

# Update on the latest version of the DWD application IUCLID format

DWD IT tools user group

24 May 2024

Dorota Burchard-Sosnowska

Daria Caselius

Clara Rueda

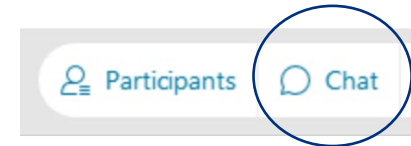
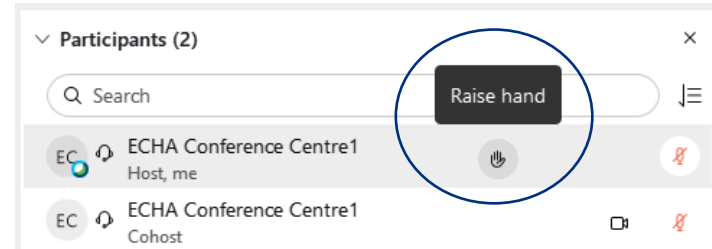
Panos Zarogiannis



# Practicalities

## → Practicalities

- For the floor, raise your hand
- Use the **Chat**:
  - Questions and comments related with the topic of the presentation.
  - To: all panellists



- ## → Meeting is being recorded for internal purposes and to allow absent group members to watch the presentation offline

Comments and questions: [ECHA\\_DWD@europa.echa.eu](mailto:ECHA_DWD@europa.echa.eu) 



## Agenda

- Information requirements for DWD applications
- DWD process, end to end solution
- Update on the DWD application IUCLID format & validation rules
- Demo on DWD application IUCLID format & validation
- Where to test IUCLID and how to report feedback
- DWD application & CBI
- Questions and answers
- <sup>3</sup>→ Next steps

# Information requirements for DWD applications



# Legal acts and details of Regulation (EU) 2024/369

Legal act	Formal number	Links to published legal acts in the Official Journal (23 April 2024)
1.IA	<b>2024/365</b>	<a href="http://data.europa.eu/eli/dec_impl/2024/365/oj">http://data.europa.eu/eli/dec_impl/2024/365/oj</a>
2.IA	<b>2024/367</b>	<a href="http://data.europa.eu/eli/dec_impl/2024/367/oj">http://data.europa.eu/eli/dec_impl/2024/367/oj</a>
3.DA	<b>2024/369</b>	<a href="http://data.europa.eu/eli/reg_del/2024/369/oj">http://data.europa.eu/eli/reg_del/2024/369/oj</a>
4.IA	<b>2024/368</b>	<a href="http://data.europa.eu/eli/dec_impl/2024/368/oj">http://data.europa.eu/eli/dec_impl/2024/368/oj</a>
5.DA	<b>2024/370</b>	<a href="http://data.europa.eu/eli/reg_del/2024/370/oj">http://data.europa.eu/eli/reg_del/2024/370/oj</a>
6.DA	<b>2024/371</b>	<a href="http://data.europa.eu/eli/reg_del/2024/371/oj">http://data.europa.eu/eli/reg_del/2024/371/oj</a>

## Key parts of Regulation 2024/369:

- Description of application procedure in Articles 3-6
- Contents of DWD application in Annex I
- Treatment of information in Article 7-10

# DWD Applicants

- EU economic operators
- EU-based representatives of non-EU operators
- National authorities

# 2024/365 – DWD application info requirements

Annex	Issue	Aim of the Annex
I	Substance/ composition identity	<ul style="list-style-type: none"><li>Identify what is being applied for</li></ul>
II	Intended use	<ul style="list-style-type: none"><li>Describe the use in a comprehensive manner</li><li>Explain relevant past assessments</li></ul>
III	Physico-chemical properties	<ul style="list-style-type: none"><li>Supporting data to understand reactions and health hazards</li></ul>
IV	Migration and identification of <b>relevant chemical species</b>	<ul style="list-style-type: none"><li>How to test for migration</li><li>Collect information on migration analytical methods</li><li>Generate concentrations at the tap (<math>C_{\text{tap}}</math>)</li><li>Conclude on the identification of the <b>relevant chemical species</b></li></ul>
V	Toxicological assessment of <b>relevant chemicals species</b>	<ul style="list-style-type: none"><li>Determine toxicological properties of <b>relevant chemical species</b>, depending on migration level of each one</li><li>Support risk assessment under Annex VI</li></ul>
VI	Risk acceptance	<ul style="list-style-type: none"><li>Determine <math>MTC_{\text{tap}}</math> for each <b>relevant chemical species</b></li><li>Ensure <math>C_{\text{tap}} &lt; MTC_{\text{tap}}</math> for each <b>relevant chemical species</b></li></ul>

