

Akt :1 Metoder för testning och godkännande av utgångsämnena, sammansättningar och beståndsdelar som ska föras upp på europeiska positivlistor

EurEau:s synpunkter:

Annex I – Introduction – Definitions

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.

Annex II – Table - 2.5.2 Composition of metallic materials

The manufacturing process should be taken into account on a relevant level of details. The manufacturing process is not always the same even when the composition of the metallic material is the same.

Annex V - Section 1 - No standard information or testing

Add substances for which EFSA has published a scientifically based opinion on tolerable daily intake to the list of cases when no standard information or testing is required.

Annex V – Section 2 – Part 1 - §1.4

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

Annex V - Section 2 – Part 1 – Tables 1 to 3

In tables 1 to 3, migration concentration limits are defined at 2,5 µg/L and 250 µg/L. It should be clarified how these limits were defined.

Some substances can have toxicological effects others than mutagenicity and genotoxicity at concentrations lower than 2,5 µg/L. PFAS are a good example of immunotoxic compounds with a low migration concentration from materials, certainly below 250 ng/L. The migration concentration cannot define the toxicological properties to be provided. All substances should be evaluated according to the same toxicological properties and their migration concentration limit should be defined according to their toxicity.

Annex VI – Section 1 - §3

The draft ECHA guidance document on the drinking water directive (Guidance on the Drinking Water Directive. Volume I: Methodologies for testing starting substances, compositions and constituents for use in the manufacture of materials or products in contact with water intended for human consumption. Draft Version 1.1) requires Mutagenicity studies, not Genotoxicity studies. Table 4 (p78) in Chapter 6.3 of this document mentions **Mutagenicity studies** in case of Low migration tier $C_{tap} < 2.5$ µg/l. But point 2.4.1 says "If the $C_{tap} < 2,5$ µg/l and screening **genotoxicity tests** are negative: $MT_{C_{tap}} = 2,5$ µg/l".

Annex VI – Section 2 – Part 2 - § 2.4.2

Technical detail to be corrected: The ALF factor should be set at 0,1, similarly to Chapter I.4 in Annex 6, where a specific migration limit divided by 20 shall be used ($0,1/2 = 1/20$)

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https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13894-Drinking-water-methodologies-for-testing-accepting-substances-compositions-constituents-in-European-positive-lists_en

Synpunkter ska lämnas senast 2023-11-16

Akt 2: Europeiska positivlistor över utgångsämnena, sammansättningar eller beståndsdelar för varje grupp av material, närmare bestämt organiska material, cementbaserade material, metalliska material, emaljer och keramiska eller andra oorganiska material, som är godkända för att användas vid tillverkning av material eller produkter i kontakt med dricksvatten

EurEau:s synpunkter:

General comment

EurEau 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:

1. technical function is not monomer
2. 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, which 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 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

The Recital 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, membranes and ion exchange resins should not be excluded from the scope of article 11. This restriction should be deleted and membranes and ion exchange resins should be included in the scope of all these Acts.

Recital 3

It should be clarified how the Member States should provide the information that is needed to determine the allocation factor.

Annex 1 – Table 1

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.

All PFAS should also be assessed in priority before the positive lists will be published. A full ban of PFAS should be applied (at least for EUPL numbers: 0329, 0359, 0403, 0723, 0729, 0730, 0751, 0752, 0754, 0757, 0767, 0775, 0819, 0963 corresponding to the CAS numbers 1187-93-5, 1623-05-8, 3825-26-1, 329238-24-6, 51798-33-5, 13252-13-6, 958445-44-8, 37486-69-4, 908020-52-0, 19430-93-4, 1190931-27-1, 1547-26-8, 27619-97-2, 9002-84-0)

The drinking water Total PFAS parametric value at 500 ng/L should be considered too.

Substances with a significant health danger should be removed from this list before its first publication.

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https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13896-Drinking-water-establishing-the-European-positive-lists-of-starting-substances-compositions-and-constituents_en

Synpunkter ska lämnas senast 2023-11-16

Akt 3: Förfarande, inbegripet informationskrav, för ansökningsprocessen för att lägga till eller ta bort ämnen från de europeiska positivlistorna.

EurEau:s synpunkter:

Recital 8

Recital (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 ion exchange 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.

