 2023, COM will publish drafts for public consultation ('Have Your Say') and WTO consultation
- → **Important: the first IUCLID DWD template is based on the status of legal acts in November 2022. But legal acts have progressed since then. We will catch up by November 2023**

1.IA - Summary of information requirements

Annex	Issue	Aim of the Annex
1	Substance/ composition identity	• Identify what is applied for
2	Intended use	• Describe the use in a comprehensive manner • Explain previous relevant assessments
3	Physico-chemical properties	• Supporting data to understand reactions and health hazards
4	Migration and identification of relevant substances	• How to test for migration • Collect information on migration analytical methods • Generate concentrations at the tap • Conclude on the identification of the "relevant substances"
5	Toxicological assessment of relevant substances	• Determine tox. properties • Support risk assessment under Annex 6
6	Risk acceptance	• Determine MTC_{tap} • Ensure $C_{tap} < MTC_{tap}$

Information requirements – Important points

→ Applications may assess not only the intentionally used substance/composition but also
  - Constituents of multi-constituent substances
  - Non-intentionally added substances (NIAS), incl. impurities
  - The constituent elements and impurities of metallic and inorganic compositions

→ Migration testing generally based on EN standards; possibilities for modelling are limited (for organic materials) and must be justified

→ Test piece shall be representative of worst foreseeable conditions of use

→ Information requirements/assessment is limited when some information on a relevant substance is available. Examples:
  - Existing CLH CMR 1A/1B, ED, PBT/vPvB, PMT /vPvM, SVHC
  - Existing parametric value in DWD Annex I
  - Existing SML for FCM younger than 15 years at the time of application submission

DWD Application process – Important points

- → A notification of intention **must be submitted** before submission of an application
- → Input from applicant
  - In response to shortcomings in the dossier following ECHA's manual check ("Accordance check") after submission
  - In response to request from RAC for clarification during RAC opinion development (applicant obliged to co-operate)
  - If desired, comments on RAC's draft opinion before finalisation
- → Input from third parties
  - Consultation of third parties on the dossier
- → RAC is allowed to group applications in its opinion making and more time allocated to drafting an opinion for joint applications

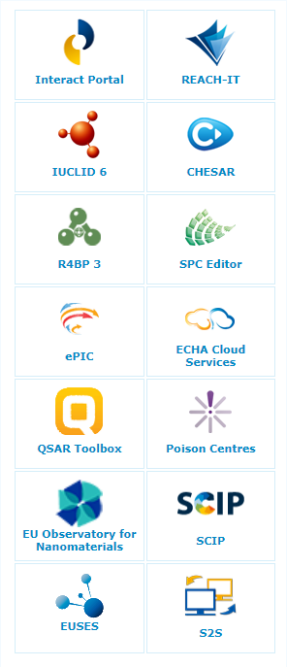
Overview of the IT infrastructure that will support DWD applicants

ECHA – an IT-based Agency

Tailor-made IT solutions to support regulatory processes

The use of ECHA IT tools is the only way to work with ECHA

DWD will rely primarily on existing tooling, adapted to fulfil needs



IT support for DWD process

- Prepare dossier
- Submit dossier
- Validate dossier
- Communicate outcome of submission
- Publish intentions

- Process application
- Record findings
- Prepare outputs
- Communicate outcomes of accordance check
- Publish dossier
- Consult interested parties
- Collect input
- Communicate comments to RAC

- Record findings
- Prepare opinion
- Consult RAC
- Consult DWD-WG
- Agree on opinion
- Communicate opinion to applicant
- Collect input
- Finalise opinion
- Communicate opinion to COM

