



**COMMISSION IMPLEMENTING DECISION (EU) 2024/368**

**of 23 January 2024**

**laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards the procedures and methods for testing and accepting final materials as used in products that come into contact with water intended for human consumption**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption <sup>(1)</sup>, and in particular Article 11(2), point (c), thereof,

Whereas:

- (1) In order to be able to test and accept final materials to be used in products that come into contact with water intended for human consumption, hygiene requirements should be set out for each category of final material, namely organic, cementitious, metallic, enamels and ceramic, or other inorganic materials. The methodologies to be used should be based, *inter alia*, on Annex V to Directive (EU) 2020/2184 and should be taken into account in the performance of the conformity assessment procedures of products.
- (2) The testing of final materials requires the identification of relevant substances and other relevant parameters. Those substances and parameters should be analysed in the migration water. It is necessary to establish the requirements for such testing procedure and analysis.
- (3) This Decision should lay down the testing requirements in order to ensure the performance of the testing. For organic, cementitious, enamel and ceramic materials, the testing requirements should be subject to a risk-based approach by categorising the product that comes into contact with water intended for human consumption. The risk-based approach ensures proportionate testing in relation to the human health risk of the final material.
- (4) The testing for each final material should be carried out in accordance with the determined testing requirements to ensure that the water intended for human consumption is wholesome and clean. In order to determine whether the final material should be accepted and approved, it is necessary to set out pass/fail criteria that the results of the testing have to meet.
- (5) In order to ensure proportionate testing, it should be possible to reduce testing for materials used in minor components and minor components of assembled products.
- (6) National competent authorities or bodies should be allowed sufficient time to adapt their national system to the new requirements for testing and acceptance of final materials. The application of this Decision should therefore be deferred.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 22(1) of Directive (EU) 2020/2184.

<sup>(1)</sup> OJ L 435, 23.12.2020, p. 1.

HAS ADOPTED THIS DECISION:

#### *Article 1*

The procedures and methods for testing and accepting final materials as used in a product as provided for in Article 11(2), point (c), of Directive (EU) 2020/2184 on the quality of water intended for human consumption are set out in the Annexes I to IV.

#### *Article 2*

#### **Definitions**

For the purposes of this Decision, the following definitions apply:

- (1) 'starting substance' means a substance that has been intentionally added in the production of organic materials or of admixtures for cementitious materials;
- (2) 'constituent' means: any of the following:
  - (a) a substance that has been intentionally used to manufacture a cementitious material;
  - (b) an alloying element present in a composition of metallic materials;
  - (c) an element or a combination of elements present in a composition of enamels, ceramic or other inorganic materials;
  - (d) a substance present in a mixture of substances.
- (3) 'product' means an object that comes into contact with water intended for human consumption, which is made of final materials and with the intention to be placed on the market;
- (4) 'assembled product' means a product that consists of two or more components, that are joined together and function as a whole unit and can be disassembled without destroying the components;
- (5) 'component' means an identifiable part of an assembled product consisting of one or more materials;
- (6) 'multilayer product' means a product that consist of two or more layers of final materials bonded together and cannot be non-destructively disassembled for the testing;
- (7) 'material' means a solid, semi-solid or liquid that is used for the manufacturing of a product that is:
  - (a) an organic composition prepared from one or more starting substances; or
  - (b) a cementitious composition prepared from one or more constituents; or
  - (c) a metallic, enamel, ceramic or other inorganic composition.
- (8) 'organic material' means a material that mainly consists of carbon-based substances;
- (9) 'metallic material' means a metal or metal alloy, and that is used either in bulk form or as metallic plating;
- (10) 'cementitious material' means a material that contains a hydraulic cement in sufficient proportion to act as the main binder by forming a hydrate structure which governs the performance of the material;
- (11) 'enamel' means a material that is a vitreous material obtained by melting at temperatures higher than 1 200 °C and fritting of a mixture of inorganic substances;
- (12) 'ceramic material' means inorganic poly or single crystalline, non-metallic solid materials subjected to high temperature in manufacture;
- (13) 'final material' means a material which is subject to testing and acceptance in accordance with the testing requirements and acceptance requirements set out in the respective Annexes I, II, III and IV to this Decision;
- (14) 'site applied material' means a final material to be produced on a construction site;
- (15) 'test piece' means a representative object of the final material that is used for the carrying out of testing in accordance with the procedures and methods for testing set out in the respective Annexes I, II, III and IV of this Decision;

