



# AP14 – ECHA activities on the safety assessment of drinking water contact materials

EFSA FCM NETWORK – 11<sup>th</sup> Meeting

23 October 2024

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# Contents

- DWD implementing legislation
- Timeline and DWD processes
- Preparation of Guidance documents
- Other developments



# DWD implementing legislation

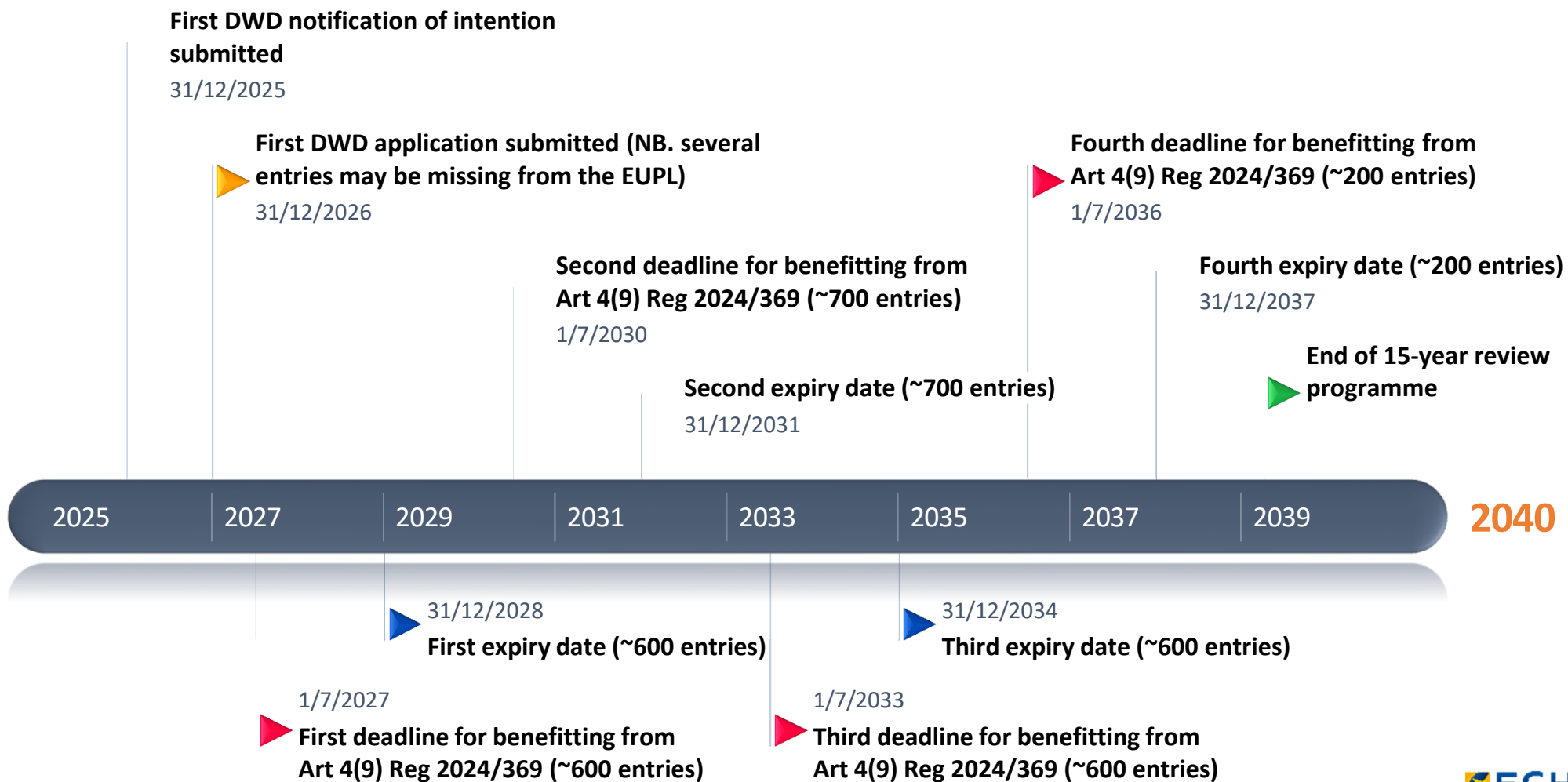
## Publication of legal acts on 23 April 2024

Old acronym	Formal number	Links to published legal acts in the Official Journal
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>

- 2024/365 → Information requirements for DWD applications
- 2024/367 → First European positive lists for the 4 material types
- 2024/369 → DWD Notification of intention and application processes