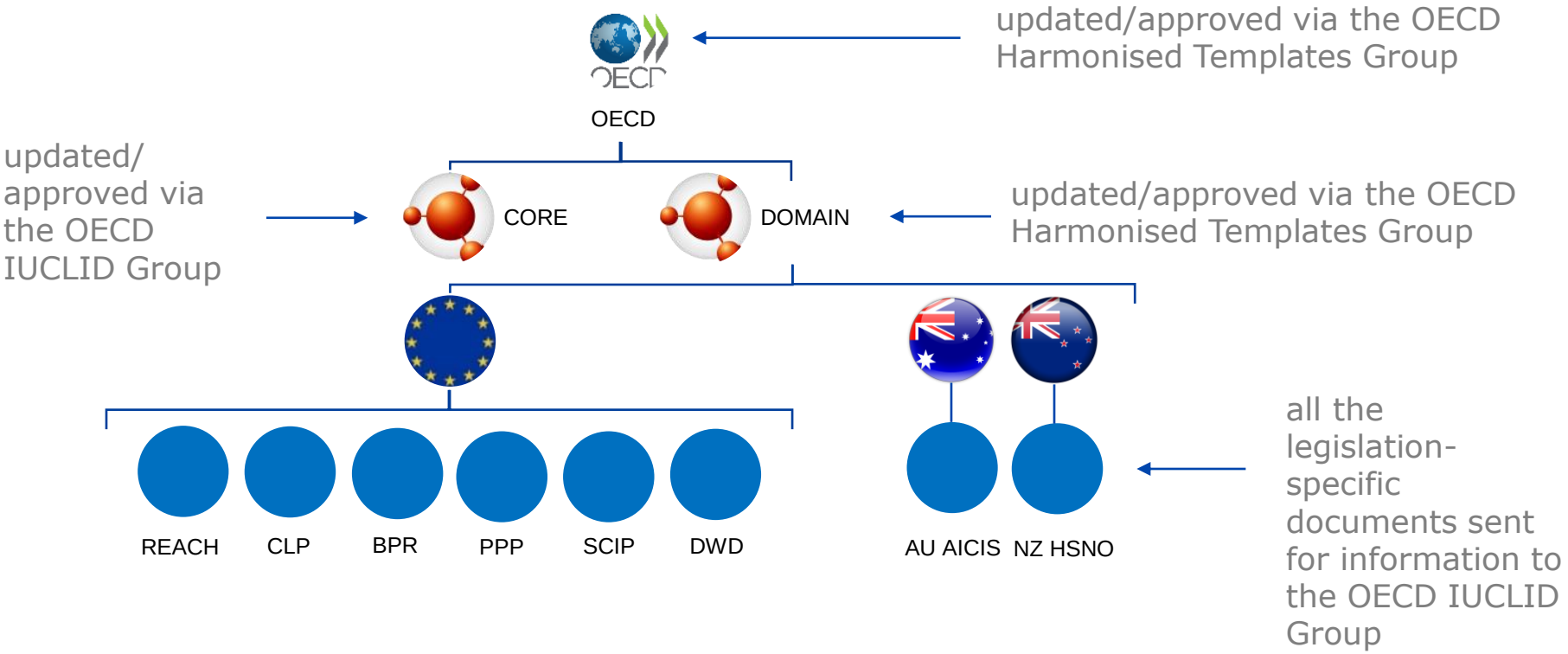
- Record COM decision
- Update EUPL

Plan for the development of the DWD IUCLID format in the next 2 years

What is IUCLID

- → **I**nternational **U**niform **C**hemica**L** **I**nformation **D**atabase
- → Worldwide known software, successfully used for several legislations
- → Standard exchange format based on predefined fields and reusable entities for
  - organising data
  - accessing information
  - comparing
  - reporting
  - evaluating
  - publishing data
- → For Competent Authorities (EU and non-EU), Industry, other stakeholders (e.g. JRC, OECD)

Harmonisation of data across different legislations



Determinants of a timeline

→ Legal deadlines
- January 2025 – first notifications of intention expected
- January 2026 – first application submission expected

→ IUCLID releases plan
- major releases, including format changes – once a year, next one in **April 2024**
- a maintenance (service) release – once a year, next one in October 2023
- additional releases in the ECHA Cloud Services – usually in January and July