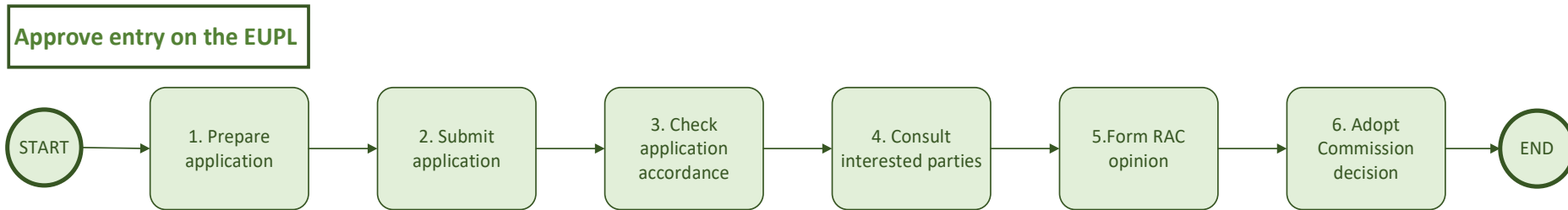
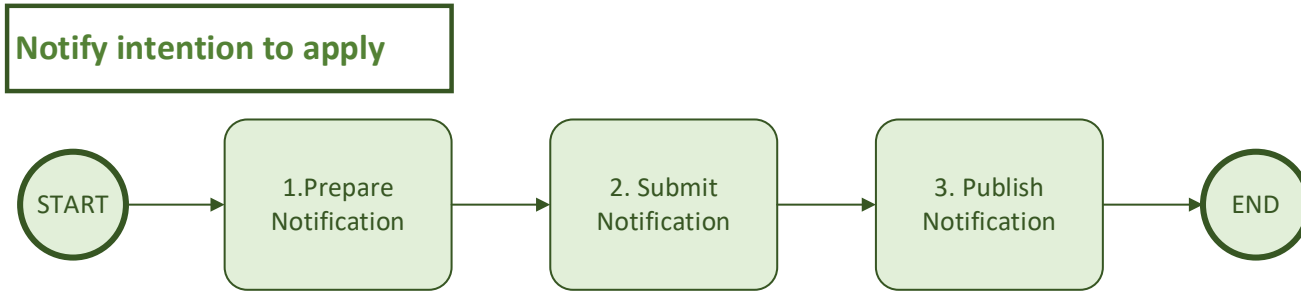
# DWD process