- (16) 'unexpected substance' means a substance that has migrated from a product, a final organic material or a final cementitious material into water intended for human consumption, that was not intentionally added during the production process of the material or product, and that was not included in the information provided in the application referred to in Article 11(5) of Directive (EU) 2020/2184;
- (17) 'formulation' means the list of all substances or constituents used in the preparation of an organic material or of a cementitious material and their relative quantities;
- (18) 'total barrier' means a barrier layer that prevents the diffusion of any substances towards the side of the final material in contact with the water intended for human consumption;
- (19) 'enhancement of microbial growth (EMG)' means the ability of final organic or cementitious materials to enhance the multiplication of micro-organisms under specified conditions;
- (20) 'migration water' means the test water that has been in contact with the test piece under the specified conditions set out in the respective Annexes I, II, III and IV.

*Article 3*

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 31 December 2026.

Done at Brussels, 23 January 2024.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX I

## FINAL ORGANIC MATERIAL

**1. GENERAL PROCEDURE FOR TESTING AND ACCEPTING FINAL ORGANIC MATERIALS AS USED IN A PRODUCT.**

The procedure for testing and accepting final organic materials as used in a product includes the following steps:

**Step 1 – Identification of relevant substances and relevant other parameters depending on:**

1. Categorisation of products or components into risk groups and corresponding testing requirements
2. Formulation review

**Step 2 – Performance of tests**

1. Migration test for
  - (a) Total Organic Carbon (TOC)
  - (b) Relevant substances
  - (c) Unexpected substances
2. Modelling of migration of relevant substances
3. Migration test for
  - (a) Odour and flavour
  - (b) Colour and turbidity
4. Testing for Enhancement of Microbial Growth (EMG)
5. Testing residual content of substances

**Step 3 – Compliance with pass/fail criteria****2. IDENTIFICATION OF RELEVANT SUBSTANCES AND RELEVANT OTHER PARAMETERS****2.1. Categorisation of products or components into risk groups and corresponding testing requirements.**

For each product or component of an assembled product, a product group and a corresponding conversion factor (CF) shall be determined in accordance with Table 5. Based on the determined CF, the product or component is categorised in a risk group (RG) in accordance with Table 1.

The categorisation in a RG determines the corresponding testing requirements including the relevant substances and relevant other parameters. The applicable testing procedure of final organic materials results from the use of these materials in products or components of assembled products.

Minor components are considered to be components categorised in risk group 3 or 4 (RG3 or RG4) and for which reduced testing requirements, as set out in Table 1, may apply in comparison with the testing requirements for the risk group 1 or 2 (RG1 or RG2).

For an assembled product, the components shall be determined. For each component in an assembled product, a product group shall be determined. If an assembled product consists of components made of the same main polymer, then the surface fraction of these components shall be cumulatively added for the determination of the product group in accordance with Table 5.

Products or components made of multilayer materials are considered as one final material consisting of several layers.

The testing shall be performed on the final materials as used in products in contact with water intended for human consumption.

The specification in Table 1 for testing 'on product or component' means that the individual product or component of an assembled product shall be used for the performance of the testing.

The specification in Table 1 for testing on 'test piece of the formulation' means that a representative test piece of the final material as used in a product or component can be considered for the testing. In this case it is not required that the individual product or component is tested.

Table 1

**Risk-based testing requirements for products or components of assembled products**

Risk group	CF in d/dm	Formulation review	Relevant substances	Screening for unexpected substances	TOC	TON <sup>(1)</sup> , TFN <sup>(2)</sup> , colour, turbidity	EMG
<b>RG1</b>	≥ 4	Yes	Yes, on product	Yes, on product	Yes, on product	Yes, on product	Yes, on product for pipes with CF >10 d/dm or test piece of the formulation
<b>RG2</b>	≥ 0,4 and < 4	Yes	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product or component	Yes, on (assembled) product or component	Yes, on component or test piece of the formulation
<b>RG3</b>	≥ 0,04 and < 0,4	Yes	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on component or test piece of the formulation
<b>RG4</b>	< 0,04	No	No	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on component or test piece of the formulation

<sup>(1)</sup> Threshold odour number

<sup>(2)</sup> Threshold flavour number

## 2.2. Formulation review

A formulation review is required in accordance with the requirements in Table 1.

### 2.2.1 Required information

For a formulation review of a final organic material the following information is required:

- (a) list of all starting substances (including their impurities and other specifications) used to produce the final organic material including all monomers, additives, aids to polymerisation, polymer production aids, pigments, colorants and fillers;
- (b) the respective percentage by mass (m/m %) of all starting substances and substances used to produce the final material, adding up to 100 %.
- (c) any other information considered relevant for the assessment of the formulation of the final organic material.

