

IUCLID FOR THE SUBMISSION AND ASSESSMENT OF APPLICATIONS

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WHAT IS IUCLID



International **U**niform **C**hemical **I**nformation **D**atabase

- IUCLID is a software to record, store, maintain and exchange data on chemical substances.
- Standard exchange format based on predefined fields for:
 - organising data
 - accessing information
 - comparing
 - reporting
 - evaluating
 - publishing data
- Co-developed by ECHA and OECD based on OECD harmonized templates (OHT)

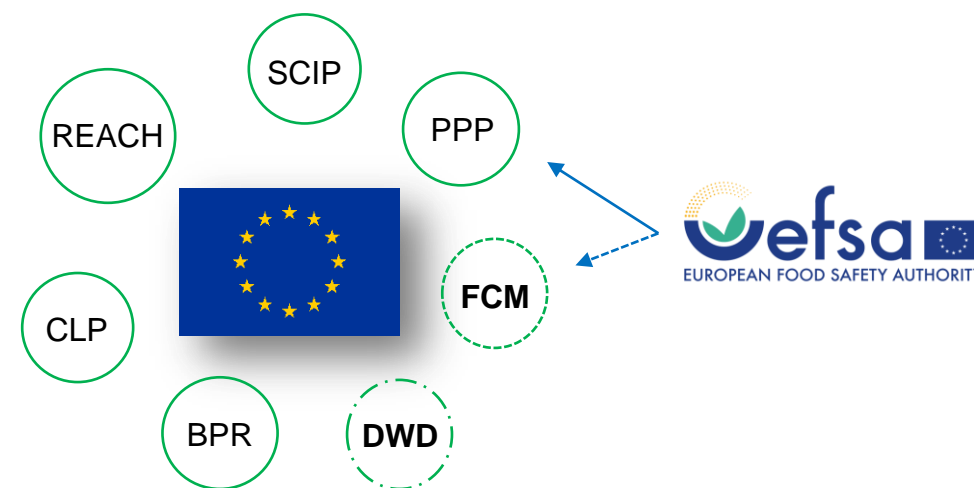


WHAT IS IUCLID



International **U**niform **C**hemical **I**nformation **D**atabase

- Central role in the IT environments of organizations managing scientific data on chemicals in a regulatory context
- EU institutions (ECHA, EFSA) are using IUCLID for submission of dossiers (e.g., on regulated products)
- ECHA is currently developing IUCLID for the submission/assessment of applications on drinking water materials (DWM) based on the drinking water directive (DWD)
- IUCLID will be also used for applications of FCM substances (Reg. (EU) 10/2011)



IUCLID FOR DRINKING WATER MATERIALS - PROGRESS



IUCLID FOR DWM - SECTIONS

DWD Article 11 application	
substance_1	
1 General information	5
1.1 Identification	1
1.2 Composition	3
1.3 Identifiers	
1.4 Analytical information	1
1.5 Related datasets (NIAS, element, substance)	
2 Physical and chemical properties	8
3 Intended application of the substance	
4 Data on migration of the substance, electrochemical tests	1
5 Toxicological data	4
6 Microbiological activity of the substance	
7 Analytical methods	2
8 Reports	
Inherited templates	

→ specific documents developed by ECHA for DWM applications

- Type of information similar to the one currently submitted for FCM substances (Reg. (EU) 10/2011)

4 Data on migration of the substance, electrochemical tests	1
4.1 Data on migration of the substance	1
Data on migration of the substance.001	
4.2 Electrochemical test (passivation)	

Results and discussion - organic, cementitious, enamels, ceramic, other inorganic materials

Migration into water + New item Import file

Average migration rate (mg/dm²*d)

Concentration (CTap) (µg/L)

Identity of non-intentionally added substances (NIAS) + New item Import file

Indication of organoleptic changes

Details on results

Any other information on results incl. tables

Overall remarks, attachments

Overall remarks

- Approach to data reporting different than other infrastructure (e.g. ESFC): every relevant single piece of information is reported separately



IUCLID FOR DWM- SECTIONS

- Report information via picklists, free text or attachments

The screenshot shows the 'Material type' picklist on the left with options: organic materials, cementitious materials, metallic materials, and enamels, ceramic and other inorganic materials. The 'Migration into water' section on the right includes fields for 'Time period', 'Duration (h)', 'Sample no.', and 'Test conditions' (circled in red). A 'New item' button and an 'Import file' dropdown are at the top of the section.