## End to end solution

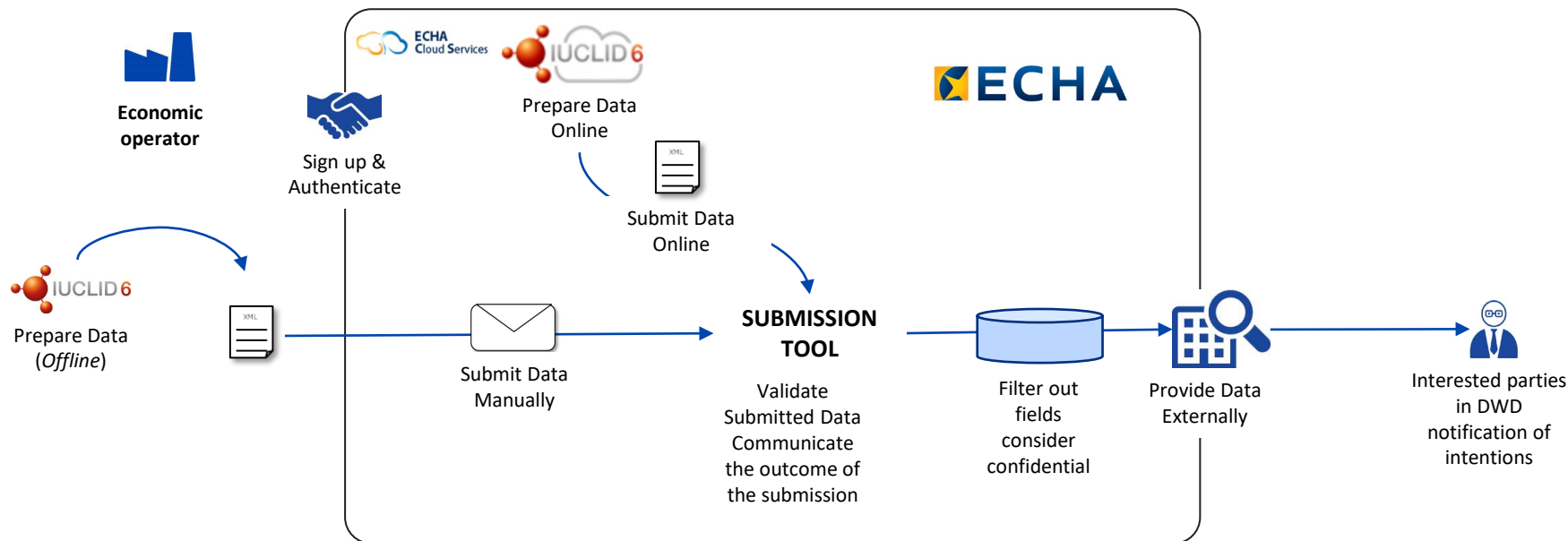




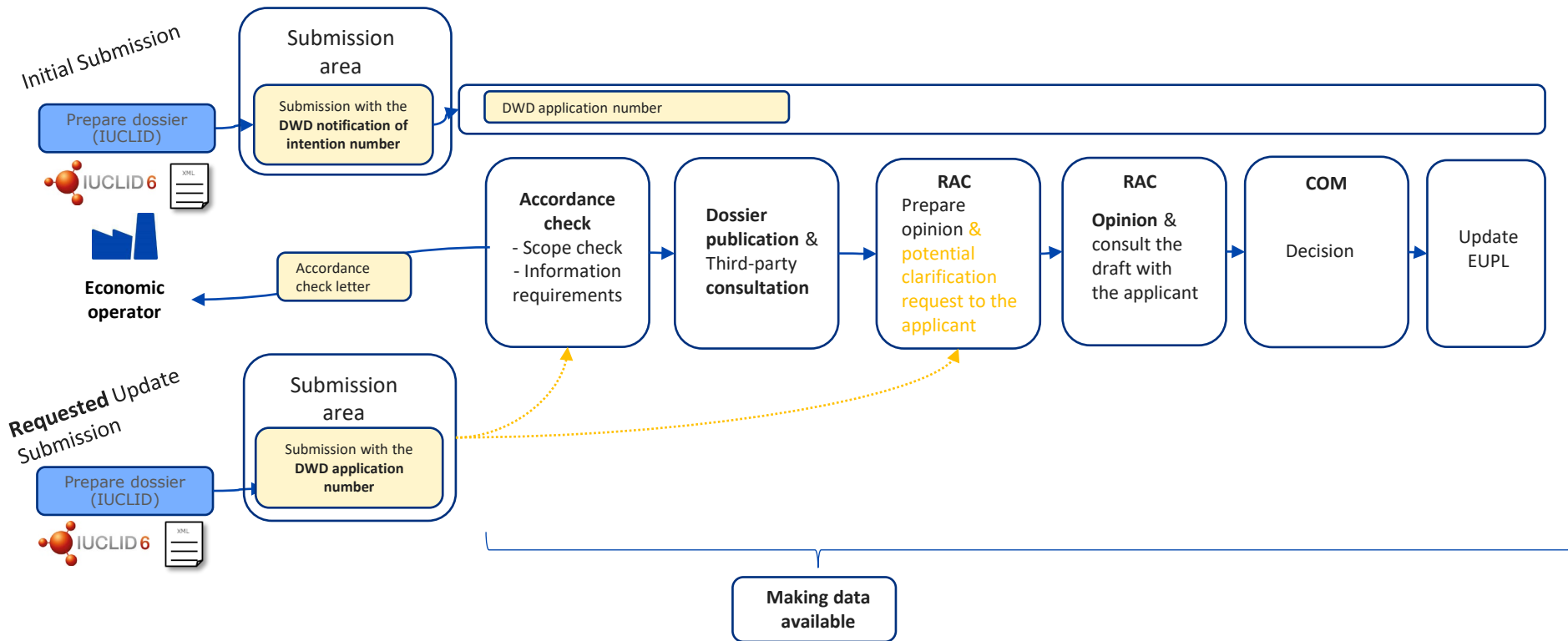
# DWD Business process



# Notification of intention to apply end to end solution



# DWD Application ( new/review/remove entry in the EUPL)



# Update on DWD application IUCLID format & validation rules



# DWD application

## Dossier specific information in the dossier header

- Type of application
- Material type
- Is it a group entry? (**EUPL number of the group entry**, scope of the group entry application)
- **Is the applicant a competent relevant authority? → Application justified by urgency without prior submission of notification of intention → Justification for urgency**
- Migration tier for the applied-for entry
- Remarks
- Submission is an update → only further to request/decision from a regulatory body and **with the confirmation that the updated submission is final**

# DWD application

## Table of contents

### 1. General information

1.1 Identification

1.2 Composition

1.3 Identifiers

1.4 Analytical information

**1.5 Relevant chemical species  
other than the applied-for  
entry (linked datasets)**

List of relevant chemical species other than the applied for entry

Material type  
organic materials

List of relevant chemical species other than the applied for entry

Relevant chemical species [+ New item](#) [Import file](#) ▼

1 [Relevant chemical species type \(organic and cementitious materials\)](#)

[Migration tier for the relevant chemical species](#)

[Physico-chemical data for the relevant chemical species are waived](#)

[Justification for waiving physico-chemical data requirements](#)

[Toxicological data for the relevant chemical species are waived](#)