Simplified timeline – major IUCLID releases

- → 06-08.2023 – feedback on the harmonised documents (OECD, Core, Domain)
- → 06-10.2023 – feedback on the DWD specific documents
- → 09-10.2023 - consultation of the format change proposals with OECD (OECD, Core, Domain)
- → 11.2023 all approved changes encoded (will appear in IUCLID in April 2024)

ECHA, IT Tools User Group, RAC DWD working group

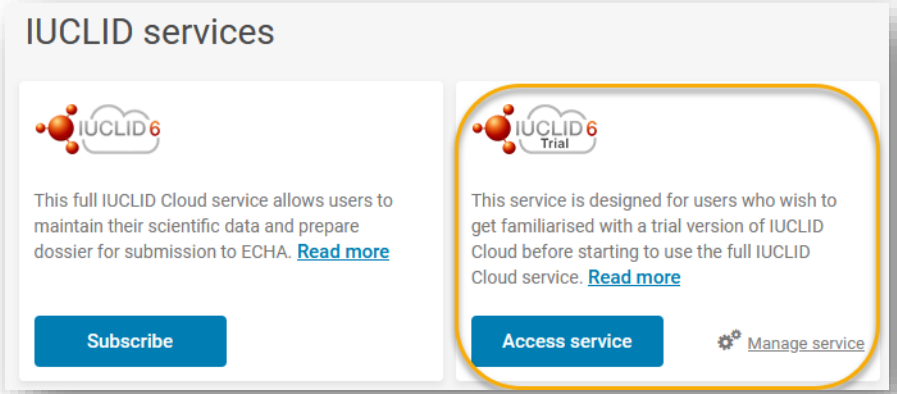
Explanation of what input can be made by the IT tools user group members

IUCLID demo

- → IUCLID Dashboard
- → What is a dataset and what is a dossier
- → Working context and a relevant table of contents
- → How to create new documents
- → Types of fields
- → Dynamic content rules
- → Related datasets
- → Examples of DWD specific documents

How to login to IUCLID

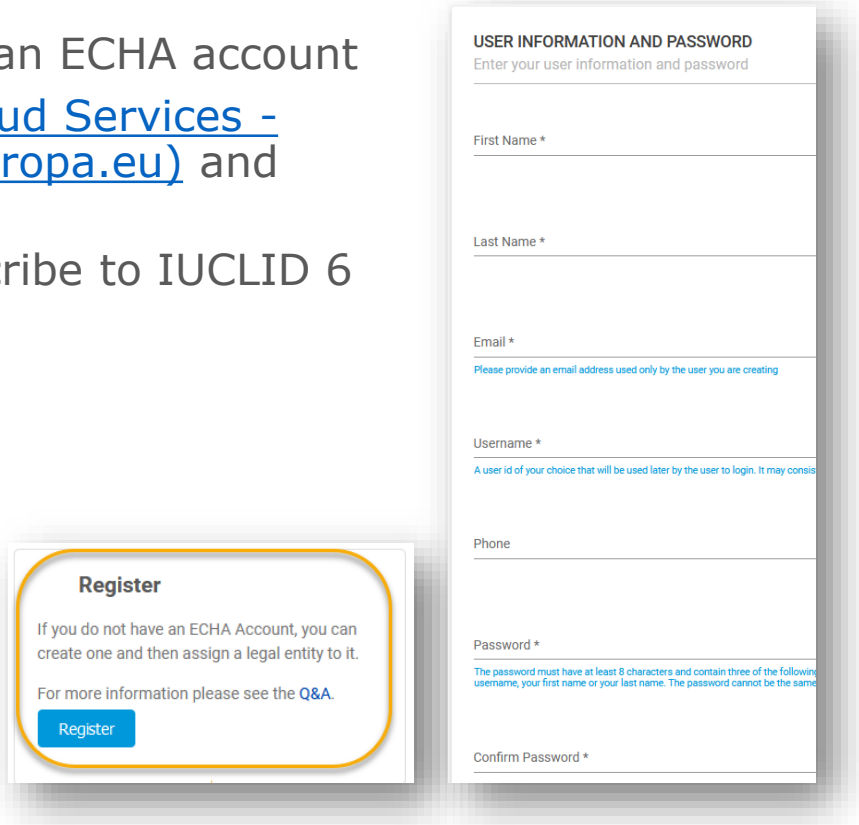
- → IUCLID instance to be used – IUCLID Cloud Trial
- → You can use your own data – other participants will not have access to them
- → If you have already an ECHA account
  - go to [ECHA Cloud Services - Home page (europa.eu)] and login
  - subscribe to IUCLID 6 Trial



