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Subject:	Proposal for a Directive of the European Parliament and of the Council on the quality of water intended for human consumption (recast) – General approach = Contributions from delegations

With a view to the Council (Environment) on 5 March 2019, delegations will find in the Annex a text proposal by Estonia and Latvia to the Presidency's compromise text for a general approach on the above-mentioned proposal, accompanied by its respective justification.

Changes in comparison to the Presidency's Compromise text (document 6876/1/19 REV 1) are marked in **bold underlined** and deletions are marked in strikethrough underlined.

ANNEX

ESTONIAN AND LATVIAN TEXT PROPOSALS TO THE PRESIDENCY'S COMPROMISE TEXT (doc 6876/1/19 REV1)

Article 10a

Minimum requirements for materials that come into contact with water intended for human consumption

1. For the purposes of Article 4, Member States shall ensure that materials that are intended to be used in new installations or, in case of ~~major~~ repair works or reconstruction, in existing installations for abstraction, treatment or distribution of water intended for human consumption and that come into contact with such water do not:

(a) directly or indirectly compromise human health protection as provided for by this Directive;

(b) adversely affect the colour, odour or taste of the water;

(c) enhance microbial growth;

(d) leach contaminants into the water at levels that are higher than necessary in view of the intended purpose.

2. For the purpose of ensuring the uniform application of paragraph 1, the specific minimum hygiene requirements for materials shall be established through implementing acts laying down:

(a) common methodologies for testing ~~and accepting~~ starting substances and compositions to be included in European positive lists, including substance or material related specific migration limits and scientific pre-conditions ~~(e.g. scientific knowledge of food contact materials, 10 % allocation factor in relation to tolerable daily intake);~~

(b) European positive lists of starting substances or compositions for each group of materials (organic, cementitious, metallic, enamels, ceramic or other inorganic material) ~~authorized to be used for manufacturing of materials,~~ including, where appropriate, conditions for their use and migration limits, determined on the basis of the common methodologies adopted pursuant to subparagraph (a).

(c) procedures and methods for testing ~~and accepting final~~ materials ~~in their final form~~, made from ~~materials or~~ combinations of starting substances or compositions on the European positive lists, including:

i) the identification of relevant substances and other parameters (such as turbidity, flavour, odour, colour, total organic carbon, the release of unsuspected substances and enhancement of microbial growth) to be tested in migration water;

ii) test methods on the effects on water quality, having regard to any appropriate EN standards;

iii) pass/fail criteria of the test results which take into account, inter alia, conversion factors of substances migration into levels estimated at the tap, conditions of application or use, where appropriate.

3. The implementing acts refered to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 20 on the basis of the principles set out in Annex VII. They shall be adopted according to the following timetable and include transitional provisions ~~where appropriate~~:

a) The common methodologies and procedures and methods referred to in paragraph 2(a) and (c) no later than 3 years [4 years] after entry into force of this ~~Diorective~~ Directive;

b) The European positive lists referred to in paragraph 2(b) shall be adopted on the basis of the methodologies referred to in paragraph 2(a) no later than 4 years [5 years] after entry into force of this Directive.

4. The first European positive lists of substances shall be based, among others, on existing national positive lists of starting substances and compositions and on the risk assessments that led to the establishment of such national lists. For this purpose, Member States shall notify the Commission of any existing national positive lists and available assessment document(s). The Commission shall regularly review and update the European positive lists of starting substances in line with the latest scientific and technological developments.

5. The Commission shall adopt implementing acts, in accordance with the examination procedure referred to in Article 20, laying down a procedure for applications from economic operators, or relevant authorities to include or remove starting substances and compositions from the European positive lists. ~~These applications shall be submitted by the Member States to the Comission.~~ The procedure shall ensure that applications are accompanied by risk assessments and that economic operators deliver the necessary information for the risk assessment to the authorities in a specific format.

~~6. Member States shall consider that final materials in their final form, approved in accordance with specific requirements set out in paragraphs 2 and 9 are compliant with the requirements set out in paragraph 1.~~

6. Member States shall take all measures necessary to ensure that materials are not in contact with water for human consumption unless they comply with the minimum hygiene requirements set out in this Article.

The minimum hygiene requirements shall become applicable 2 years after the adoption of the implementing act referred to in paragraph 3 (b).

Materials which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in paragraph 8.

This shall not prevent Member States from adopting more stringent protective measures for the use of materials in specific or duly justified circumstances, in accordance with Article 193 TFEU. Such measures shall be notified to the Commission.

5. ~~In the absence~~ Pending the adoption of rules ~~adopted pursuant~~ referred to in paragraph 2, Member States shall be entitled to maintain or adopt national measures on specific minimum hygiene requirements for starting substances or materials referred to in paragraph 1, provided they comply with the rules of the Treaty.

~~8. Products in contact with drinking water pursuant to article 3 and Annex I (3(e)) to Regulation (EU) No 305/2011 and other product related EU legislation, as well as non-harmonised products, shall respect the requirements of this Directive. The Commission may~~

The Commission shall request one or several European standardisation organisations to draft a European standard for uniform compliance testing of the materials and final product in order to facilitate compliance with this article, in accordance with Article 10 of Regulation (EU) No 1025/2012.

