

Kortfattet oversigt over retsakterne

Retsakt 1: Alle stoffer, der anvendes til fremstilling af materialer og produkter, skal som udgangspunkt være testet og vurderet i forhold til sundhed, før de må anvendes. Retsakten fastsætter metoder for test og accept af sådanne stoffer.

Retsakt 2: Stoffer, som må anvendes til fremstilling af materialer og produkter, vil fremgå af EU Positiv Listerne. ECHA (Det Europæiske Kemikalieagentur) skal vedligeholde positivlisterne. Retsakt 2 fastsætter dannelsen af EU Positiv Listerne.

Retsakt 3: Retsakten fastsætter procedurer og regler for optagelse af nye stoffer på EU Positiv Listerne eller fjernelse af stoffer fra listerne.

Retsakt 4: De færdigproducerede materialer og produkter skal på samme vis underlægges test og sundhedsmæssig vurdering i forhold til afsmitning til drikkevandet. Retsakten fastsætter procedurer og metoder for test og accept af de færdige produkter.

Retsakt 5: Producenter bliver underlagt en kontrolordning, som skal sikre, at materialer og produkter lever op til drikkevandsdirektivets krav ved efterlevelse af retsakterne. Dette sikres via audit af en uvildig tredje part (certificeringsenhed), og som dokumentation overensstemmelseserklæringer (certifikater). Retsakten fastsætter regler for denne ordning.

Retsakt 6: Retsakten fastsætter regler for mærkning af produkter der er godkendt til drikkevand efter drikkevandsdirektivets artikel 11.

På de følgende sider findes DANVAs høringssvar til de enkelte retsakter.

Act 1 (Methodologies for testing/accepting substances, compositions & constituents in European positive lists)

DANVA, the Danish Water and Wastewater Association represents approximately 100 municipal drinking and wastewater companies. Member companies provide highly efficient drinking water supply, wastewater treatment, nutrients recovery, energy production and climate change adaptation. Drinking water of high quality exclusively extracted from groundwater.

Inorganic constituents of cementitious materials are not regulated in the acts. Since the concrete industries are rapidly changing and are looking for alternatives to Portland cement clinker as binder for concrete there is need for a regulation of alternative binders such as slag, fly ash, silica fume, volcanic ashes and others. The regulation of materials in contact with drinking water should include inorganic constituents of cementitious materials.

In Annex V, Section 1. *No standard information or testing*, it could be useful to add to the list of cases when no standard information or testing is required for substances for which EFSA has published a scientifically based opinion on tolerable daily intake.

The principle, described in Annex V, section 1, "the higher the migration, the greater the amount of data required" should be substituted by the precautionary principle and an approach like the Threshold of Toxicological Concern, TTC, recommended by EFSA. If $C_{tap} < 2.5 \text{ microg/L}$ and the toxicity of the substance is high, the first approach could not guarantee that the data generated to fulfil the information requirements are adequate for risk assessment. See EFSA Guidance <https://doi.org/10.2903/j.efsa.2019.5708>

In Tables 1 to 3 in Annex V, section 2, migration concentration limits are defined at $2,5 \text{ }\mu\text{g/L}$ and $250 \text{ }\mu\text{g/L}$. It should be clarified how these limits were defined.

The migration concentration cannot define the toxicological properties to be provided, as some substances can have toxicological effects others than mutagenicity and genotoxicity at concentrations lower than $2,5 \text{ }\mu\text{g/L}$. All substances should be evaluated according to their toxicological properties and their migration concentration limit should be defined according to their toxicity.

Act 2 (Establishing the European positive lists of starting substances, compositions, and constituents)

DANVA, the Danish Water and Wastewater Association represents approximately 100 municipal drinking and wastewater companies. Member companies provide highly efficient drinking water supply, wastewater treatment, nutrients recovery, energy production and climate change adaptation.

DANVA supports the full ban of all PFAS uses, including all PFAS starting substances in Annex I Table 1 of the Annexes of Act 2. There are at least 14 PFAS in the EUPL list. Some compounds (for example EUPL 0757, 0752 in Annex I Table 1 of the Annexes of Act2) have these characteristics: “technical function is not monomer” and “not having a harmonized classification under REACH- No data available”.