How to login to IUCLID

→ If you don’t have an ECHA account

- go to [ECHA Cloud Services - Home page (europa.eu)] and register
- login and subscribe to IUCLID 6 Trial



Which documents are priority to comment on

Numbering of the sections:
DWD Article 11 application

→ In period June – August 2023:

- Identification (1.1)
- Composition (1.2)
- Identifiers (1.3)
- Analytical information (1.4)
- all the documents in section 'Physical and chemical properties' (2)
- all the documents in section 'Toxicological data' (5)
- Analytical methods (7)

→ In period June – October 2023:

- Related datasets (1.5)
- Intended application of the substance (3)*
- Data on migration of the substance (4.1)
- Electrochemical test (passivation) (4.2)
- Reports (8)

→ There is <u>no need to review</u>:

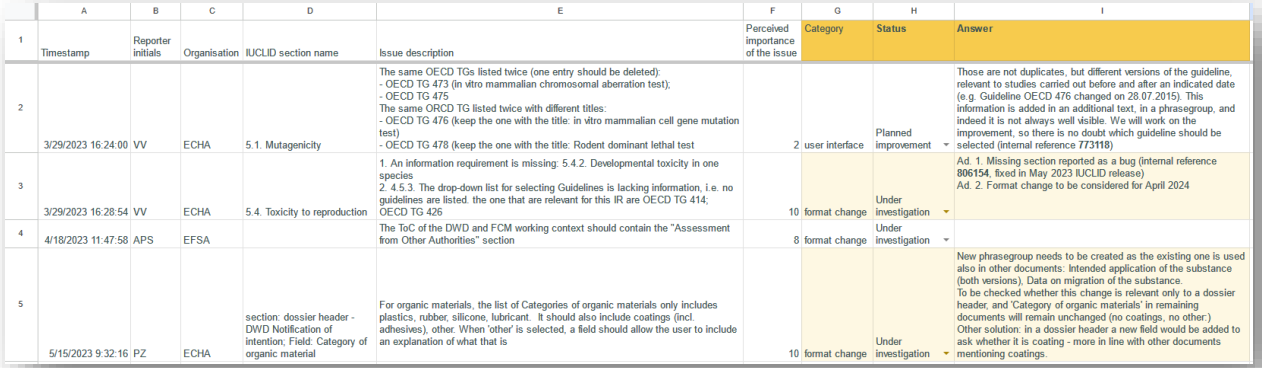
- Microbiological activity of the substance (6) – will be removed

*document 'Intended application of the substance' has two versions for two working contexts

How to provide your feedback

→ All the comments, requirements can be submitted via a dedicated webform and seen in the spreadsheet

- Please indicate your organisation and initials so we could contact you to clarify the requirement
- Please do not insert any confidential or personal details, as your comments will be visible to every one involved in DWD format review
- If you need to provide a screenshot, please do it by e-mail, indicating also a spreadsheet row to which your feedback has been added
- You can comment on existing entries provided by other users (right click on the selected cell to add comment)



