



# IUCLID FOR THE SUBMISSION AND ASSESSMENT OF APPLICATIONS

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11<sup>th</sup> meeting of the EFSA FCM Network  
Parma, 22-24 October 2023

# 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)

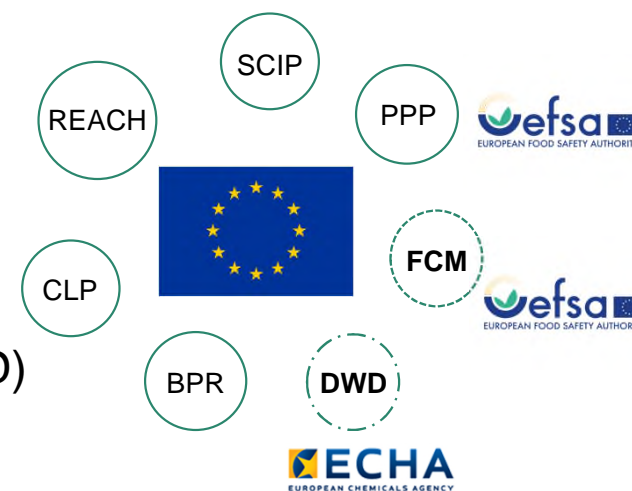


# WHAT IS IUCLID

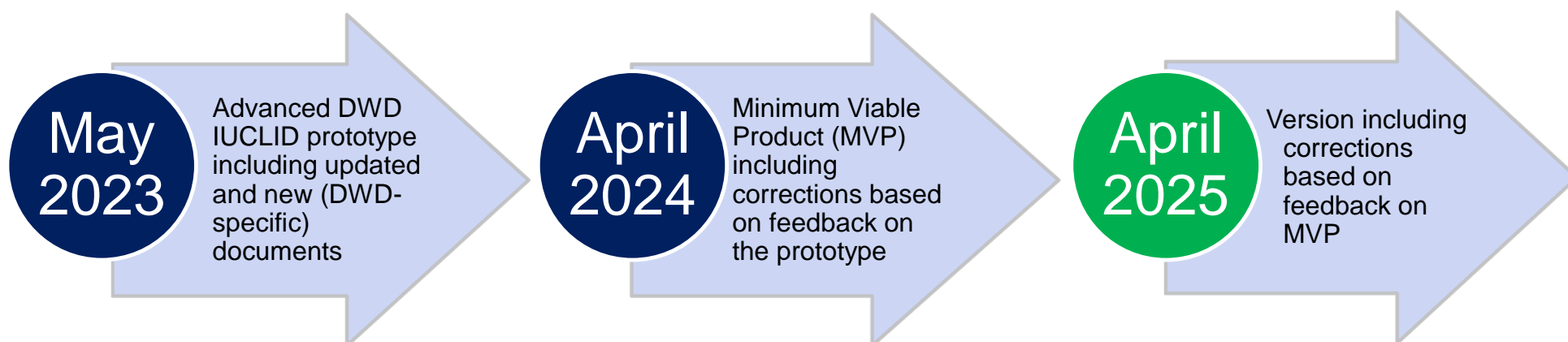


International **U**niform **C**hemical **I**nformation **D**atabase

- 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 on regulated products
- ECHA is currently developing IUCLID for the submission/assessment of applications on drinking water materials (DWCM) 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 CONTACT MATERIALS - PROGRESS



version to be used for first notifications of intention from January 2026

DWD applications from January 2027





# IUCLID FOR DWCM - SECTIONS

1 General information	4
1.1 Identification	1
1.2 Composition	1
1.3 Identifiers	1
1.4 Analytical information	1
1.5 Relevant chemical species other than the applied-for entry (linked datasets)	
2 Classification and labelling	1
3 Physical and chemical properties	2
4 Intended use of the applied-for entry	1
5 Data on migration of the substance, electrochemical tests	3
6 Analytical methods	
7 Toxicological data	3
8 Risk acceptance	
9 Assessment by other authorities	
10 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)

5 Data on migration of the substance, electrochemical tests	3
5.1 Data on migration of the substance	+
• Data on migration of the substance.001	
• Data on migration of the substance.002	
5.2 Data on electrochemical test and passivation tendency of a metallic material	1

Experimental study migration test results
Migration into water
Diffusion-based modelling
Model details and parameters
The modelling software used
Temperature of the system (°C)
Material under test
Geometry of the material
S/V ratio (dm <sup>-1</sup> )
Thickness of the material (Dp)

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



## Slide 5

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**ZP3**

New slide, previous version is hidden above

ZAROGIANNIS Panagiotis, 19/09/2024

# IUCLID FOR DWCM- SECTIONS

- Report information via picklists, free text or attachments

The screenshot shows the 'Material type' picklist with options: organic materials, cementitious materials, metallic materials, and enamels, ceramic and other inorganic materials. Below it, the 'Migration into water' section is visible, containing fields for 'Time period', 'Duration (h)', 'Sample no.', and 'Test conditions' (which is circled in red).

- Repeatable block of fields

The screenshot shows the 'Experimental study migration test results' section with a 'Migration into water' sub-section. It contains a list of fields: Test temperature (°C), S/V-ratio (dm<sup>-1</sup>), Migration period length, Test water type, and Total number of migration periods. A 'New item' button is highlighted with a red box.

The screenshot shows multiple instances of the 'Experimental study migration test results' section, each with a 'Migration into water' sub-section. The fields are repeated for each instance, showing values like Test temperature (20), S/V-ratio (20), Migration period length (24 h), Test water type (test water), and Total number of migration periods (8).

The screenshot shows the 'Relevant chemical species' section. It includes a 'New item' button and an 'Import file' button. Below, there is a list of fields: Relevant chemical species type (organic and cementitious materials), MTCTap (µg/L), Basis for selecting an MTCTap value, Justification for the derivation of the MTCTap value, and Residual concentration of the relevant chemical species in the material (% w/w). The 'Relevant chemical species' title is circled in red.

- Generate a report

The screenshot shows the 'View Dossiers' section with a dropdown menu open. The menu options are: Export to i6z, Create document PDF/RTF, Create component PDF/RTF, Generate report, Compare, Clone, Copy data from ..., and Bulk operations. The 'Generate report' option is highlighted.

## Slide 6

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**ZP4**

New slide, previous version is hidden above

ZAROGIANNIS Panagiotis, 19/09/2024

# IUCLID FOR FOOD CONTACT MATERIALS



International Uniform Chemical Information Database

- IUCLID format will be used to submit applications used for risk assessment of FCM instead of ESFC (likely in **2026-2028**).
- IUCLID is intended to be used not only for submission, but also to evaluate data (contrary to the presently used system) → substantial change in the working of EFSA and MS
- EFSC will be kept as tool linked to IUCLID to interact with applicants (i.e. only administrative aspects, not for submitting data)



# IUCLID FOR FOOD CONTACT MATERIALS - PROGRESS

## **ECHA-EFSA collaborations (FIP unit)**

- FCM WG kept informed on ongoing work on DWD IUCLID format
- EFSA participating in ECHA's DWD Guidance and IT Tools User Group

## **Building of the FCM IUCLID format (FDP unit):**

- Definition of the “table of content” (i.e. high-level categories) to be applied to the IUCLID format → currently under finalisation
- Adaptation of already available templates (e.g. as OHT, from DWD) and building of ad-hoc templates (i.e. those not available as OHT/ not adaptable) → ongoing



# 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:

- Is already being built considering the DWD IUCLID format
- 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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