

Update on the latest version of the NoI IUCLID format and 2024 work plan

DWD IT tools user group 15 May 2024

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Agenda

- \rightarrow Role and tasks of the IT tools user group
- \rightarrow Update on legal acts & information requirements
- \rightarrow DWD process, end to end solution
- → Update on the DWD NoI IUCLID format & validation rules
- → Demo on DWD NoI IUCLID format & validation
- \rightarrow Where to test IUCLID and how to report feedback
- \rightarrow Notification of intention & CBI
- \rightarrow Questions and answers
- $\xrightarrow{2}$ Next DWD IT tools user group events



Practicalities

- \rightarrow 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

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Role and tasks for the DWD IT tools user group



General objectives

- → Engage the user community in the development of the system
- → Learn from experience and gather improvement ideas
- → Analyse different scenarios
- → Identify the areas where extra attention is needed to provide adequate support/guidance
- → Overall, to provide informal, non-binding technical advice



Share the user group activities with relevant experts within your organisations, **collect feedback** and report this through the user group



Coming tasks

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



Update on legal acts & information requirements



Publication of legal acts in the Official Journal

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

Reminder:

- 2024/365 \rightarrow Information requirements for DWD applications
- 2024/367 \rightarrow First European positive lists for 4 material types
- 2024/369 \rightarrow DWD NoI and application processes



2024/369 – DWD Notification of intention process

→ A notification of intention must be submitted by economic operators before submission of an application

Article 2

Notification of intention

- 1. A potential applicant shall submit to ECHA a notification of its intention to submit within a determined period of time an application for the inclusion of a starting substance, composition or constituent in the European positive lists. Unless the potential applicant is a competent relevant authority for an application justified by urgency, this notification shall be made within 12 months prior to the submission of the application.
- 2. ECHA shall acknowledge receipt of the notification of the intention.
- \rightarrow The legislation does not define the contents of the NoI
- → ECHA's advice on NoI contents is provided in the draft Guidance Volume IV (currently being reviewed by the DWD Guidance user group)

How to keep up to date (link)



DWD

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.

Legislation

Drinking Water Directive

Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 human consumption (recast)

bg cs da de el en es et fi fr hr hu it it iv mt ni pi pt ro sk si sv

European positive lists

Commission Implementing Decision (EU) 2024/367 laying down rules for the a European Parliament and of the Council by establishing the European positive I constituents authorised for use in the manufacture of materials or products tha consumption

bg cs da de el en es et fi fr hr hu it It Iv mt ml pl pt ro sk sl sv

Information requirements and risk assessment methodologies fc

Commission Implementing Decision (EU) 2024/365 laying down rules for the a European Parliament and of the Council as regards methodologies for testing a constituents to be included in the European positive lists

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Procedure for submission of notifications of intention and application

Commission Delegated Regulation (EU) 2024/369 supplementing Directive (EU Council by laying down the procedure regarding inclusion in or removal from the transmission of tra