# Timeline and DWD processes

# Submission timeline (and peak loads)



## Reminder: types of DWD applications

- **New** starting substance, composition or constituent  
DWD applications for new groups of substances are not allowed
- **Review** of a starting substance, composition or constituent:  
Review applications related to a group of substances will end up in the creation of a single-substance entry (with a new EUPL Number)
- **Removal** of a starting substance, composition or constituent

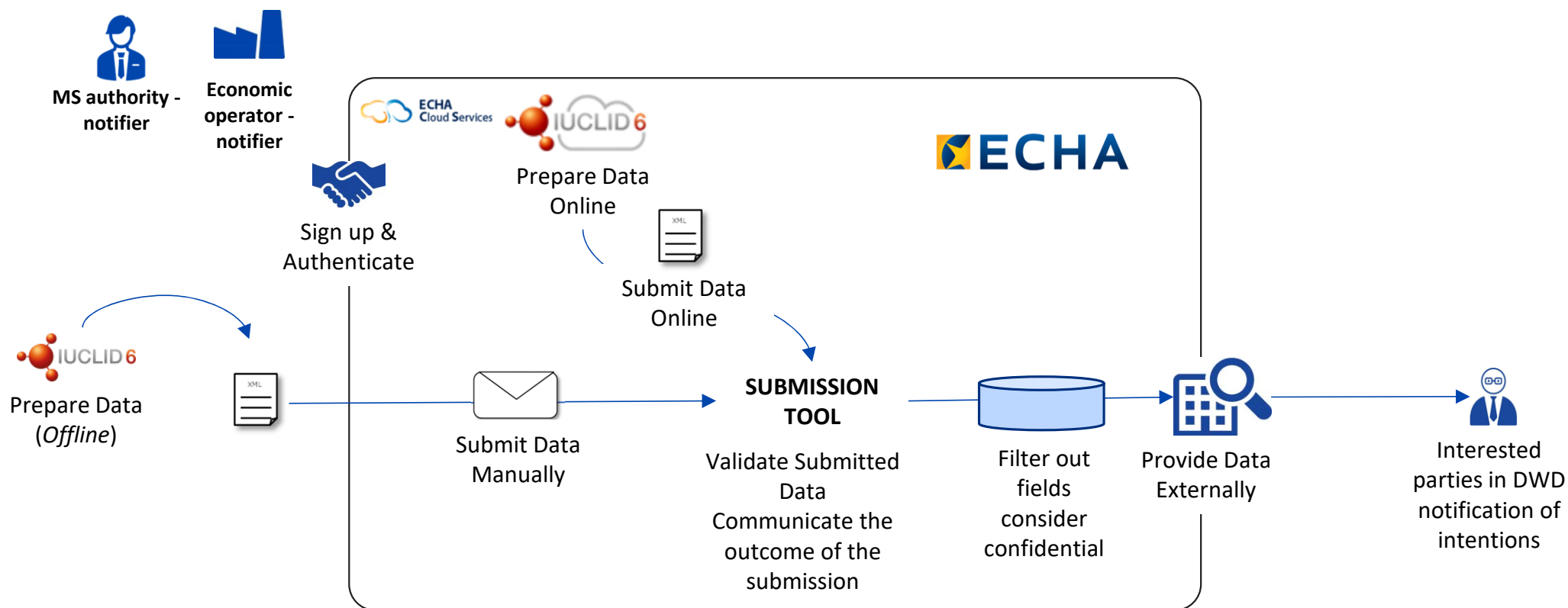
## 2024/369 – DWD Notification of intention process

- A notification of intention **must be submitted** before submission of an application (except by authorities in urgent cases)
- The legislation does not define the contents of the notification of intention → in ECHA Guidance (Volume IV)
- Two categories of information requested
  - Mandatory
  - Recommended (meaning 'optional' but ECHA recommends providing it)