EurEau 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.”

Recital 4

It is stated that the Commission should be empowered to request the Agency to prepare and submit an application. It is not clear what process will initiate a request from the Commission to the Agency and does it mean that a national public authority cannot submit an application ?

Chapter III – Article 3 - §6

The text should specify whether a competent authority can ask for an application covering several starting substances, compositions, organic constituents, nanoforms or entries.

Chapter III – Article 6

Who constitutes “interested parties” should be specified.

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https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13712-Drinking-water-Adding-or-removing-starting-substances-compositions-or-constituents-from-the-European-positive-lists_en

Synpunkter ska lämnas senast 2023-11-13

Akt 4: Metoder för testning och godkännande av de slutmaterial som används i produkter i kontakt med dricksvatten.

EurEau:s synpunkter

Article 2 – Definitions

- Def. 16: It should be clear that “all substances” includes organic substances not on the positive lists, due to they are not expected to be present in the drinking water at levels exceeding 0,1 µg/l and inorganic constituents in cementitious materials.
- Def. 18: Microbial growth is not limited to organic and cementitious materials, it could be extended to other materials as well. Therefore, the definition should not include the type of material

Annex I - §2.2.3.b and Annex 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.
- These provisions are loopholes that will reduce the confidence that drinking water suppliers can have in the regulation based on article 11. There is a contradiction between article 11 and annex V of the DWD. Article 11, 4. says that “The European positive lists shall contain the only starting substances, compositions or constituents that are authorised for use as referred to in point (b) of the first

subparagraph of paragraph 2.” The possibility to use other substances than those on the positive lists is introduced in the annex but is excluded in the main text.

Annex III

- 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.

Annex I – §2.2.1

- Values of 0,02% for RG1, 0,05% for RG2 and 0,1% for RG3 should be removed. All substances intentionally added in a product should be declared without thresholds.

Annex I – §2.2.4 Tables 2 & 3

- LOD (Limit Of Detection) should be changed to LOQ (Limit Of Quantification)

Annex 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 these secondary amines are also aromatic. Moreover, secondary amines can lead to nitrosamines especially in case monochloramine is used as disinfectant. 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.

Annex I – Chapter 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, or the year of publication could be mentioned with the added comment that a most recent published version could be used too.

Annex I – Chapter 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.

Annex I – Chapter 4 – §4.3.1 and Annex III – §4.3.1

- The pass/fail criteria for TON, TFN is set at ≤ 8.0 for the 3rd migration period or for the 9th migration period. This criteria is less severe than the one used by some Member States, such as in Denmark where the criteria is set at = 1.0 for the 3rd migration period or for the 9th migration period.

Annex II – Chapter 3 - §3 & 4.2

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

Annex III – Chapter 3 - §3.1

- The testing conditions should refer to EN 14944-1 and 14944-3 for experimental conditions

Annex III – Chapter 3 - §3.2.2

- Refer to EN 15768, similarly to organic materials.

Annex III – Chapter 3 - §3.2.3

- Refer to EN standards for TOC, Odour, Flavour, Colour, Turbidity, similarly to organic materials.

Annex III – Chapter 3 - §3.3

- Refer to CEN/TR 16364, similarly to organic materials

Annex IV – Chapter 3 - §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.

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Synpunkter ska lämnas senast 2023-11-16

Akt 5: Förfarande för bedömning av överensstämmelse som ska vara tillämpligt på produkter som omfattas artikel 11.

EurEau:s synpunkter

Akt 5 som gäller krav de organisationer som ska granska att produkter och material uppfyller dricksvattendirektivets krav har inte granskats av arbetsgruppen. Vi valde att prioritera bort denna akt för att hinna med de övriga nio dokumenten.

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https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13895-Drinking-water-conformity-assessment-procedure-for-products-that-come-into-contact-with-drinking-water_en

Synpunkter ska lämnas senast 2023-11-16

Akt 6: Märkning som ska användas för att ange att produkter i kontakt med dricksvatten uppfyller kraven i artikel 11.

EurEau:s synpunkter

Article 2.

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.

Annex - §1

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.

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https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13713-Drinking-water-Marking-of-products-in-contact-with-drinking-water_en

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