The TOTAL PFAS parametric value under DWD is 500 ng/L. For the interim period before total ban of PFAS, it must be noted that accepted migration can't cause exceedance of the parametric value in drinking water. The Draft Act 4 Annexes Annex I. 2.2.3 *Acceptance of starting substances* allows migration up to 100 ng/L at the consumer's tap, which is too much to comply with e.g. the PFAS requirement in drinking water.

Unless and until a full ban is in place, per- and polyfluoroalkyl substances should be systematically tested due to their widespread dissemination in the environment, since PFAS's are a major issue in EU and should be considered as an obliged migration parameter to be tested.

Reference: OECD New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs) [consulted 21/10/2023] <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/>

Recital 1 states that “Sacrificial anodes, membranes and ions exchange resins are water treatment chemicals and/or filter media and are covered by Article 12, therefore they are excluded of the scope of Article 11”. Membranes and ion exchange resins should not be considered as treatment chemicals and/or filter media. These materials are produced by polymerisation processes including monomers and other additives. Moreover, updated EN-standards to test membranes (EN 12873-4:2021) and ion exchange resins (EN 12873-3:2019) as products intended for use in contact with drinking water are available. Therefore membranes and ion exchange resins should not be excluded from the scope of article 11. The restriction should be deleted, and membranes and ion exchange resins should be included in the scope of all delegated Acts on materials in contact with drinking water.

In Recital 3 it should be clarified how the Member States should provide the information needed to determine the allocation factor.

Article 3 Water services are continuously buying materials from the market often with contracts spanning several years and use the resulting stocks for many more. Materials purchased before the date of entry into force of this Act (31 December 2026) may be used after the end of the transition period (31 December 2030), so that existing stocks of materials and spare parts constituted before 31 December 2026 do not have to go to waste after 2030.

All substances should first be assessed according to REACH and CLP legislations before the first publication of the positive lists. For example, tetrafluoroethylene is categorized as Carcinogenic 1B according to the REACH regulation 1907/2006.

Considering the world wide challenges with PFAS we propose all PFAS substances to be removed from the positive list before it enters into force. In general, any substance with a significant health danger should be removed from this list before its first publication.

We observe, that some PFAS (e.g. EUPL 222) currently on the list, do not have the same Maximum Tolerable Concentration as other substances of the perfluoro- and polyfluorocarbon group. If the substances are kept on the list, all PFAS should be considered as a group of chemicals where all individual substances must be considered equally. Next all PFAS should also be assessed in priority prior to the publishing of the positive list.

Act 3 (Adding or removing starting substances, compositions or constituents from the European positive lists)

DANVA, the Danish Water and Wastewater Association represents approximately 100 municipal drinking and wastewater companies. Member companies provide highly efficient drinking water supply, wastewater treatment, nutrients recovery, energy production and climate change adaption. Drinking water of high quality exclusively extracted from groundwater.

The introductions point (8) states that “Sacrificial anodes, membranes and ions exchange resins are water treatment chemicals and/or filter media and are covered by Article 12, therefore they are excluded of the scope of Article 11”.

Membranes and ion exchange resins should not be considered as treatment chemicals and/or filter media. Membranes and resins are produced by polymerisation processes including monomers and other additives. Moreover, updated EN-standards to test membranes (EN 12873-4:2021) and ion exchange resins (EN 12873-3:2019) as products intended for use in contact with drinking water are available.

DANVA considers that membranes and ion exchange resins evidently fall under the scope of article 11. To avoid misunderstandings the following phrasing could be used: “Membranes and ion exchange resins are produced by polymerisation processes including monomers and other additives therefore they are in the scope of Article 11.”

Act 4 (Procedure and methodologies for testing and accepting final materials)

DANVA, the Danish Water and Wastewater Association represents approximately 100 municipal drinking and wastewater companies. Member companies provide highly efficient drinking water supply and wastewater treatment and climate change adaption. Drinking water of high quality exclusively extracted from groundwater.

The cut-off values in Anx I, §2.2.1 should be removed. All substances intentionally added in a product should be declared without thresholds.

Anx I, §2.2.3.b and Anx III, §2.2.3.b: Starting substances that are not on the positive list should not be allowed in organic materials or cementitious materials, even if their migration rate is not exceeding 0,1 µg/L and these are not classified according to REACH and CLP regulations.