The cut-off value, below which details of the formulation (i.e. the chemical composition of starting substances or impurities) are not required, expressed as mass percentage in the formulation is:

- (a) for one substance: 0,02 % for RG1, 0,05 % for RG2 and 0,1 % for RG3 materials; and
- (b) for the sum of all such substances: 0,1 % for RG1, 0,2 % for RG2 and 0,5 % for RG3.

In case of multilayer products with a total barrier, only the layers between the barrier and the surface in contact with drinking water shall be considered. The formulation shall be specified for each layer to be considered.

### 2.2.2 Relevant substances

The formulation shall be evaluated and compared with the accepted starting substances of the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367 <sup>(1)</sup>. One of the objectives of the evaluation is to define the relevant substances, which shall be analysed in the migration water.

The relevant substances are:

- (a) Starting substances used in the formulation, listed in the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367 and for which an  $MTC_{tap}$  applies;
- (b) Substances like impurities, degradation or reaction products specified in the condition of use of the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367 used in the formulation;
- (c) All substances set out in Table 4 of Annex I of Commission Implementing Decision (EU) 2024/367 of starting substances for organic materials if stabilizers with alkylphenol structural moieties are used;
- (d) Starting substances used in the formulation, their impurities, degradation and reaction products not listed in the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367, but accepted under section 2.2.3 (b) of this Annex;
- (e) Aluminium, ammonium, barium, cobalt, copper, europium, gadolinium, iron, lanthanum, lithium, manganese, terbium and/or zinc, if the respective salts of authorised acids, phenols or alcohols, authorised in accordance with note 2. 'Scope of an authorisation', point ii. of the Annex I of Commission Implementing Decision (EU) 2024/367 are used;
- (f) Starting substances of polymeric substances authorised in accordance with note 2. 'Scope of an authorisation', point iii. of the Annex I of Commission Implementing Decision (EU) 2024/367 for which an  $MTC_{tap}$  applies;

<sup>(1)</sup> Commission Implementing Decision (EU) 2024/367 of 23 January 2024 laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council by establishing the European positive lists of starting substances, compositions and constituents authorised for use in the manufacture of materials or products that come into contact with water intended for human consumption (OJ L, 2024/367, 2024.04.23, ELI: [http://data.europa.eu/eli/dec\\_impl/2024/367/oj](http://data.europa.eu/eli/dec_impl/2024/367/oj)).

- (g) Starting substances of pre-polymers and natural or synthetic polymers authorised in accordance with note 2. 'Scope of an authorisation', point v. of the Annex I of Commission Implementing Decision (EU) 2024/367 for which an  $MTC_{tap}$  applies;
- (h) Antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium if pigments or colorants are used in the formulation not complying with the purity requirements in accordance with section 4.6 of this Annex or if the purity testing was not performed;
- (i) Primary aromatic amines (PAA) if organic pigments or colorants are used in the formulation not complying with the purity requirements in accordance with section 4.6 of this Annex or if the purity testing was not performed;
- (j) Antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium if fillers are used in the formulation not complying with the purity requirements according to section 4.6 of this Annex or if the purity testing was not performed;
- (k) In case additional material-specific criteria apply (see section 2.2.4): all substances or group of substances for which an  $MTC_{tap}$  has been set;
- (l) In case of migration test with chlorinated test water: haloacetic acids (HAAs) and trihalomethanes total, as defined in part B of Annex I – to Directive (EU) 2020/2184.

For multilayer materials, the relevant substances shall be determined for each layer between the total barrier and the drinking water individually.

### 2.2.3 Acceptance of starting substances

Organic materials shall only be made of :

- (a) starting substances listed in the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367; or
- (b) starting substances for which no migration of the substance, its impurities and/or its reaction and degradation products into drinking water occurs at levels exceeding 0,1 µg/l at the consumer's tap. This only applies to substances that do not belong to either one of the following categories:
  - (1) substances classified as carcinogenic, mutagenic, toxic for reproduction category 1A or 1B, endocrine disrupters (ED) for human health category 1, persistent, bioaccumulative and toxic substances (PBT) or very persistent and very bioaccumulative substances (vPvB) in accordance with Regulation No. 1272/2008 (CLP); or being included in the candidate list as substances of very high concern (SVHC) under Regulation (EC) No 1907/2006 (REACH) for the ED, PBT or vPvB properties;
  - (2) substances intentionally added in nanoform;
  - (3) monomers of the main polymers in the material.