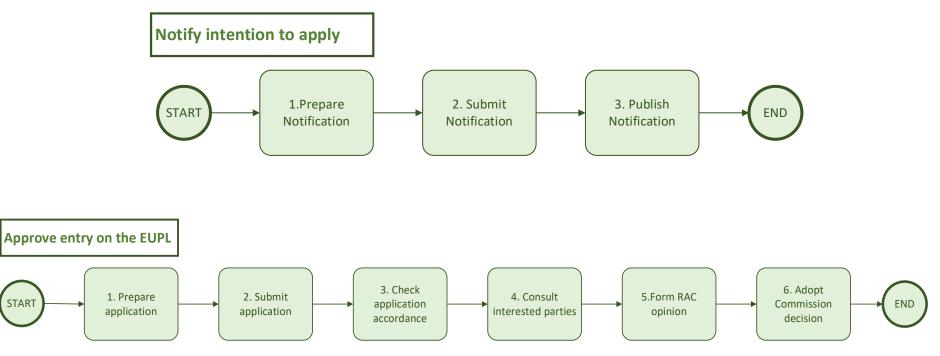




DWD process End to end solution

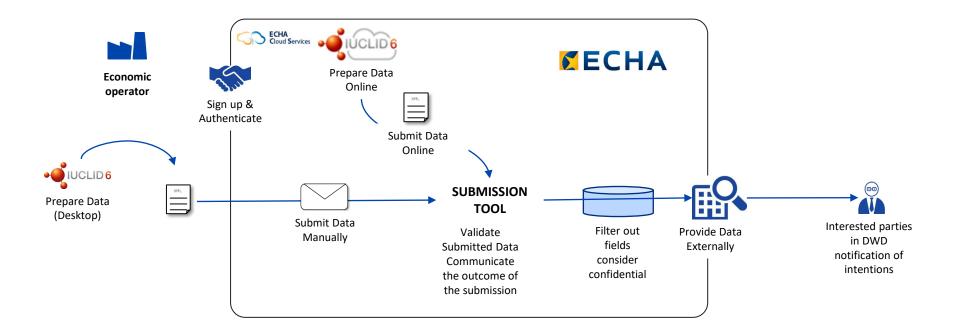


DWD Business process





Notification of intention to apply end to end solution



The applicant will receive a DWD notification number, it is the key to start the DWD application FECH

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Update on DWD NoI IUCLID format & validation rules



IUCLID in the DWD solution

- → IUCLID (International Uniform ChemicaL Information Database) will be used at the first step of the DWD process to prepare:
 - Notification of intention
 - Application
- → Applicants will use both harmonised (with other legislations) and specific DWD documents to insert data
- \rightarrow Validation assistant will be used to check completeness of inserted data
- → Outcome: .i6z file (dossier) containing all required data
- \rightarrow Achieved milestones:
 - May 2023 first version of the DWD IUCLID format released
 - April 2024 Minimum Viable Product



Simplified timeline – major IUCLID releases



Advanced DWD IUCLID prototype



Minimum Vialable Product (MVP) including corrections based on expert feedback and development of the legal framework

April 2025

Version including corrections based on feedback on MVP

version of the format to be used for first notifications of intention (while validation will be completed in October 2025)

- → 05-10.2024 feedback on the DWD IUCLID format (detailed information on dedicated slides)
 - IT Tools User Group involved
- \rightarrow 09-10.2024 consultation of the format change proposals with OECD (OECD, Core, Domain)
- → 11.2024 all approved changes encoded (will appear in IUCLID in April 2025)



DWD Notification of intention

Dossier specific information in the dossier header

- → Type of intended application
- → Material type
- → Is it a group entry? (**EUPL number of the group entry**, scope of the group entry application)
- → Tentative application submission date
- → Remarks
- → Submission is an update → Reason for updating

 Type of intended application Or Or

 new starting substance, composition, or constituent which does not exist in the EUPL

 review of a starting substance, composition, or constituent that is listed in the EUPL

 removal of a starting substance, composition, or constituent that is listed in the EUPL

 removal of a starting substance, composition, or constituent that is listed in the EUPL

 The submission is an update

Reason for updating New data on identification.



DWD Notification of intention

Table of contents

General information Identification Composition Identifiers

2. Intended use of the notified entry

Regulatory programme 0 ^ 0 ^

Drinking Water Directive application number

Drinking Water Directive notification of intention number



IUCLID Validation assistant

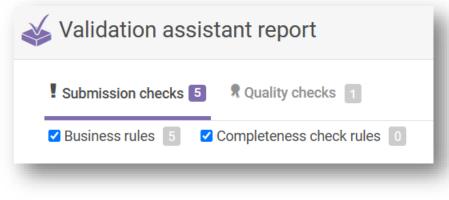
- → Verifies data against the regulation requirements
- → Ensures the data are available and harmonised
- → Assists industry during dossier preparation
- → Validates submitted dossiers at ECHA's side





How does it work in IUCLID

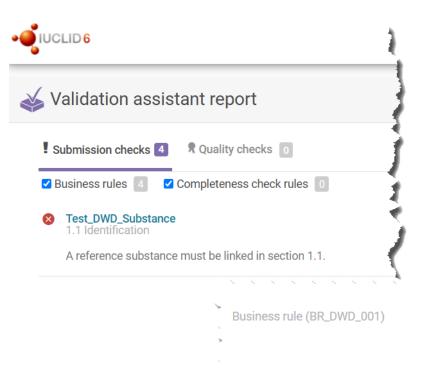
- → The validation is based on a specific **working context**, such as "*DWD Notification of intention"*, "*DWD Application"*
- → The outcome presented in the **Validation assistant** report under the Submission and Quality checks tabs





How does it work in IUCLID

- → The failure message indicates:
 - The location in the dataset/dossier which has an issue
 - The description of the issue and brief instructions on how to fix it
 - Rule ID