Anx I, §2.2.4 Tables 2 & 3: LOD (Limit Of Detection) should be changed to LOQ (Limit Of Quantification)

Anx I, §2.2.4 Tables 3 & 4: The large difference of MTC_{tap} between primary aromatic amines and secondary amines is not justified, some of the secondary amines are also aromatic and can lead to nitrosamines. The lower of the two MTC_{tap} should be retained. The LOQ for nitrosamines should be lowered to 10ng/L, in line with drinking water parametric values in some Member States.

Anx I, Sec. 3: As a general comment, the year of publication of an EN standard should not be mentioned as these standards could be revised in the future. A comment like *most recent published version* could be added instead.

Anx I, Sec. 4 Table 6: According to the Precautionary Principle, it is advised to set the MTC_{tap} at 0,1 µg/L. Act 1 states that "*The acceptance methodology should be based on a reasonable worst-case risk assessment of each relevant substance*". An approach such as the Threshold of Toxicological Concern recommended by EFSA should be used. This applies to both identified substances without a known MTC_{tap} and unidentified substances. For the sum of unidentified substance, it is advised to set the MTC_{tap} at 0,5 µg/L.

Anx I, §4.2.4 and Anx III, §4.2.4: The pass/fail criteria for TOC should reflect the different water sources and practices across Europe. The TOC should be stricter than proposed. In Denmark the criterion for cold water is set at $C_n \leq 0.3$ mg/l and $M_n \leq 0,01$ mg/dm²day for the 3rd migration period or for the 9th migration period. Measured TOC from successive migration periods shall show a falling trend from 3rd to 9th migration period. For other products than pipes $C_n \leq 1.5$ mg/l and $M_n \leq 0,15$ mg/dm²day. A long range of products can meet these requirements check www.dk-vand.org

Anx I, §4.3.1 and Anx III, §4.3.1: The pass/fail criteria for TON and TFN should reflect the different water sources and practices across Europe. These criteria should be stricter than proposed. In Denmark the criteria are set at = 1.0 for the 3rd migration period or for the 9th migration period for all pipes and other products. Check www.dk-vand.org

Anx II, Sec. 3 : The reference to the dynamic rig test method described in EN 15664-1 should be included, as it is in Act 1.

Anx III, General comment: Fly ash can be added to concrete for cementitious materials and up to 5% residual carbon is allowed in fly ash. The amount of unspecified organic substances that are unintentionally added to concrete with fly ash could be as high as the addition of intentional added substances that are on the positive list. Therefore fly ash should be considered to be an organic constituent of cementitious materials.

Anx III: In §3.1 there should be a reference to EN 14944-1 and 14944-3.

Anx III: In §3.2.2 there should be a reference to EN 15768.

Anx III : In §3.2.3 there should be references to EN standards for TOC, Odour, Flavour, Colour, Turbidity, similarly to organic materials.

Anx III, In §3.3 there should be reference to CEN/TR 16364.

Anx IV, §3.2.4: Testing with both chlorinated and non-chlorinated water should not be restricted to PAH analysis. Chlorination levels vary widely between operators regardless of the materials used.

Act 5 (Conformity assessment procedure for products that come into contact with drinking water)

Der afgives ikke høringssvar til denne retsakt, da den omhandler procedurer for afgivelse af overensstemmelseserklæringer, og at man i EurEau-regi blev enige om, at vandforsyningsbranchen er en sekundær interessant til denne retsakt.

Act 6 (Marking of products in contact with drinking water)

DANVA, the Danish Water and Wastewater Association represents approximately 100 municipal drinking and wastewater companies. Member companies provide highly efficient drinking water supply, wastewater treatment, nutrients recovery, energy production and climate change adaption. Drinking water of high quality exclusively extracted from groundwater.

The proposed symbol seems unpractical to affix to many types of products. The symbol consists of three picture elements, the twelve stars, the tap and the glass. A simpler symbol, for example just the glass will just as effectively show that a product is suitable for drinking water.

The marking does not refer to the drinking water directive. "Suitable for drinking water" doesn't indicate the reference or justification. The text could be replaced with a reference to the drinking water directive. If the text is replaced with a reference to the drinking water directive, no translation will be needed.

Symbol shall be at least 5 mm high unless technical reasons do not allow it. Who decides if technical reasons do not allow the symbol to be at least 5 mm high? If it is left to the manufacturer, different manufacturers can make different decisions for similar products.

Text should have the same allowance to be reduced in size as the symbol.