[Justification for waiving toxicological data requirements](#)

[Link to relevant chemical species dataset](#)  
relevant chemical species

Remarks

Attached document(s)

- << [DWD](#) [Relevant chemical species](#)
- ▼ [relevant chemical species](#)
  - ▼ **1 General information**
    - > 1.1 Identification
    - 1.3 Identifiers
    - 1.4 Analytical information
  - 2 Classification and labelling**
  - ▼ **3 Physical and chemical properties**
    - 3.10 Water solubility
    - 3.11 Partition coefficient (n-octanol/wat
  - 6 Analytical methods**
  - > **7 Toxicological data**
  - 9 Assessment by other authorities**
  - 10 Reports**
  - Inherited templates

# DWD application

2. Classification and labelling
3. Physical and chemical properties
4. Intended use of the applied-for entry
5. Data on migration of the substance, electrochemical tests
  - 5.1 Data on migration of the substance
  - 5.2 Data on electrochemical test and passivation tendency of a metallic material
6. Analytical methods
7. Toxicological data
8. **Risk acceptance**
9. **Assessment by other authorities**
10. Reports

# DWD application

## 8. Risk acceptance

Risk acceptance

Material type  
organic materials

Relevant chemical species + New item Import file

1 Relevant chemical species  
DWD reference substance

Relevant chemical species type (organic and cementitious materials)

MTCtap ( $\mu\text{g/L}$ )

Basis for selecting an MTCtap value

Justification for the derivation of the MTCtap value

Residual concentration of the relevant chemical species in the material (% w/w)

Justification for the residual concentration of the relevant chemical species

Attached document

Ctap ( $\mu\text{g/L}$ )