Validation checks for NoI

- → 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_007 'Material type' under the Dossier header and Intended Use of the Substance must be aligned



Demo of the latest DWD NoI IUCLID format & validation



IUCLID demo



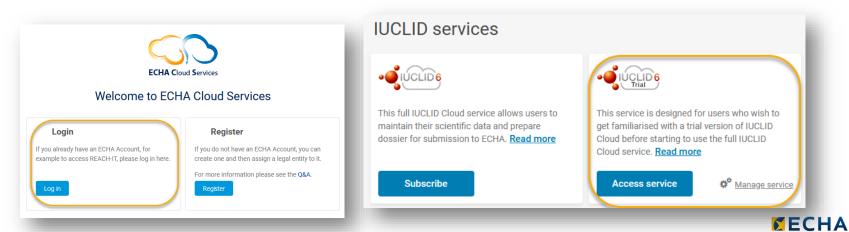
- → DWD Notification of intention
- → Dossier header
- → Table of contents
 - How to create new documents
 - Types of fields
 - Dynamic content rules
- → Validation assisstant
- → Dossier creation



Where and how to test IUCLID and how to report feedback

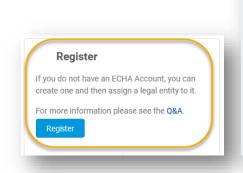
How to login into IUCLID

- → IUCLID instance to be used IUCLID Cloud Trial
- → You can use your own data other participants will not have access to them
- \rightarrow 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 <u>ECHA Cloud Services</u> -<u>Home page (europa.eu)</u> and register
 - login and subscribe to IUCLID 6 Trial

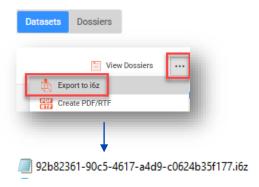


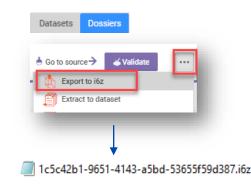
Enter your	r user information and password
First Name	*
l ast Name	
Last Name	*
Email *	
	A .
Username *	
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A user id of you	
A user id of you Phone Password *	
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How to export data

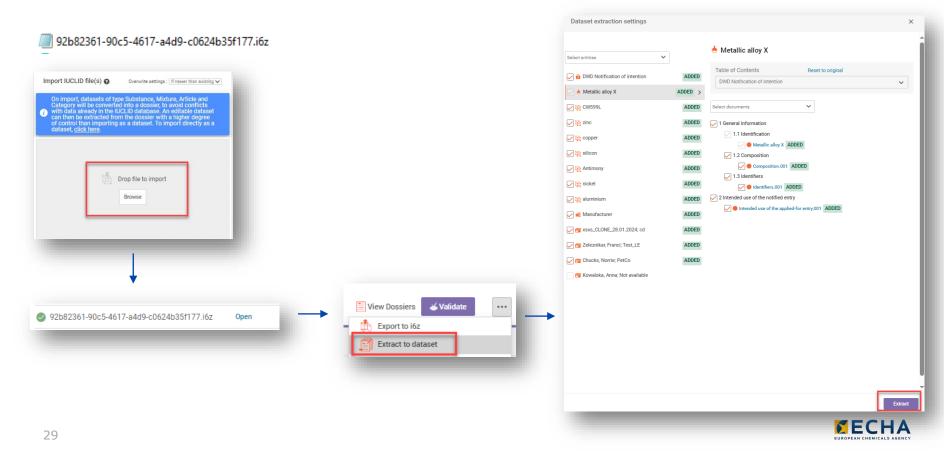
- \rightarrow to back up your data (if a subscription is not used for 3 months, expires)
- \rightarrow to archive it and use later in other IUCLID instances
- \rightarrow to share them with other users







How to import data (and extract to dataset)



Finalisation of NoI format & validation check feedback

- → Feedback on **IUCLID format**: End of **August** 2024
- → Feedback on **Validation checks**: End of **June** 2024
 - Target release October 2024
 - NOTE: If any suggested checks are on documents which are subject to format updates, the proposed changes cannot be implemented for October 2024