The relevant notes of the Annex I to Commission Implementing Decision (EU) 2024/367 establishing the European positive list of starting substances for organic materials shall be considered in the acceptance of starting substances.

### 2.2.4 Material-specific requirements

For polyamide or polyurethane resin coatings, requirements on the release of primary aromatic amines (PAA) apply, as specified in Table 2.

Requirements for rubbers are listed in Table 3.

Requirements for organic materials other than rubbers made of starting substances bearing N-functionalities, such as aminic, amidic or quaternary, when tested with chlorinated test water are listed in Table 4.

Table 2

#### Requirement for polyamides and polyurethane resin coatings

Parameter	Restriction
Sum of Primary Aromatic Amines (PAA)	$MTC_{tap} = N.D.$ (LOD = 0,1 µg/l) <sup>(1)</sup>

<sup>(1)</sup> Method should be improved to have a Limit of Detection (LOD) of 0,1 µg/l.

Table 3

**Requirements on amines and nitrosamines for rubbers**

Parameter	Restriction
Sum of Primary Aromatic Amines (PAA) (a.o. aniline, o-toluidine)	MTC tap = N.D. (LOD = 0,1 µg/l) <sup>(1)</sup>
Sum of secondary amines <sup>(2)</sup>	MTC tap = 250 µg/l
Sum of N-nitrosamines <sup>(3)</sup>	MTC tap = N.D. (LOD = 0,1 µg/l)

<sup>(1)</sup> Method should be improved to have a Limit Of Detection (LOD) of 0,1 µg/l.

<sup>(2)</sup> sum of dibutylamine (CAS 111-92-2), diethylamine (CAS 109-89-7), dimethylamine (CAS 124-40-3), dicyclohexylamine (CAS 101-83-7), cyclohexylethylamine (CAS 5459-93-8), diphenylamine (CAS 122-39-4), dibenzylamine (CAS 103-49-1), benzyl-N-methylamine (CAS 103-67-3), benzylidenebenzylamine (CAS,780-25-6) N-methylaniline (CAS 100-61-8), N-ethylaniline (CAS 103-69-5), N-butylaniline (CAS 1126-78-9)

<sup>(3)</sup> sum of N-Nitroso-di-n-butylamine (CAS 924-16-3), N-Nitroso-diethanolamine (CAS 1116-54-7), N-Nitroso-diethylamine (CAS 55-18-5), N-Nitroso-diisopropylamine (CAS 601-77-4), N-Nitroso-dimethylamine (CAS 62-75-9), N-Nitroso-di-n-propylamine (CAS 621-64-7), N-Nitroso-ethyl phenylamine (CAS 612-64-6), N-Nitroso-methyl ethylamine (CAS 10595-95-6) N-Nitroso-methyl phenylamine (CAS 614-00-6), N-Nitroso-morpholine (CAS 59-89-2), N-Nitroso-piperidine (CAS 100-75-4), N-Nitroso-pyrrolidine (CAS 930-55-2)

Table 4

**Requirements on nitrosamines for final materials other than rubbers made of starting substances bearing N-functionalities when tested with chlorinated test water**

Parameter	Restriction
Sum of N-nitrosamines <sup>(1)</sup>	MTC tap = N.D. (LOD = 0,1 µg/l)

<sup>(1)</sup> sum of N-Nitroso-di-n-butylamine (CAS 924-16-3), N-Nitroso-diethanolamine (CAS 1116-54-7), N-Nitroso-diethylamine (CAS 55-18-5), N-Nitroso-diisopropylamine (CAS 601-77-4), N-Nitroso-dimethylamine (CAS 62-75-9), N-Nitroso-di-n-propylamine (CAS 621-64-7), N-Nitroso-ethyl phenylamine (CAS 612-64-6), N-Nitroso-methyl ethylamine (CAS 10595-95-6) N-Nitroso-methyl phenylamine (CAS 614-00-6), N-Nitroso-morpholine (CAS 59-89-2), N-Nitroso-piperidine (CAS 100-75-4), N-Nitroso-pyrrolidine (CAS 930-55-2)

**3. TESTING REQUIREMENTS****3.1. Migration testing****3.1.1. Standards**

For testing the release of relevant substances, unexpected substances and TOC, the following standards shall be used to obtain the migration waters:

- (a) For factory-made products: EN 12873-1:2014;
- (b) For site-applied materials: EN 12873-2:2021.

For testing odour and flavour, colour and turbidity, standard EN 1420:2016 shall be used to obtain the migration waters.

