ECHA activities on drinking water contact materials

EFSA FCM NETWORK – 8th Meeting

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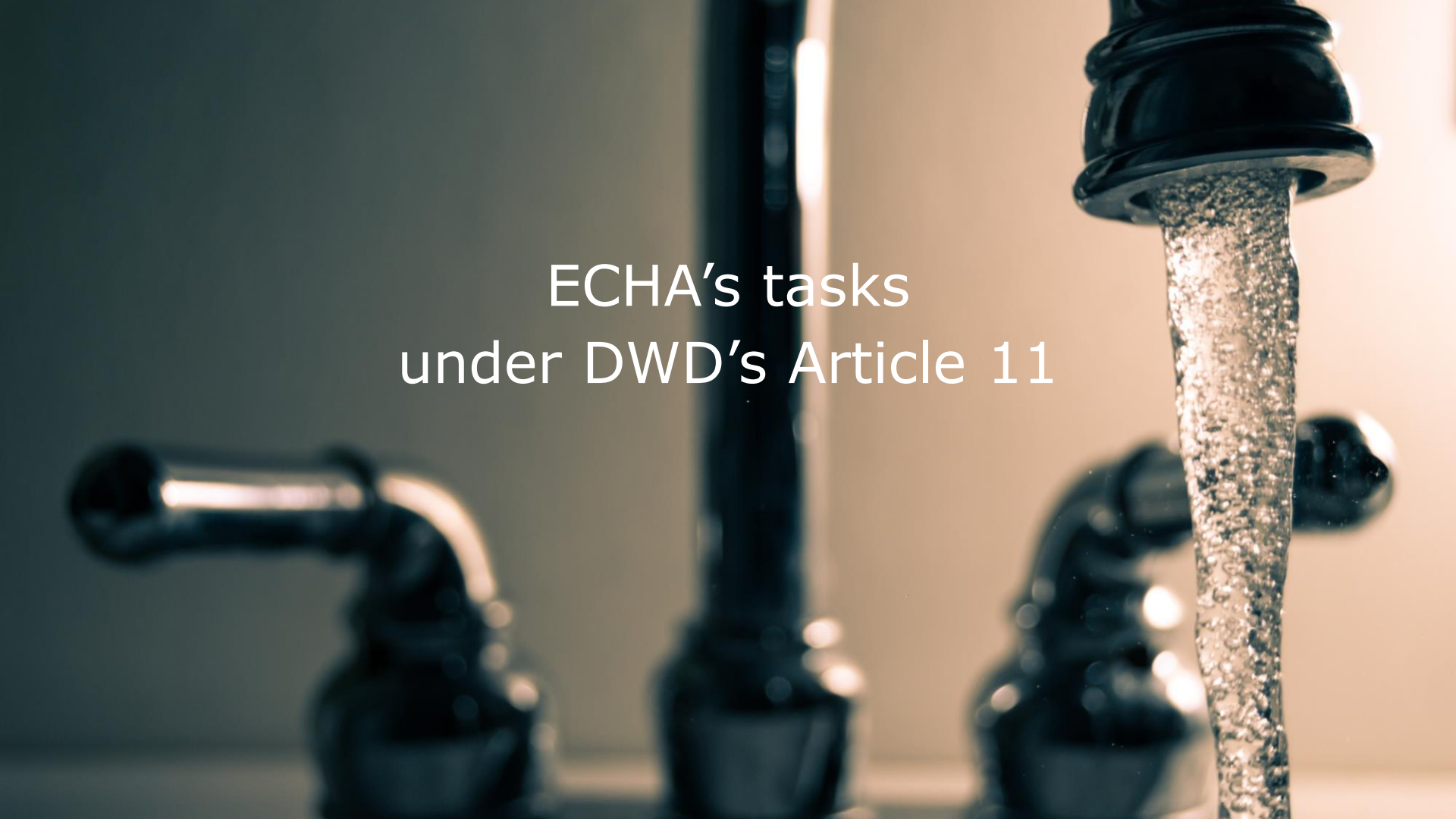
Agenda