The screenshot shows the 'List of non-intentionally added substances (NIAS)' section. It includes a 'NIAS' picklist, a 'New item' button, and an 'Import file' dropdown. The text 'Attached document(s)' is circled in red.

- Repeatable block of fields

The screenshot shows the 'Results and discussion - metallics' section. It includes a 'Migration into water' section with a 'New item' button (highlighted with a yellow box) and an 'Import file' dropdown. Below this is a repeatable block of fields for 'Type of test', 'Time period', 'Duration (weeks)', 'Sample no.', 'Test conditions', 'Concentration in the test water', and 'Relative area (%)'. The first item in the block is shown with values: long-term leaching test, second, 3, #1, Description of test conditions., 0.1 mg/L, and 50.

The screenshot shows the 'Type of test' section. It includes a 'Type of test' picklist and a 'New item' button. Below this is a repeatable block of fields for 'Type of test', 'Time period', 'Duration (weeks)', 'Sample no.', 'Test conditions', 'Concentration in the test water', and 'Relative area (%)'. The first item in the block is shown with values: long-term leaching test, third, relevant remarks, 4, #2, Description of test conditions., 0.05 mg/L, and 50.

- Generate a report

The screenshot shows the 'View Dossiers' section. It includes a 'Validate' button and a 'Create dossier' button. A dropdown menu is open, showing options: Export to i6z, Create document PDF/RTF, Create component PDF/RTF, Generate report, Compare, Clone, Copy data from ..., and Bulk operations.

IUCLID FOR FOOD CONTACT MATERIALS



IUCLID 6

International Uniform Chemical Information Database

- IUCLID format **will be used** to submit applications used for risk assessment of FCM instead of ESFC (likely in **2025-2027**).
- Given the similarity between FCM and DWM safety assessments, the FCM IUCLID format will build on the DWD IUCLID format that is currently developed by ECHA (adaptations to the specific requirements are needed)
- IUCLID will be used not only for submission, but also to access and evaluate data (contrary to the presently used system) → substantial change in the working of EFSA and MS
- Collaborations between ECHA and EFSA
 - EFSA FCM WG kept informed on ongoing work on DWD IUCLID format
 - EFSA participating in ECHA's DWD Guidance and IT Tools User Group



IUCLID FOR FOOD CONTACT MATERIALS – ECHA-EFSA COLLABORATIONS

Guidance user group

- Review and provide comments on the ECHA guidance documents aimed at supporting applicants to submit DWM applications to ECHA and the ECHA's Committee for Risk Assessment in assessing the applications

IT Tools User Group

- Testing and providing feedback to ECHA on the IUCLID-based format that applicants will use to prepare their applications



- Getting familiar with the IUCLID environment and identify adaptations needed for future use for FCM applications



FINAL CONSIDERATIONS ON THE USE OF IUCLID FOR FCM

- IUCLID is widely used in EU to handle information on chemicals and will be soon used for submission and evaluation of applications in the field of FCM.
 - Access to EFSA applications by MS representatives will be done via IUCLID.
 - MS may wish to also use IUCLID for their applications within national legislation
 - Useful/key for interoperability, access, sharing data/information between EU and MSs as well as amongst MSs
- The IUCLID format for applications of FCM substances:
 - Will be built adapting IUCLID for DWM → ideally a fast process
 - EFSA is kept informed on IUCLID DWD format, identifying key elements to be considered when building the FCM IUCLID format.
 - Update to FCM Network next year



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