	A	B	C	D	E	F	G	H	I
1	Timestamp	Reporter initials	Organisation	IUCLID section name	Issue description	Perceived importance of the issue	Category	Status	Answer
2	3/29/2023 16:24:00	VV	ECHA	5.1. Mutagenicity	The same OECD TGs listed twice (one entry should be deleted): - OECD TG 473 (in vitro mammalian chromosomal aberration test); - OECD TG 475 The same ORCD TG listed twice with different titles: - OECD TG 476 (keep the one with the title: in vitro mammalian cell gene mutation test) - OECD TG 478 (keep the one with the title: Rodent dominant lethal test	2	user interface	Planned improvement	Those are not duplicates, but different versions of the guideline, relevant to studies carried out before and after an indicated date (e.g. Guideline OECD 476 changed on 28.07.2015). This information is added in an additional text, in a phrasegroup, and indeed it is not always well visible. We will work on the improvement, so there is no doubt which guideline should be selected (internal reference **773118**)
3	3/29/2023 16:28:54	VV	ECHA	5.4. Toxicity to reproduction	1. An information requirement is missing: 5.4.2. Developmental toxicity in one species 2. 4.5.3. The drop-down list for selecting Guidelines is lacking information, i.e. no guidelines are listed. the one that are relevant for this IR are OECD TG 414; OECD TG 426	10	format change	Under investigation	Ad. 1. Missing section reported as a bug (internal reference **806154**, fixed in May 2023 IUCLID release) Ad. 2. Format change to be considered for April 2024
4	4/18/2023 11:47:58	APS	EFSA		The ToC of the DWD and FCM working context should contain the "Assessment from Other Authorities" section	8	format change	Under investigation	
5	5/15/2023 9:32:16	PZ	ECHA	section: dossier header - DWD Notification of intention; Field: Category of organic material	For organic materials, the list of Categories of organic materials only includes plastics, rubber, silicone, lubricant. It should also include coatings (incl. adhesives), other. When 'other' is selected, a field should allow the user to include an explanation of what that is	10	format change	Under investigation	New phrasegroup needs to be created as the existing one is used also in other documents: Intended application of the substance (both versions), Data on migration of the substance. To be checked whether this change is relevant only to a dossier header, and 'Category of organic materials' in remaining documents will remain unchanged (no coatings, no other:) Other solution: in a dossier header a new field would be added to ask whether it is coating - more in line with other documents mentioning coatings.

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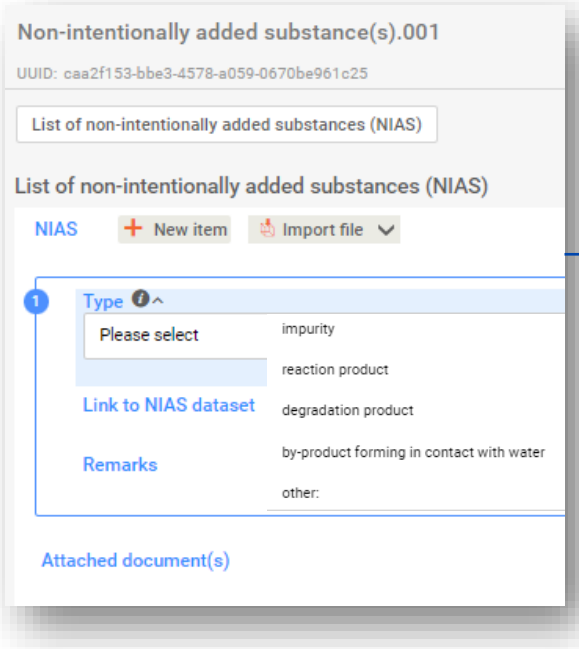
How we can support your work

→ IUCLID format specifications for selected documents (in a .doc format)



EU Drinking Water Directive Template #N/A: Non-intentionally added substance(s) *(Version [1.1]-[December 2022])*