1. ECHA’s tasks under DWD’s Article 11
2. The 1st European positive lists for drinking water contact materials
3. Information requirements and DWD application system
4. Timeline



ECHA’s tasks under DWD’s Article 11

DWD and Article 11

→ Directive 2020/2184 a recast of the original Drinking Water Directive (DWD) of 1998

- Came into force on 12 January 2021

→ **Objectives of DWD**: protect citizens and the environment from the harmful effects of contaminated drinking water and to improve access to drinking water

→ **Objectives of Article 11**:

- Minimum hygiene requirements for materials to protect human health
- Better functioning of the internal market

ECHA's tasks under DWD Article 11

2021-2024

- → Creation of the 1st European Positive Lists (EUPL) and prioritisation of their entries
- → Support to DG ENV in drafting implementing legislation prescribed by DWD Article 11
- → Preparation for the DWD review programme
  - Drafting guidance
  - Setting up the DWD application process
  - Setting up IT tools and systems
  - Preparing helpdesk

2025 onwards

- → ECHA maintains the EUPL
  - Receives, validates and processes applications
  - RAC issues opinions
- → Mainly industry and MSCAs submit applications to:
  - Review/renew existing entries
  - Add new entries
  - Remove existing entries
- → ECHA supports applicants


The 1st European positive lists
for drinking water
contact materials

The 1st EU positive lists

→ Four EUPLs:
- Organics, containing starting substances
- Metallics, containing metallic, alloy, plating compositions
- Cementitious, containing organic constituents
- Enamels/Ceramics/other Inorganics, containing compositions

→ EUPLs created on basis of:
- Existing national lists notified to ECHA in 2021
- Plastic FCM list of Regulation (EU) No. 10/2011

Prioritisation of entries in the 1st EU positive lists

- → Review of 1st EUPL in 2025-2040
- → ECHA will propose expiry dates to stagger submissions of review applications
  - Current thinking: 3, 6, 9 and 12 years from 2025 (TBC)
- → Key drivers for assigning expiry dates:
  - Hazard profile (higher hazard → shorter expiry date)
  - Knowledge on hazard (no REACH registration → shorter expiry date)
  - Knowledge on substance identity (unclear ID → shorter expiry date)
  - Availability of a risk assessment (if already assessed by an national authority or EFSA (since 2010) → longer expiry date)

Example: prioritisation of organics positive list

Starting point: origin of entries –
plastic FCM List Reg 10/2011, 4MSI Core & Combined Lists, national lists of DE, FR, NL, IT

Tier 1: REACH registration status

Tier 2: Hazard

Tier 3: Availability and date of Risk Assessment

corrections

Exemptions from REACH registration
REACH Annex IV and V, food ingredients, food additives, food flavourings, Polymers

Alignment with assessments under FCM
EFSA prioritisation of FCMs with no SML

Year	# substances
2028	500
2031	550
2034	450
2037	300

Current status of 1st EU positive lists

Material type	Size of list (approx.)
Organic	**1800**
Cementitious	**380**
Metallic	**70**
Inorganic	**13**

Expiry date	Number of entries up for review (4/2022, approx.)
2028	**600**
2031	**700**
2034	**600**
2037	**400**

Information requirements and DWD application system

What legislation must be drafted?