Risk characterisation ratio

## 9. Assessment by other authorities

### Assessment in EU/EEA

Biocidal active substance

Biocidal active substance status

Biocidal active substance approval: start date

Biocidal active substance approval: end date

Biocidal product type

Biocidal active substance approval: toxicological safety value

- Food contact material starting substance
- 4MS Initiative approval
- Other assessments



# Validation areas for Applications

- **Substance identity** under sections 1.1\_Identification, 1.2\_Composition
  - *Example: BR\_DWD\_001 - A reference substance must be linked in section 1.1*
- **Material type alignment** with the relevant documents in the dossier/dataset
  - *Example: BR\_DWD\_008 - 'Material type' under the Dossier header must be aligned with all 'Material type' entries in the dossier*
- **Study information** requirement
  - *BR\_DWD\_014 - under the Appearance/state of the substance a key study, weight of evidence or data waiver must be provided*

# Demo of the latest DWD application IUCLID format & validation



# IUCLID demo



- Dossier header
- Table of contents
  - How to create new documents
  - Types of fields
  - Dynamic content rules
  - DWD specific documents
  - Copy data from...
- Validation assistant
- Dossier creation

# Where and how to test IUCLID and how to report feedback



# Which documents are priority to comment on

## → In period May – August 2024:

- Identification (1.1)
- Composition (1.2)
- Identifiers (1.3)
- Analytical information (1.4)
- Classification and labelling (2)
- all the documents in section 'Physical and chemical properties' (3)
- all the documents in section 'Toxicological data' (7)
- Analytical methods (6)

## → In period May – October 2024:

- Dossier header
- Relevant chemical species other than the applied-for entry (linked datasets) (1.5)
- Intended use of the applied-for entry (4)
- Data on migration of the substance (5.1)
- Data on electrochemical test and passivation tendency of metallic material (5.2)
- Risk acceptance (8)
- Assessment by other authorities (9)

# Validation checks for Applications

- The due date for the feedback on validation of a DWD application - **end of Aug 2024**
- Target release October 2025

# How to provide your feedback

- All the comments, requirements can be submitted via a dedicated [webform](#) and seen in the [spreadsheet](#)
- Please indicate your 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 everyone involved in DWD format review
  - Please indicate details such as IUCLID working context, section number and name, validation rule number
  - 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 (tab Form responses 3; right click on the selected cell to add comment)

## IUCLID 6 - Drinking Water Directive - Testing report

You can see the list of issues reported so far and the provided answers from this link: <https://docs.google.com/spreadsheets/d/18LaqHzmNRlx61gzJ5G37qLJDCVxb2PKPgStSzE/edit?usp=sharing>

Kirjautu Googleen, jotta voit tallentaa edistymisesi. [Lue lisää](#)

\* Pakollinen kysymys

Reporter initials \*

Timestamp	Reporter initials	Organisation	IUCLID section name	Issue description	Issue	Category	Status	Answer
4/2/2024 11:56:42	PZ	ECHA	4 - Type of product or component	HelpText should be expanded to add the following: "Do not use the "Other" option to apply for the use of the starting substance, composition or constituent as a sacrificial anode, filtering membrane or ion exchange resin. Such products fall outside the scope of Article 11 of the Drinking Water Directive".	8	format change (DWD)	Under investigation	scheduled for April 2025
4/2/2024 12:08:13	PZ	ECHA	DWD Application - Dossier header	The helpText when someone submits an update and needs to confirm that there will not submit further updates needs to change to: "You are required to check this box and by doing so to confirm that this submission is the final submission in relation to the specified communication from ECHA. No further submission will be made, the dossier update functionality will be disabled after this submission and ECHA will start its assessment of this submission".	7	format change (DWD)	Under investigation	scheduled for April 2025

# DWD application & CBI





# CBI in Commission Delegated Regulation 2024/369

- Article 10(2): the following shall be considered confidential and may not be made publicly available:
  - a. **identification of an applicant in case of a designated representative;**
  - b. **manufacturing process** of substance and process of its use;
  - c. **any link between any operators** in the same supply chain
  - d. **information received from another Union body, agency or a Member State**, for which confidentiality has been granted by the body that provided this information to ECHA;
  - e. **an impurity, unless that impurity is a relevant chemical species.**
  