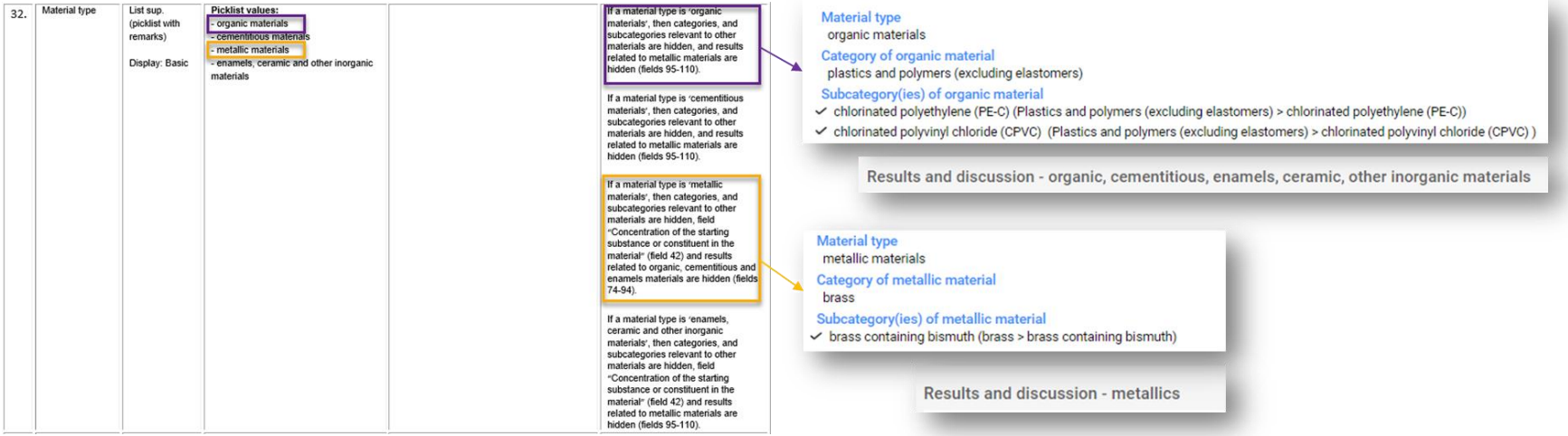
LEGISLATION_NAME Template #N/A: Non-intentionally added substance(s) *(Version [1.1]-[December 2022])*

The following table gives a detailed description of the type of information prompted for by the data entry fields.

Line no.	Field name	Field type Display type	Picklist Freetext template	Help text	Remarks Guidance Cross-reference
1.	**List of non-intentionally added substances (NIAS)**	**Header 1**			
2.	**NIAS**	**Block of fields (repeatable) Start**			
3.	Type	List (picklist) Display: Basic	**Picklist values:** - impurity - reaction product - degradation product - by-product forming in contact with water - other:		
4.	Link to NIAS dataset	Link to entity (single) Display: Basic		Link a substance dataset.	**Cross-reference:** SUBSTANCE
5.	Remarks	Text (2,000 char.) Display: Basic		Provide a short description how the substance became a NIAS / why the substance is considered as a NIAS. Does it form during hydrolysis of the IAS? A detailed description of the process should be provided in the field Description in the composition in the linked substance dataset.	

