

# Progress with the review of the latest version of the DWD application IUCLID format

DWD IT tools user group

14 June 2024

Dorota Burchard-Sosnowska

Daria Caselius

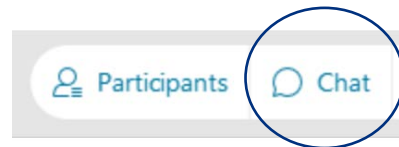
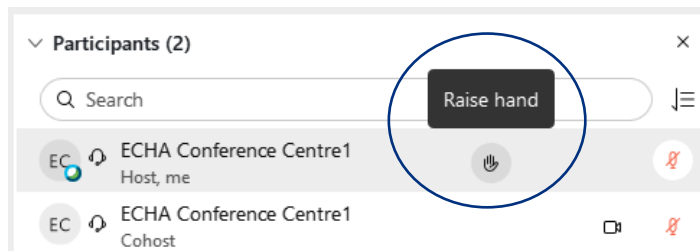
Panos Zarogiannis



# 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

- Initial experience looking at the IUCLID format and questions from members
- IUCLID functionalities
- Reminder: where to test IUCLID and how to report feedback
- Next steps

Initial experience looking at  
the IUCLID format

Questions received from IT  
tools user group members

# Questions on starting substances from members (1)

- 1. Migration from REACH dossier of a monomer with no additional info** (no NIAS/NO technical functions)
  - No alerts
- 2. Compared to REACH = Uses** - Main information on intended use need to be evaluated with multiple departments and customer surveys – too detailed
- 3. Intended use of the notified entry**
  - Organic material subcategory double PVDF
- 4. Type of product or component**
  - Select/deselect all works, No multiple selections, there is no possibility to select more than 1 product/component without closing the window
- 5. Meaning of “Worst case in matrix”** for migration test – based on non-standard parameter
  - Maximum dosage (concentration) in the material?
  - Quantity put into the market or tonnage of the material per year?

# Questions on starting substances from members (2)

## 6. Migration test on intermediates

- NIAS: can be used the migration performed for food contact 10/2011 (worst case extraction in alcohol and acetic acid)?

## 7. Details on migration impurities

- Describe the presence of the NIAS (which might also be a substance constituent) migrating from the material, taking into account at least the following:
  - (a) physico-chemical properties;
  - (b) technical functions;
  - (c) interaction with the matrix;
  - (d) water characteristics;
  - (e) results of analysis of testing waters by applying an appropriate screening method.
- Every block must be repeated for every impurities (there can be 30 impurities in one NIAS report...) upload of one report is sufficient?

## 8. Commission Decision 4.IA is on final product

- Which are the mandatory points for intermediates (plastic – pellets)?

## 9. Composition.001 Attached description/justification

- Importing an PDF is not possible

## 10. Cannot import migration .pdf file

- How to attach analysis reports from laboratory with migration data?

# Questions on alloys from members (1)

1. Reference substances for alloys and their constituents and impurities
2. Will there be a list prepared in IUCLID to select the entry/group entry from (and avoid duplications/different naming/...)?
3. How to use “Legal entity composition” and “Boundary composition” for alloys?
4. How will different grades of the alloy be included in an application?
5. Alloy constituents/impurities will be listed in their metallic form and concentration provided. Are min/max/typical composition all mandatory?

## Questions on alloys from members (2)

6. Are impurities defined as 'unintended' but present constituents (originated from the manufacturing process) or are impurities identified as any constituents that is below a certain concentration %?
7. Analytics: please confirm typical analyses used, e.g. XRD, XRF, ICP
8. CLP mixture effects of constituents & using hazard data from each constituent to develop combined effects assessment for risk assessment calculation



# IUCLID functionalities (Demo)

# IUCLID demo



- Reuse of a data prepared in another working context
  - documents used by both working contexts
  - documents specific to DWD
- Copy data from...
- Dataset for a relevant chemical species
- Import of a dossier to IUCLID
- Extract to dataset

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

# Finalisation of format & validation check feedback

- Feedback on **IUCLID format (NoI)**: End of **August** 2024
- Feedback on **IUCLID format (application)**: End of **August/October** 2024
- Feedback on **Validation checks (NoI)**: End of **June** 2024
  - Target release October 2024
- Feedback on **Validation checks (application)** - end of **Aug** 2024
  - Target release October 2025

# Which DWD application documents are priority to comment on

→ In period May – August 2024:

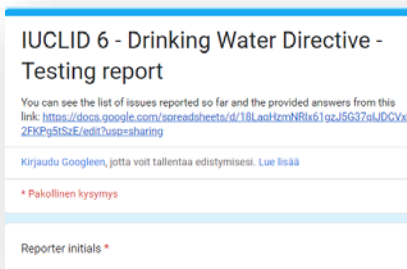
- Identification (1.1)
- Composition (1.2)
- Identifiers (1.3)
- Analytical information (1.4)
- Classification and labelling (2)
- all the documents in section 'Physical and chemical properties' (3)
- all the documents in section 'Toxicological data' (7)
- Analytical methods (6)

→ 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)

# How to provide your feedback

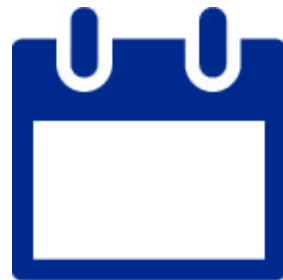
- All the comments, requirements can be submitted via a dedicated [webform](#) and seen in the [spreadsheet](#)
- Please indicate your initials so we could contact you to clarify the requirement
  - Please **do not insert any confidential or personal details**, as your comments will be visible to everyone 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)



Timestamp	Reporter initials	Organization	IUCLID section name	Issue description	Priority	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". 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"	3	format change (DWD)	Under investigation	scheduled for April 2025
4/2/2024 12:08:13	PZ	ECHA	DWD Application - Dossier header		7	format change (DWD)	Under investigation	scheduled for April 2025

Next DWD IT tools user group  
events

# Next DWD user group meetings



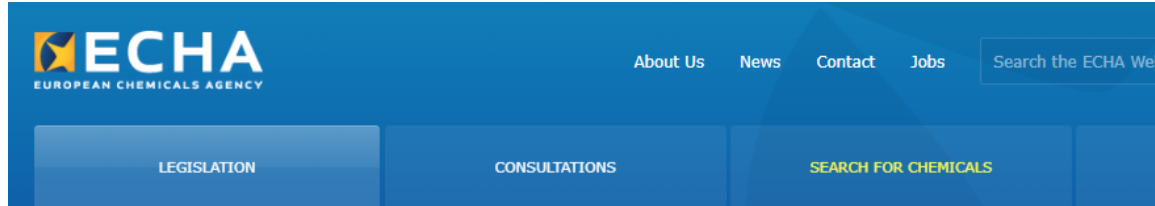
- End Aug- Early Sept 2024 – Meeting to catch-up with testing progress, if feedback from the group is received
- Q4 2024 – Filtering rules for the DWD application template
- Q4 2024 – First version of the submission tool

**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

## 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 Chemicals and Cosmetics Classification) is a standard for chemical safety data sheets (SDS) and is used by ECHA to manage chemical information.

- 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 applicants will use to submit DWD notifications
- The validation rules that will be used to check the 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

## 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.

# 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



@EU\_ECHA



@EUECHA



EUchemicals