- → Article 11 requires the adoption of several COM decisions
- → Three COM decisions of relevance to ECHA:
  - **Implementing Act 1.IA**: Methods for testing and accepting starting substances, compositions and constituents on the EUPL
  - **Implementing Act 2.IA**: First EUPLs
  - **Delegated Act 3.DA**: Process for applications submitted to ECHA
- → Roles in the drafting
  - ECHA actively drafts, DG ENV reviews and comments on drafts
  - Upon ECHA-DG ENV agreement, drafts are shared with experts from Member States (Sub-group on Substances – DK, DE, FI, FR, HU, IT, MT, NL, PT, SE, plus DG ENV, JRC, EFSA as observer)
- → But also Guidance documents
  - ECHA drafts, MSCAs and stakeholders to review

Draft Implementing Act 1.IA (1)

→ Describes information requirements and how testing shall be undertaken for reviewing/adding a new entry in a EUPL

→ Information requirements addressed in 1.IA:

1. Substance/composition identity
   - EC/CAS Nos, alloy notations, constituents, NIAS, analytical methods, nanoforms
2. Physico-chemical properties
   - Typical REACH registration phys-chem data
3. Use applied for and migration of substance(s) to drinking water
   - Emphasis on measured data based on EN standards (e.g. EN 12873), conversion factors, analytical methods
4. Microbiological activity
   - Under investigation – only in-can preservatives PT6 to be allowed on EUPL
5. Hazard assessment – based on a FCM-inspired tiered approach
   - Migration-tier based
   - Start from EFSA note of Guidance thresholds, and take 10% default value for drinking water, 2 litres/day by person weighing 60 kg, i.e. MTC_{tap} = SML ÷ 20
6. Risk acceptance

Draft Implementing Act 1.IA (2) – Tox requirements

Low migration below 2.5 µg/l	Medium migration 2.5 - 250 µg/l	High migration above 250 µg/l
A. Mutagenicity in vitro 1. Ames test, TG 471 2. *In vitro* cytogenicity in mammalian cells (Micronucleus test, TG 487). 3. *In vitro* gene mutation study in mammalian cells in case of NEGATIVE results from 1 and 2 (REACH Annex VIII – X) Follow-up positive results: Appropriate *in vivo* studies to be considered **ADME = Absorption, Distribution, Metabolism and Excretion*	**A. Mutagenicity in vitro** Same as for low migration **B. Repeated dose toxicity and evidence that the substance is not bioavailable in humans** 1. 90-day study (TG 408) 2. Information to demonstrate the absence of potential for bioaccumulation in humans 3. Reproductive toxicity screening study (TG 421/422) (REACH Annex VIII – IX)	**A. Mutagenicity in vitro** Same as for low migration **B. Repeated dose toxicity and information on ADME*** 1. Long-term toxicity/ carcinogenicity (TG 453) 2. Relevant information on ADME **C. Toxicity on reproduction** 1. Extended one generation reproductive toxicity study (REACH Annex X) **D. Toxicity on development** 1. PNDT study in one species (REACH Annex IX) and in two species (REACH Annex X)

Draft Implementing Act 1.IA (2) – MTC_{tap} derivation

→ Maximum Tolerable Concentration at the tap = MTC_{tap} = limit value which becomes a condition of authorisation

→ Hazard characterisation steps:

1. Identification of critical effects
2. For effects where a threshold identified:
   - Identification of most relevant dose descriptor (e.g. NOAEL) for systemic threshold effects
   - Application of appropriate assessment factors → Systemic DNEL
   - Calculate MTC_{tap}

$$\mathbf{MTC_{tap}\ (mg/l) = \frac{DNEL\ (mg/kg/d)\ x\ 60\ (kg)}{2\ (l/d)\ x\ 10}}$$