9. To the extent that Union legislation does not exhaustively harmonise rules relating to products that consist of materials referred to in paragraph 1, Member States may apply national measures related to these products, in order to satisfy the requirements of Article 4 and 10a.

~~10. The Commission shall adopt an implementing act establishing harmonised specifications for a conspicuous, clearly legible and indelible marking for products in contact with drinking water that may be used to indicate conformity with this Article.~~

11. The Commission shall, no later than 8 9 years after the date of transposition of this Directive, based in particular on experience gained with the application of Regulation (EU) No 1935/2004 and Regulation (EU) No 305/2011, review the functioning of the system as set out in this Article and present a report to the European Parliament and the Council assessing whether:

(a) the protection of human health is adequately ensured throughout the Union;

(b) the proper functioning of the internal market for materials in contact with water intended for human consumption is ensured;

(c) there is a need for any further legislative proposal on the matter.

12. For the national implementation of the requirements of this Article, Article 4 (2) shall apply accordingly.

13. For the purpose of this Article:

'starting substance' shall mean an intentionally added substance for the production of organic materials, or of admixtures for cementitious materials;

'composition' shall mean the chemical composition of a metal, enamel, ceramic or other inorganic material.

ANNEX VII

PRINCIPLES FOR SETTING COMMON METHODOLOGIES

Groups of materials

1 Organic materials

Organic materials may ~~only~~ be made of the starting substances in compliance to the minimum hygiene requirements given in the positive list and in general for substances for which it can be ruled out that the substance and its reaction products are present at levels exceeding 0.1 µg/l in water for human consumption unless - for specific substances a more stringent value is needed taking into account their toxicity. Where applicable practice for materials in contact with drinking water can be based on what is already in operation at the European level for materials in contact with food (positive list) (Commission Regulation (EU) No 10/2011, hereinafter referred to as: 10/2011/EC). The Union list of Commission Regulation (EU) No 10/2011 shall form the basis of the European positive List for organic materials.

Organic materials shall be tested according to table 1 in line with specified EN testing methods and must satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into levels expected at the tap.

2 Metallic materials

~~Only~~ metallic materials included in the positive list of compositions shall be in compliance to the minimum hygiene requirements under this Directive ~~shall be used~~. The limitations stipulated in the European positive list in respect of the composition of these materials, their use for certain products and the use of these products shall be complied with.

Compositions shall be tested according to table 1 in line with specified EN testing methods and must satisfy the requirements stipulated therein.

3 Cementitious materials

Cementitious materials are made of constituents (inorganic or organic). The organic constituents are made from starting substances. Cement-bound materials in contact with water for human consumption may ~~only~~ be made of the constituents' types in compliance to the minimum hygiene requirements given in the European positive list (approved constituent list). Certain constituent types may only be made of the starting substances given in the positive lists and substances for which it can be ruled out that the substances and their reaction products are present at levels exceeding 0.1 µg/l in water for human consumption. Other constituent types must comply with appropriate European Standards.

Cement-bound materials shall be tested according to table 1 in line with specified EN testing methods and must satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into levels expected at the tap.

4 Enamels and ceramic materials

Enamels and ceramic materials in contact with water for human consumption may ~~only~~ be made of the starting substances types in compliance to the minimum hygiene requirements given in the European positive list (approved composition list) under this Directive.

There has to be an assessment of the metallic elements used in the composition of these materials.

Enamels and ceramic materials shall be tested according to table 1 in line with specified EN testing methods and must satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into levels expected at the tap.

5 Exceptions for assessment of materials used in minor and assembled components

Describing the tests, requirements, and procedure for approval of assembled components, specifically detailing the definition and evaluation of minor components, parts, and materials. For this goal 'minor' refers to a level of influence on the drinking water quality that does not require the full testing.

Table 1. Testing related to material types

Criteria	Organic (1)	Metallic (2)	Cementitious	Enamels and ceramic materials
European Positive lists				
Positive lists of starting substances organic materials	**X**	**N.N.**	**X**	**N.N**
Positive lists of accepted metallic compositions	**N.N.**	**X**	**N.N.**	**N.N**
Approved Constituent list Cementitious materials	**N.N.**	**N.N.**	**X**	**N.N.**
Positive list of accepted enamels and ceramic compositions	**N.N**	**N.N**	**N.N**	**X**
Organoleptic tests				
Odour and flavour	**X**	**N.N.**	**X**	**N.N.**
Color and Turbidity	**X**	**N.N.**	**X**	**N.N.**
General hygiene assessments				
Leaching of total organic carbon	**X**	**N.N.**	**X**	**N.N.**
Surface residues (metals)	**N.N.**	**X**	**N.N.**	**N.N.**
Migration testing				
Relevant DWD parameters	**X**	**X**	**X**	**X**
SML of PL substances	**X**	**N.N.**	**X (3)**	**N.N.**
Unsuspected substances (GCMS)	**X**	**N.N.**	**X (3)**	**N.N.**
CL compliance	**N.N.**	**X**	**N.N.**	**X**
Enhancement of microbial growth	**X**	**N.N.**	**X (3)**	**N.N.**

N.N: Not necessary

SML: Specific Migration Limit <u>(based on 10% allocation factor)</u>

GCMS: Gas Chromatography – Mass Spectrometry (screening method)

(1) Specific exceptions to be determined in line with paragraph 5 of this Annex;

(2) Metals will not be subject to organoleptic testing because it is generally accepted that if DWD limits are met, organoleptic problems are unlikely to arise;

(3) Depending on the existence of organic substances in the composition.