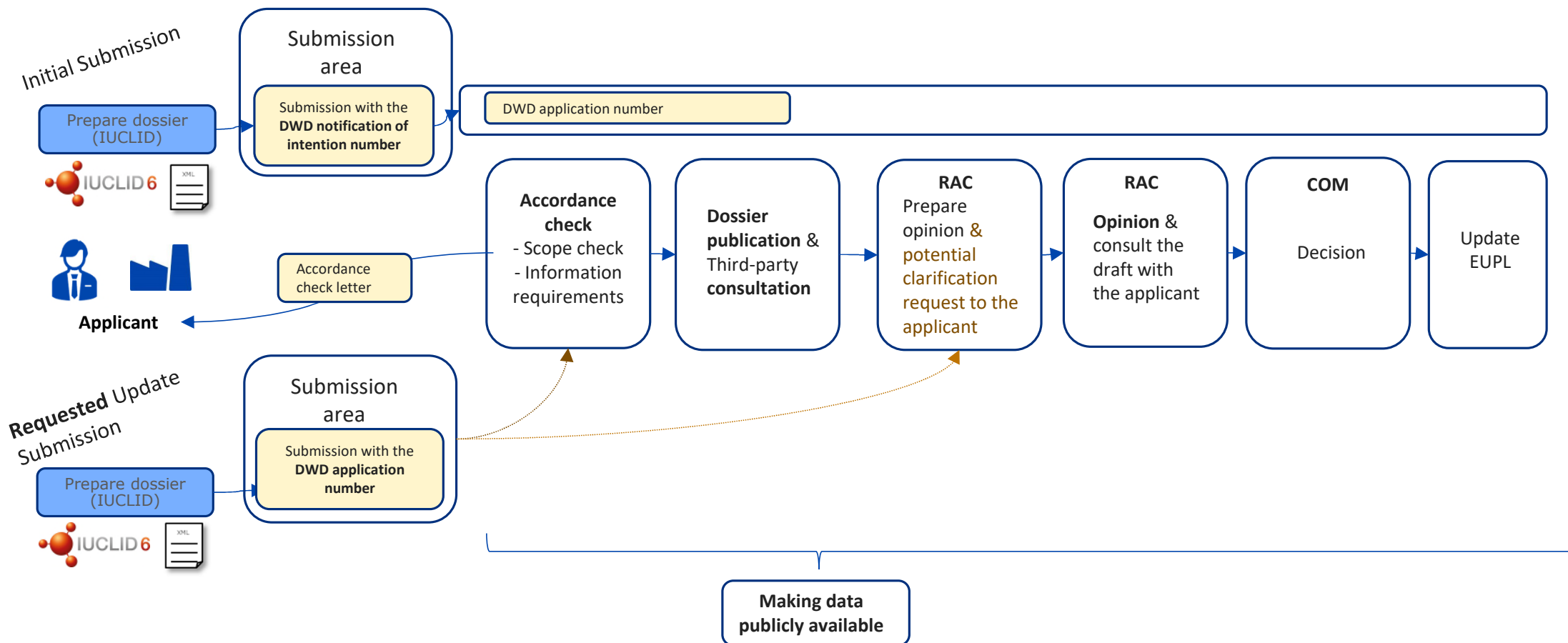
Mandatory information (example for organic materials)	Recommended information (example for organic materials)
<ul style="list-style-type: none"><li>• Type of application (new, renew, removal)</li><li>• Material type</li><li>• Anticipated application submission date</li><li>• EUPL Number if available</li><li>• Name and identifiers (EC, CAS Numbers)</li><li>• Type of notified entry (mono-, multi-constituent, UVCB*, polymer, other)</li><li>• State/form</li><li>• Identities and concentration ranges of constituents</li></ul>	<ul style="list-style-type: none"><li>• Identities of monomers and other reactants</li><li>• Technical function</li></ul>

\*UVCB = Substances of Unknown or Variable composition, Complex reaction products or Biological materials

# Notification of intention to apply end-to-end solution



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



# DWD application in IUCLID

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)**
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
- <sup>11</sup>10. Reports

# DWD application in IUCLID

April  
2024

## 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

# ECHA's DWD Guidance documents

# ECHA's DWD Guidance documents

- 5 volumes of Guidance
  - **Volume I:** How to identify and test the 'applied-for entry' (ca. 180 pages)
  - **Volume II:** How to demonstrate that the risk from the use of the 'applied-for entry' is acceptable (ca. 180 pages)
  - **Volume III:** How to define the scope of an application, how to employ a representative (ca. 40 pages)
  - **Volume IV:** How to prepare a notification of intention (ca. 30 pages)
  - **Volume V** (prepared by the Joint Research Centre (JRC)): How to submit a sample of the 'applied-for entry' to JRC after a positive opinion of RAC (ca. 10 pages)
- In addition – Document summarising test methods to be used for phys-chem properties, migration estimation and hazard assessment