- CBI aspects yet to be addressed fully in the IUCLID format

# Questions and answers



# Next DWD IT tools user group events



# Next DWD user group meetings

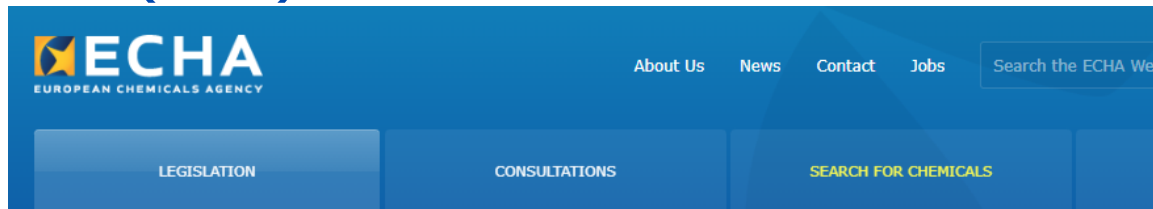


- 14 June 2024 (11:00-12:30 Helsinki time - TBC)
  - Catch-up with the groups progress with trialling and testing the latest IUCLID formats
- Q4 2024 – Meeting to catch-up with testing progress, if necessary
- Q4 2024 – Filtering rules for the DWD application template
- Q4 2024 – First version of the submission tool

**The user group can still accept new members, feel free to encourage relevant organisations/future applicants to join us!**

For any questions on the running of this user group: [ECHA\\_DWD@echa.europa.eu](mailto:ECHA_DWD@echa.europa.eu)

# How to keep up to date ([link](#))



ECHA > Legislation > DWD > Understanding DWD

## DWD

Understanding DWD

European positive lists

Legislation

Support to applicants

[Tools to prepare and submit DWD data](#)

[DWD IT user group](#)

## Understanding the Drinking Water Directive

The Drinking Water Directive (DWD) aims to protect people and the environment from the harmful effects of contaminated drinking water and to improve access to drinking water. It came into force on 12 January 2021 following a review of the original Drinking Water Directive of 1998.

The directive introduces minimum requirements for materials that are in contact with water meant for human consumption throughout the EU. Harmonising these requirements ensures protection of people in the EU and improves the functioning of the internal market.

Article 11 of the revised directive sets out the framework for minimum hygiene requirements for materials in contact with drinking water. This framework was legally adopted by the European Commission as six legal acts, which were published on 23 April 2024.

## Tools to prepare and submit DWD data

ECHA is developing IT tools to help applicants prepare and submit the information needed to initiate the process to update the European positive lists.

Data preparation in IUCLID

The IUCLID (International Uniform Chemi

### KEY DOCUMENTS

- [ECHA account manual](#) [PDF]

### RELATED LINKS

- [IUCLID Website](#)
- [IUCLID 6 release notes](#) [PDF]
- [Terms and conditions for using the Cloud Services](#) [PDF]

## DWD IT user group

The DWD IT user group has been set up by ECHA to help in developing the IT tools authorities will use to prepare and submit DWD dossiers from the end of 2025.

These IT tools include:

- The IUCLID format that ap
- The validation rules that wi information.

Previous or planned meeting	Topic
13 June 2023	Introduction to the IT tools user group [PDF]
15 May 2024	Improved (2024) IUCLID format for DWD Notifications
24 May 2024	Improved (2024) IUCLID format for DWD applications

# Thank you for your participation!

ECHA\_DWD@echa.europa.eu

[echa.europa.eu/subscribe](https://echa.europa.eu/subscribe)



Connect with us



[echa.europa.eu/podcasts](https://echa.europa.eu/podcasts)



European Chemicals Agency



[@one\\_healthenv\\_eu](https://www.instagram.com/one_healthenv_eu)



[@EU\\_ECHA](https://twitter.com/EU_ECHA)



[@EUECHA](https://www.facebook.com/EUECHA)



[EUchemicals](https://www.youtube.com/EUchemicals)