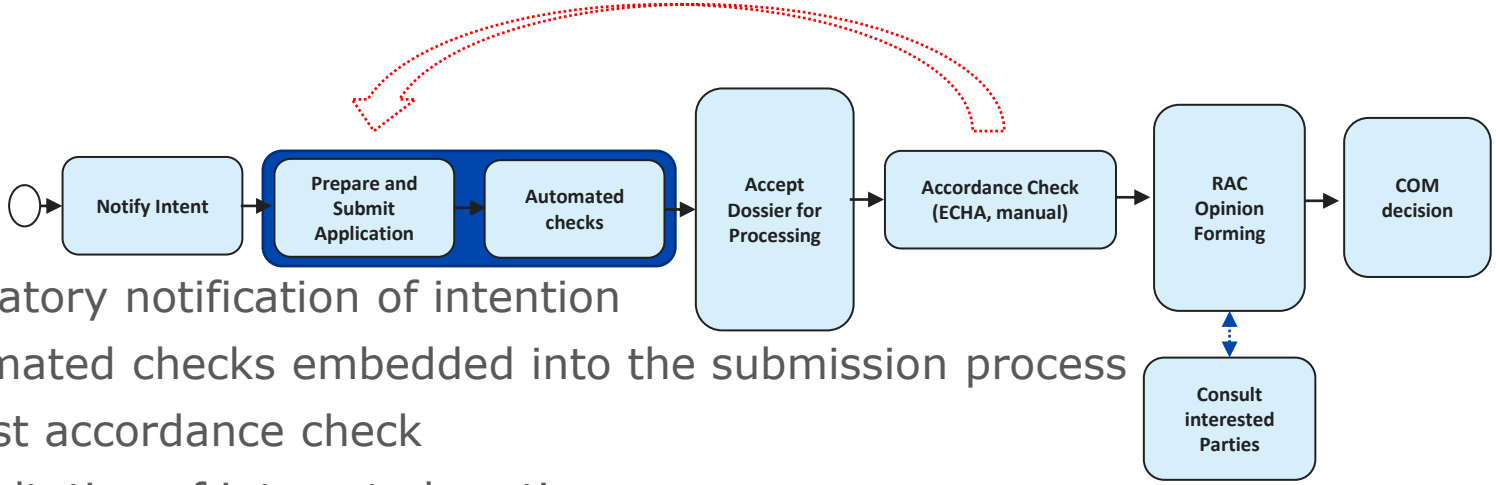
3. For effects where a threshold is not identified:
   - MTC_{tap} of 0.1 µg/L must be applied

Draft Implementing Act 2.IA

- → Presents the EUPLs per material type with all entries with their expiry dates and any derogations
- → Parts of each EUPL table:
  1. SID (EC/CAS No, name)
  2. Approved use(s) in drinking water contact materials (incl. material category, e.g. "*rubber*")
  3. Generic technical function, e.g. "*additive*", "*polymer production aid*"
  4. MTC_{tap}
  5. Conditions of use (including any restrictions)
  6. Expiry date
- → Additional conditions for certain substances, transitional arrangements, derogations (cf. FCM Reg No. 10/2011)

Draft Delegated Act 3.DA (1)

→ Describes how an application for adding/renewing/ removing an entry can be submitted to ECHA



→ Mandatory notification of intention

→ Automated checks embedded into the submission process

→ Robust accordance check

→ Consultation of interested parties

→ RAC opinion making, incl. consultation with applicant on draft opinion

→ Obligation on applicant to provide additional information upon request

Draft Delegated Act 3.DA (2)

- → Inspiration and lessons learnt from REACH Authorisation, harmonised classification (CLP) and biocides (BPR)
- → Fully IT-based process – Dossiers will be prepared in IUCLID
- → Process requires flexibility to cope with high expected workload
- → Emphasis on transparency – ECHA to publish:
  - Notification of intention & date of submission of an application
  - Applications that pass the accordance check, for consultation
  - RAC opinion
  - Notice of withdrawal of application

Timeline

Timeline

Event or task	Deadline
Entry of directive into force	12/01/2021 ✓
Deadline for submission of national positive lists & accompanying information to ECHA	12/07/2021 ✓
Adoption of methodologies for testing & accepting substances to the EUPLs (Art 11(2)(a)) **- Implementing Act 1 – 1.IA**	12/01/2024
Adoption of first EU positive lists with expiry dates (Art 11(2)(b)) - **Implementing Act 2 – 2.IA**	12/01/2025
Adoption of procedure for applications and proposals submitted to ECHA (Art 11(5)) - **Delegated Act 3 – 3.DA**	12/01/2024 (NB. not specified in the DWD)

Thank you

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