How to provide your feedback

- \rightarrow All the comments, requirements can be submitted via a dedicated <u>webform</u> and seen in the <u>spreadsheet</u>
 - 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 <u>e-mail</u>, 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 ☆ @ @ Zapisano na Dysku Plik Edytuj Widok Wstaw Formatuj Dane Narzędzia Rozszerzenia Pomoc	
IUCLID 6 - Drinking Water Directive -	Menu 5 c ⊕ 🚭 100% v \$ % .0, .0, 123 Domy_ v − 10 + Β Ι ⇔ <u>Λ</u> δ. ΕΠ ⊕ v Ε v <u>J</u> v μ × Δ v ∞ ΕΓ ΕΙ V Ε v <u>Σ</u> Ξ v Σ	
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/18LaqHzmNRIx61gzJ5G37qJJDCVxb ZKPQ5f5Zc/edit?uspc=sharing	Re por indi por indi ter organisatio ULLID section ULLID section of issue description of issue of isu	
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How we can support your work

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

Field name

Line

	no.	Field name	Display type	Freetext template	Help text
Intended use Characteristics of the material Material type metallic materials Metallic material category (metallic composition category) @^ @^ copper-zinc aluminium alloys copper-zinc-aluminium-tin alloys copper-zinc-aluminium-tin alloys copper-zinc-aluminium-silicon-iron alloys copper-zinc-arsenic alloys	5.	Metallic material category (metallic composition category)	List sup. (picklist with remarks) Display: Basic	Picklist values: - copper-zinc alloys - copper-zinc-aluminium alloys - copper-zinc-aluminium-fin alloys - copper-zinc-arsenic alloys - copper-zinc-arsenic-aluminium alloys - copper-zinc-arsenic-antimony-aluminium alloys - copper-zinc-arsenic-antimony-aluminium alloys - copper-zinc-arsenic-antimony-aluminium alloys - copper-zinc-arsenic-antimony-aluminium alloys - copper-zinc-arsenic-antimony-aluminium alloys - copper-zinc-arsenic-antimony-aluminium alloys - copper-zinc-silicon-phosphorus-alloys - copper-silicon-zinc-manganese-phosphorus alloys - copper-ini-plad-phosphorus alloys - copper-nickel-manganese-iron alloys - copper alloys not elsewhere categorised - coppers - tinned copper pipes and tinned copper fittings - aluminium - steel/iron - platings - passive compositions	If the metallic composition is a passive one, select the "passive alloys" option. If you are notifying a metallic composition that does not fall under any of the existing metallic composition categories and requires the creation of a new category, select the "new category" option below and identify the constituents and the impurities of the new category, in Section 1.2.

Field type

Dicklin



More information on IUCLID

IUCLID product

IUCLID (International Uniform

maintain and exchange data

application for both regulatory

various regulatory programme

Programme (CoCAP) and the

IUCLID implements the OECC

provide regulatory authorities

common format, facilitating th

Chemicals (REACH).

IUCLID website

Home IUCLID product

IUCLID > IUCLID product

IUCLID format

- Planned releases
- Template manager (ITEM)
- Data validation
- Report generator
- Data filtering
- Public REST API
- Data Uploader
- Data Extractor
- Text Analytics
- QSAR Toolbox integration

	LID <mark>6</mark>	Sign In Search the IUCLID 6 website			
Home	IUCLID product	Download	Support	News	
IUCLID > Support > Documentation					
 Training material Videotutorials Webinars 	Documentation				
 System requirements 	The documentation	concerning the IUCLID format	the report generator and the IU	CLID Public API can	

The documentation concerning the IUCLID format, the report generator and the IUCLID Public API can now be found under 'IUCLID Product'.

User manual

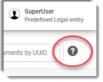
Verification of downloads

The user manual of IUCLID 6 describes the functionality of IUCLID 6 that is accessible via its web interface. There is a link to the manual in the upper right of the web interface, as shown in the image to the right.

When a release of IUCLID is published, it is delivered with its own version of the user manual. Between releases, any additions or corrections that are deemed necessary, are included in the English version published on this page.

Translations of this manual are provided below. Note that the version in English is the original and most recent version, although the content in the translations is still relevant.

bg cs da de el es et fi fr hr hu it It Iv mt nl pl pt ro sk sl sv



iuclid6.echa.europa.eu

More information on IUCLID

IUCLID LinkedIn Group

IUCLID is the essential tool for any organisation or individual that needs to record, store, submit, and exchange data on chemical substances in the format of the OECD Harmonised Templates. Follow IUCLID on LinkedIn in.

access from <u>iuclid6.echa.europa.eu</u>





Notification of intention & CBI



What is considered Confidential Business Information?

