

## ANNEX V

**PRINCIPLES FOR SETTING METHODOLOGIES REFERRED TO IN ARTICLE 11**  
**Groups of materials**

## 1. Organic materials

Organic materials shall only be made of:

- (a) the starting substances listed in the European positive list of starting substances to be established by the Commission in accordance with point (b) of the first subparagraph of Article 11(2); and
- (b) substances in relation to which there is no possibility that the substance and its reaction products are present at levels exceeding 0,1 µg/l in water intended for human consumption, unless for specific substances a more stringent value is needed taking into account their toxicity.

Organic materials shall be tested in accordance with Table 1 in line with methods for testing specified in relevant European standards or, in the absence thereof, an internationally or nationally recognised method and shall satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into estimated levels at the tap.

## 2. Metallic materials

Only metallic materials included in the European positive list of compositions to be established by the Commission in accordance with point (b) of the first subparagraph of Article 11(2) 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.

Metallic materials shall be tested in accordance with Table 1 in line with methods for testing specified in relevant European standards or, in the absence thereof, an internationally or nationally recognised method and shall satisfy the requirements stipulated therein.

## 3. Cementitious materials

Cementitious materials shall only be made of one or more of the following:

- (a) organic constituents listed in the European positive list of constituents to be established by the Commission in accordance with point (b) of the first subparagraph of Article 11(2);
- (b) organic constituents in relation to which there is no possibility that the constituents and their reaction products are present at levels exceeding 0,1 µg/l in water intended for human consumption; or
- (c) inorganic constituents.

Cement-bound materials shall be tested in accordance with Table 1 in line with methods for testing specified in relevant European standards or, in the absence thereof, an internationally or nationally recognised method and shall satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into estimated levels at the tap.

## 4. Enamels and ceramic materials

*Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

Enamels and ceramic materials shall only be made of starting substances from the European positive list of compositions to be established by the Commission in accordance with point (b) of the first subparagraph of Article 11(2), after carrying out an assessment of the elements used in the composition of these materials.

Enamels and ceramic materials shall be tested in accordance with Table 1 in line with methods for testing specified in relevant European standards or, in the absence thereof, an internationally or nationally recognised method and shall satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into estimated levels at the tap.

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

For assembled products: minor components, parts and materials shall be described in detail and testing shall be reduced accordingly. For this purpose, ‘minor’ refers to a level of influence on the quality of water intended for human consumption that does not require full testing.

**Table 1. Testing related to material types**

Criteria	Organic (See Note 1)	Metallic (See Note 2)	Cementitious	Enamels and ceramic materials
European positive lists				
European positive list of starting substances for organic materials	X	N.N.	X	N.N.
European positive list of accepted metallic compositions	N.N.	X	N.N.	N.N.
European positive list of constituents for cementitious materials	N.N.	N.N.	X	N.N.

<sup>a</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

N.N.: Not necessary

MTC<sub>tap</sub>: Maximum tolerable concentration at the tap (either derived from the opinion of ECHA for the purposes of inclusion of the substance in the European positive list, or based on a specific migration limit set in Commission Regulation (EU) No 10/2011<sup>a</sup> and considering a 10 % allocation factor and water consumption of 2 litres per day)

GCMS: Gas Chromatography – Mass Spectrometry (screening method)

Note 1: Specific exceptions to be determined in line with point 5 of this Annex.

Note 2: Metals shall not be subject to organoleptic testing because it is generally accepted that if the parametric values set out in Annex 1 are met, organoleptic problems are unlikely to arise.

Note 3: Depending on the existence of organic substances in the composition.

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**Table 1. Testing related to material types**

European positive list of compositions for enamels and ceramic materials	N.N.	N.N.	N.N.	X
Organoleptic tests				
Odour and flavour	X	N.N.	X	N.N.
Colour 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 parameters of this Directive	X	X	X	X
MTC <sub>tap</sub> of PL substances	X	N.N.	X (See Note 3)	N.N.
Unexpected substances (GCMS)	X	N.N.	X (See Note 3)	N.N.
Compliance with compositions lists	N.N.	X	N.N.	X
Enhancement of microbial growth	X	N.N.	X (See Note 3)	N.N.

**a** Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

N.N.: Not necessary

MT<sub>Tap</sub>: Maximum tolerable concentration at the tap (either derived from the opinion of ECHA for the purposes of inclusion of the substance in the European positive list, or based on a specific migration limit set in Commission Regulation (EU) No 10/2011<sup>a</sup> and considering a 10 % allocation factor and water consumption of 2 litres per day)

GCMS: Gas Chromatography – Mass Spectrometry (screening method)

Note 1: Specific exceptions to be determined in line with point 5 of this Annex.

Note 2: Metals shall not be subject to organoleptic testing because it is generally accepted that if the parametric values set out in Annex I are met, organoleptic problems are unlikely to arise.

Note 3: Depending on the existence of organic substances in the composition.