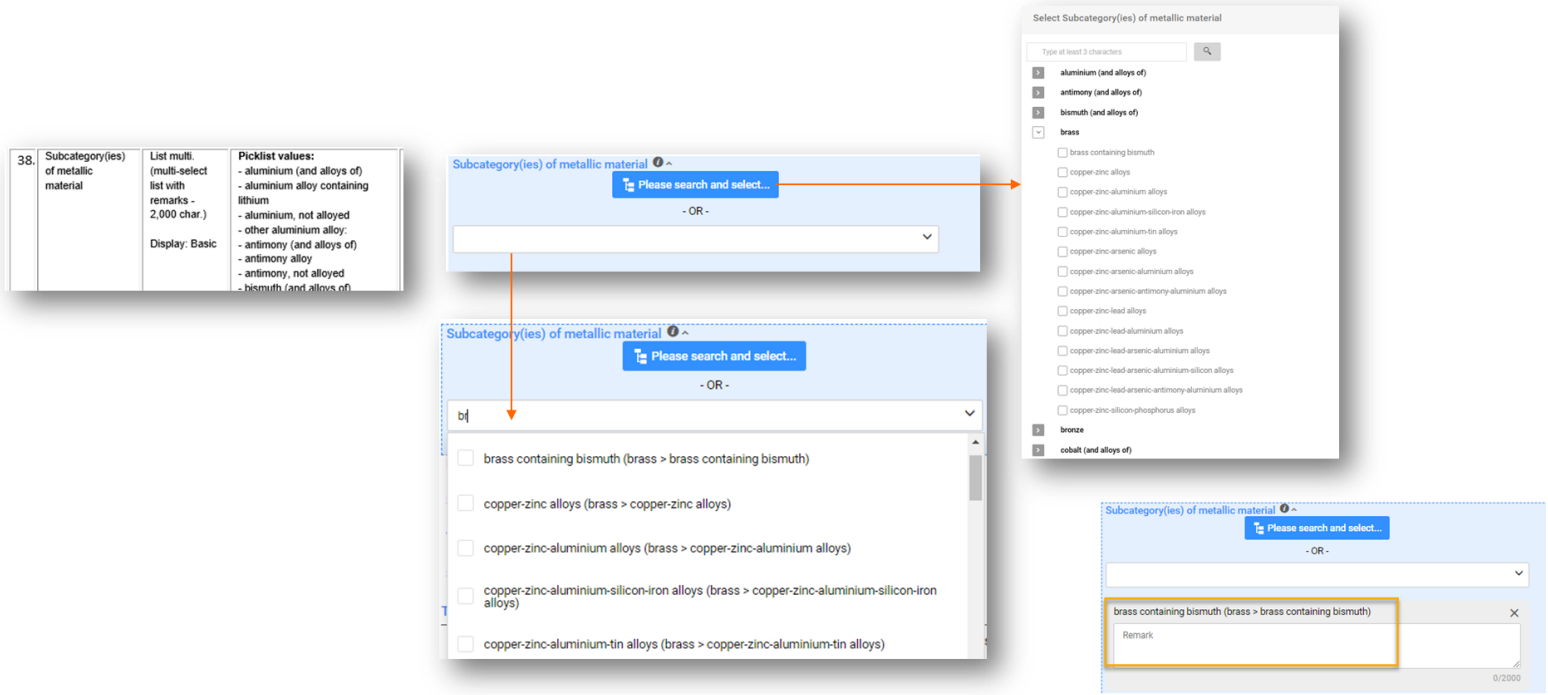
How to understand the IUCLID format specifications?

→ Dynamic content rules



How to understand the IUCLID format specifications?

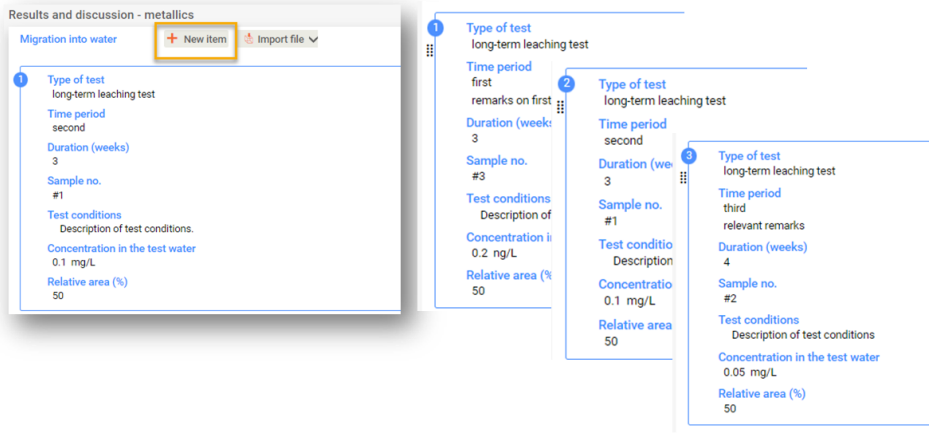
→ Long pick lists (hierarchical)



How to understand the IUCLID format specifications?