- The name and contact details of the notifier if a representative is appointed (Article 3(3) of Regulation 2024/369)
- 2. The concentration ranges (% w/w) of constituents of the notified entry
- 3. The identities and maximum concentrations of impurities (this information is recommended in a metallic composition above 0.02% (w/w))

This approach is subject to review by ECHA and the DWD Guidance user group (draft Guidance Volume IV) during 8-31 May 2024



What information in the NoI will be treated as CBI (I)

Alloy X for IT tools user group demo

Ô ۲ v

Dossier header

 Type at least 3 characters 	×	UUID: 1c5c42b1-9651-4143-a5bd-53655f59d387
		Dossier template Dossier subject Dossier specific information
DWD Notification of intention		Dossier template
📥 Metallic alloy X		Version dwd 2.0
 Y 1 General information 	3	Dossier name (given by user) Alloy X for IT tools user group demo
 1.1 Identification 	1	Submission Type DWD Notification of intention
> 📥 Metallic alloy X		
 1.2 Composition 	1	Dossier subject
> Composition.001		Dossier subject Metallic alloy X CW599L CW599L (Cu10Zn12)
 1.3 Identifiers 	1	Submitting legal entity
Identifiers.001		Dossier submission remark Fictional composition
 2 Intended use of the notified entry 	1	Dossier creation date/time 08/05/2024 16:16
Intended use of the applied-for entry	y.001	
Inherited templates		Dossier specific information
		Type of intended application review of a starting substance, composition, or constituent that is listed in the EUF Material type metallic materials
		Is it a group entry?
		no EUPL Number of the group entry
		Scope of the group entry application
		Tentative application submission date 03/01/2027 00:00



What information in the NoI will be treated as CBI (II)

Alloy X for IT tools user group demo ⇒ View Dossiers 1c5c42b1-9651-4143-a5bd-53655f59d387 • Type at least 3 characters × UUID: 2a042e68-47f7-40a5-87f4-0d4c7646960a Hide empty field **General Information** Constituents Impurities of a metallic composition Characterisation of nanoforms Â DWD Notification of intention General Information Metallic alloy X Name Metallic alloy X 3 1 General information Type of composition legal entity composition of the substance V 1.1 Identification State / form solid: bulk Metallic alloy X * Constituents 1.2 Composition Composition.001 **Reference substance** Concentration range Remarks 1.3 Identifiers \sim 1 http://www.action.com/action/a Remainder of composition 33 - 40 % (w/w) Identifiers.001 2 topper | EC 231-159-6 | 7440-50-8 60 - 67 % (w/w) 2 Intended use of the notified entry ~ Intended use of the applied-for entry.001 Impurities of a metallic composition Inherited templates Reference substance Concentration range Remar 1 t silicon | EC 231-130-8 | 7440-21-3 0 - <= 0.2 % (w/w)2 httimony | EC 231-146-5 | 7440-36-0 0 - <= 0.1 % (w/w)3 hickel | EC 231-111-4 | 7440-02-0 0 - <= 0.15 % (w/w) 4 aluminium | aluminum | EC 231-072-3 | 7429-90-5 0 - <= 0.2 % (w/w)Characterisation of nanoforms Name of nanoform



Next DWD IT tools user group events



Next DWD user group meetings



- → 24 May 2024 (11:00-12:30 Helsinki time)
 - Presentation of the latest IUCLID formats for DWD applications
- \rightarrow 14 June 2024 (11:00-12:30 Helsinki time TBC)?
 - Catch-up with the groups progress with trialling and testing the latest IUCLID formats ?
- \rightarrow Q4 2024 Meeting to catch-up with testing progress, if necessary
- \rightarrow Q4 2024 Filtering rules for the DWD application template
- \rightarrow 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: <u>ECHA_DWD@echa.europa.eu</u>

How to keep yourselves up to date (link)

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

KEY DOCUMENTS

- The IUCLID (International Uniform Chemic
- ECHA account manual [PDF]
- RELATED LINKS
- IUCLID Website
- IUCLID 6 release notes [PDF]
- Terms and conditions for using the Cloud Services [PDF]

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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.

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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.

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 w information.

tap _i itwi	Previous or planned meeting	Торіс			
	13 June 2023	Introduction to the IT tools user group [PDF]			
	15 May 2024	Improved (2024) IUCLID format for DWD Notification			
	24 May 2024	Improved (2024) IUCLID format for DWD application			



Thank you for your participation! ECHA_DWD@echa.europa.eu echa.europa.eu/subscribe

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EUchemicals