## Focus on toxicokinetics (TK) – ECHA-EFSA collaboration

- Toxicokinetics information requirements for DWD applications under all migration tiers
- For the drafting of the relevant parts of Guidance Volumes I and II ECHA requested expert support
- An informal group on TK was set up very quickly
  - Two members of ECHA's Risk Assessment Committee (RAC)
  - Two members of the RAC DWD Working Group
  - Three EFSA experts
    - Emma di Consiglio
    - Gilles Rivière
    - Laurence Castle
- Worked together in April-September 2024

# Focus on toxicokinetics (TK) – ECHA-EFSA collaboration outcome

- Now guidance distinguishes more clearly the type/amount of information needed for the medium vs high migration tier
- New section “*Data to demonstrate the absence of potential of accumulation in humans*” has been added
  - **Threshold for accumulation in humans based on Log Kow**
  - “[...] *Thresholds for screening substances that do not have the potential to accumulate in mammals, have been set to a log K<sub>ow</sub> < 2 and a log K<sub>oa</sub> > 5 [...]*”
    - Note: **FCM use log Kow < 3** – If an applicant refers to data, available under the FCM for the same relevant chemical species, this information would be evaluated and probably accepted
- Where accumulation is demonstrated, or lack of accumulation potential is not fully demonstrated, it is the responsibility of the applicant to show that any (potential) accumulation will not be associated with toxic effect
  - Additional guidance will be provided on potential consequences in such cases for substances at medium migration tier

# DWD Guidance documents timeline

- Draft guidance documents are being commented by
  - RAC, RAC DWD WG, DWD Guidance user group
    - DWD Guidance user group includes EFSA and experts with FCM expertise
- Last round of comments in:
  - October 2024 for all 5 volumes
  - November 2024 for document on test methods
- Aim to have the guidance documents available in English language published on ECHA website at start of 2025
  - Translation envisaged for the volumes on testing, risk acceptance and notification of intention

# Other developments


## Internal ECHA work on the implementation of DWD

- Extensive work on the IT solution for the DWD
  - DWD is a pilot for important improvements to IT systems used in several regulatory processes
- Development of the accordance check process
  - Accordance check is the assessment of completeness and quality of submitted applications before RAC is involved
- A DWD Working Group of RAC has been established
  - Up to 4 meetings per year
  - Has already looked at past applications to Member States
  - Will work with ECHA in establishing the assessment methodology for DWD applications

## ECHA's DWD user groups

- DWD Guidance user group
  - Informal, non-binding advice to help ECHA make the Guidance fit for purpose
- DWD IT tools user group
  - Informal, non-binding advice to help ECHA develop the IUCLID formats and other IT tools for applicants
- Periodic meetings since 2023
- Tasks are assigned and user groups report back with comments and inputs
- Use groups will continue their work into the future

Updates to DWD pages on ECHA's website ([link](#))



ECHA  
contact  
form

[illegible]

[ECHA](#) > [Legislation](#) > [DWD](#) > [Understanding DWD](#)

## DWD

## Understanding DWD

### European positive lists

## Legislation

- Support to applicants

## Legislation

## Drinking Water Directive

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

[\[a\]](#) [\[b\]](#) [\[c\]](#) [\[d\]](#) [\[e\]](#) [\[f\]](#) [\[g\]](#) [\[h\]](#) [\[i\]](#) [\[j\]](#) [\[k\]](#) [\[l\]](#) [\[m\]](#) [\[n\]](#) [\[o\]](#) [\[p\]](#) [\[q\]](#) [\[r\]](#) [\[s\]](#) [\[t\]](#) [\[u\]](#) [\[v\]](#) [\[w\]](#) [\[x\]](#) [\[y\]](#) [\[z\]](#)

## 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 the consumption

30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50

## Information requirements and risk assessment methodologies for

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

[30](#)
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#### Procedure for submission of notifications of intention and applica

Commission Delegated Regulation (EU) 2024/369 supplementing Directive (EU) 2022/2557 of the European Parliament and of the Council by laying down the procedure regarding inclusion in or removal from the list of entities to which the Directive applies.

## 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.

## Planned events and resources

- Webinar is planned for late November 2024 to present...
  - The DWD application process
  - The first European Positive Lists
  - Information requirements for notifications and applications
  - How ECHA is supporting future applicants
- Hopefully, a larger more interactive event in 2025 after guidance documents are released
- Some helpful links
  - Subscribe to [news](#)
  - Join free [events](#)
  - [ECHA Helpdesk](#)
  - [LinkedIn discussion groups](#)
    - IUCLID

# Thank you

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