POSITION PAPER ACCOMPANYING THE ESTONIAN AND LATVIAN PROPOSAL

We draw attention to the fact that the Presidency proposal on Article 10a and Annex VII essentially entails harmonisation legislation on materials and products that come into contact with water intended for human consumption.

We emphasise that such a harmonisation legislation should respect the requirements set out in the **Decision No 768/2008/EC** of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, and the **reference provisions** for Community harmonisation legislation for products as set out in Annex I of this Decision.

In particular, in accordance with this Decision:

- Community harmonisation legislation shall restrict itself to setting out the **essential requirements** determining the level of such protection and shall express those requirements **in terms of the results to be achieved (art 3 p. 1);**

- Where Community harmonisation legislation sets out essential requirements, it shall provide for recourse to be had to **harmonised standards**, which shall express those requirements in technical terms and which shall, alone or in conjunction with other harmonised standards, provide for the **presumption of conformity with those requirements**, while maintaining the possibility of setting the level of protection by other means. (Art 3 p 2);

- Where Community harmonisation legislation **requires conformity assessment** to be performed in respect of a particular product, the procedures which are to be used shall be chosen from among the modules set out and specified in Annex II of the Decision (Art 4 p 1);

- Where a product is subject to several Community acts within the scope of this Decision, **consistency among conformity assessment procedures shall be ensured by the legislator** (Art 4 p 2).

Therefore, we are of the view that the objective to harmonise the minimum requirements for materials that come into contact with water intended for human consumption, is best achieved through a **separate product legislation.** The Commission could put forward such a proposal based on a thorough impact assessment.

Another alternative, would be to rely on the existing harmonisation legislation, where applicable (i.e. Construction Products Regulation (EU) No 305/2011) and to apply the mechanisms foreseen in the **Directive 2001/95/EC on general product safety to the non-harmonised products.** In particular, Art 3 and Art 4 (General safety requirement, conformity assessment criteria and European standards) are applicable.

We are very concerned about the fact that in the Council **major policy changes are introduced without any impact assessment at EU level**. Substantial changes have been proposed that have an impact on how we approach the conformity assessment of the products and set the limits on the free movement in single market legislation. It is very difficult to say what will be the impact to our competent authorities, industry, to the availability of the products and to the price of drinking water. Therefore, **we are not able to assess the added-value of this proposal in view of the potential costs related to the implementation**. We are also worried about the administrative burden to the economic operators relating to the EU positive lists, as they will have double burden from getting first their substances in the list and then certifying their products to enter the market.

In the spirit of compromise, we could accept the Presidency proposal that foresees development of the EU positive lists of starting substances and compositions. However, for the text to be acceptable in view of legal clarity, we propose that following aspects should be clarified:

1) Updating the EU positive lists:

- The procedure for applications to include or remove starting substances and compositions from the European positive lists should be **set in the implementing act**. It is not clear in the Presidency text what the role of the Member States' competent authorities would be and how much administrative burden this will bring. Ideally, the application dossiers **shall be submitted to the Commission directly**. The Commission shall, in cooperation with the Member State competent authorities, assess the application and decide the inclusion of a substance or composition in the list, based on the available scientific evidence.

- The European positive lists of starting substances and compositions **should be used as a basis for compliance testing of materials but it should not result in a ban** of all other substances allowed to be used in the materials.

- It should be possible for economic operators to certify the compliance of materials to the minimum hygiene requirements through the conformity assessment procedures, inter alia **based on harmonised standards**. Allowing materials to be accepted only through the procedures set out in the implementing act in para 2 (c) would be too restrictive. Therefore, we would like to delete the references to accepting and authorising materials.

- In p. 3 a longer period is needed to set up the common methodologies and the EU positive lists. The **time-frame foreseen to set up the system in the Presidency text is not sufficient** and it might jeopardize the availability of products. Additionally, **transitional provisions** should be foreseen, in order to allow products to be brought in compliance with the new requirements. We suggest that the transitional period would be **2 years after the adoption of first EU positive lists.**

2) Conformity assessment of materials and products:

- Conformity assessment of materials and final products (p. 2 (c), p.8) shall be **based on harmonised standards**. The **Commission shall mandate** European standardisation organisations to draft a European standard for uniform compliance testing of materials and final products.

- It is not clear what is meant under "materials in their final form", we suggest to **delete "in their final form**" or add a definition.

- **Delete p. 10** on the new system of quality marking – in the case of harmonised products this would be in contradiction with the requirements of CE-marking. According to Construction Production Regulation, the CE marking should be the only marking of conformity of the construction product. We also believe that it would rather create confusion for the consumers.