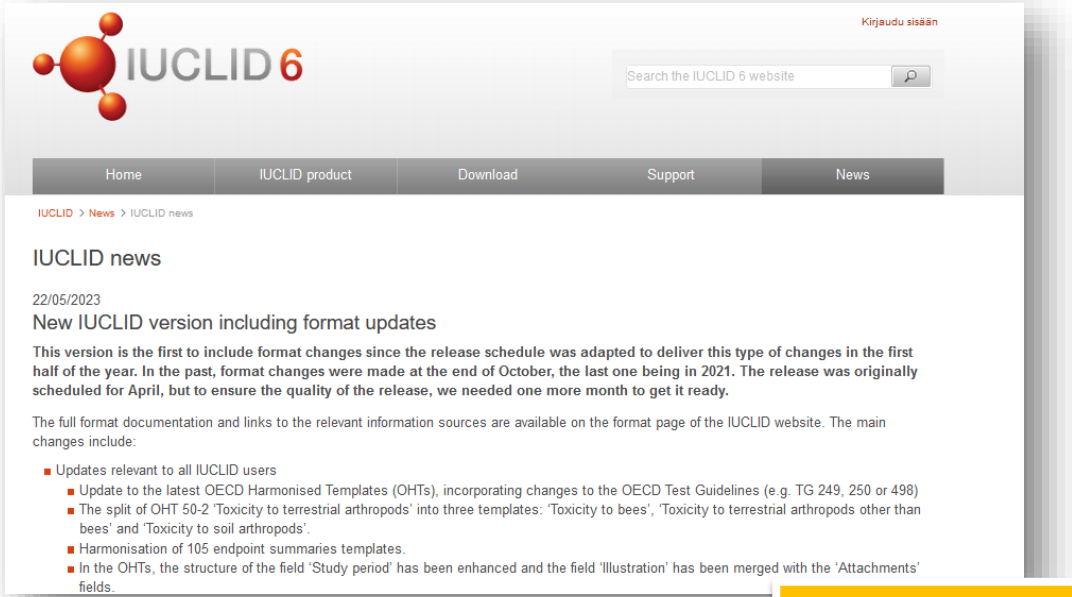
→ Repeatable block of fields

Results and discussion - metallics	Header 1		
Migration into water	Block of fields (repeatable) Start		Indicate the migration of the test substance into water for the test conditions indicated in the corresponding subfield. Multiply this block of fields for the different time period and samples.
Type of test	List (picklist) Display: Basic	Picklist values: - long-term leaching test - other:	
Time period	List sup. (picklist with remarks) Display: Basic	Picklist values: - first - second - third - fourth - fifth - other:	
Duration (weeks)	Numeric (decimal) Display: Basic		
Sample no.	List (picklist) Display: Basic	Picklist values: - #1 - #2 - #3 - #4	Select a consecutive sample number from drop-down list if more than one test runs are reported.
Test conditions	Text (255 char.) Display: Basic		Briefly specify the relevant test conditions, e.g. contact time, concentration of substance and the limit of detection.
Concentration in the test water	Numeric (decimal including unit) Display: Basic	Unit [xx]: - mg/L - ng/L - µg/L	Quantify the concentration of the assessed substance in the test water. For more detailed information or tables use fields 'Details on results' or 'Any other information on results incl. tables', respectively.
Relative area (%)	Numeric (decimal) Display: Basic		Indicate relative area.
Migration into water	Block of fields (repeatable) End		



More information on IUCLID

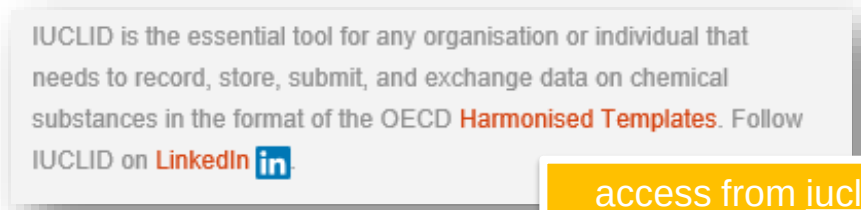
IUCLID website



iuclid6.echa.europa.eu

More information on IUCLID

IUCLID LinkedIn Group



access from iuclid6.echa.europa.eu

direct link:
https://www.linkedin.com/groups/12043483

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