The mentioned EN standards leave options for testing. The following provisions in sections 3.1.2, 3.1.3, 3.1.4 and 3.1.5 substantiate these standards.

**3.1.2 Test piece**

For a product or a component of which the size does not allow the practical application of the testing, a representative test piece for the testing shall be provided.

Special attention shall be given to the production of the test piece.



### 3.1.3. *Temperature of testing*

All products shall be tested at  $23\text{ °C} \pm 2\text{ °C}$  (cold water test condition).

Additionally, products that are normally used for warm or hot applications shall be tested at  $60\text{ °C} \pm 2\text{ °C}$  or  $85\text{ °C} \pm 2\text{ °C}$ , respectively. For this purpose, warm water corresponds to normal operating temperatures between  $30\text{ °C}$  and  $70\text{ °C}$  and hot water corresponds to operating temperatures exceeding  $70\text{ °C}$ .

Multilayer products shall always be tested at  $60\text{ °C} \pm 2\text{ °C}$  or  $85\text{ °C} \pm 2\text{ °C}$  additionally, even when not used at these temperatures.

### 3.1.4. *Type of test water*

Cold water test ( $23\text{ °C} \pm 2\text{ °C}$ ) shall be performed with chlorinated and non-chlorinated test water.

In case a warm or a hot water test is required, this test shall only be performed with non-chlorinated test water.

### 3.1.5. *Migration periods*

For cold water tests the migration samples of the 1st, 2nd and 3rd migration period according to standards shall be analysed. The compliance with the pass/fail criteria shall be assessed at the 3rd migration period (10th day of testing). If the pass/fail criteria set out in sections 4.2 and 4.3 are not met at the 3rd migration period the testing can be extended and the 5th, 7th and 9th period shall be analysed additionally. In this case the pass/fail criteria shall be assessed at the 9th migration period (31st day of testing).

For warm or hot water tests the migration samples of the 1st, 6th and 7th migration period shall be analysed. The compliance with the pass/fail criteria shall be assessed at the 7th migration period (10th day). If the pass/ fail criteria set out in sections 4.2 and 4.3 are not met at the 7th migration period the testing can be extended and the 12th, 17th and 22nd period shall be analysed additionally. In this case the pass/fail criteria shall be assessed at the 22nd migration period (31st day).

For multilayer products an extended warm or hot water migration test is always required to ensure that substances originating from different layers appear in the migration water. To ensure sufficient substance diffusion and equilibration across layer boundaries, it is required that the multilayer product has undergone a storage period at room temperature for at least 30 days.

## 3.2. **Analysis of migration waters**

### 3.2.1. *Relevant Substances*

The relevant substances defined in section 2.2.2 shall be analysed in the migration waters (see section 3.1.5).

The methods for analysis of relevant substances in migration waters shall be validated and documented in accordance with EN ISO/IEC 17025:2017 or other equivalent standards accepted at international level.

### 3.2.2. *Unexpected Substances*

Unexpected substances are only determined in the migration waters of the cold water test.

For the identification and semi-quantitative analysis of unexpected substances a GC-MS screening shall be conducted according to EN 15768:2015.

### 3.2.3. *Relevant other parameters*

The relevant other parameters shall be analysed in the migration waters according to the following standards:

- (a) Total Organic Carbon (TOC) shall be determined according to EN 1484:1997 as non-purgeable organic carbon;
- (b) Odour shall be determined as Threshold Odour Number (TON) according to EN 1420:2016 and EN 1622:2006;

- (c) Flavour shall be determined as Threshold Flavour Number (TFN) according to EN 1420:2016 and EN 1622:2006;
- (d) Colour shall be determined according to EN ISO 7887:2011 – method C;
- (e) Turbidity shall be determined according to EN ISO 7027-1:2016 - nephelometry.

### 3.3. Mathematical modelling

Where generally recognised diffusion models exist on the basis of experimental data, mathematical modelling for estimation of migration levels may be used as alternative to the migration testing of relevant substances for certain types of final organic materials.

If these recognised diffusion models predict that the migration of the substance complies with the maximum tolerable concentration at the tap ( $MTC_{\text{tap}}$ ), migration testing for these substances is not necessary. For the assessment of some parameters and for modelling, the content of the respective substances in the final material shall be determined.

If compliance is not shown by using the models, migration testing shall be performed.

The following mathematical modelling approaches may be used:

- (a) Migration modelling according to CEN/TR 16364:2012 or other equivalent standards accepted at international level, simulating a migration test according to the EN 12873-1:2014 and EN 12873-2:2021;
- (b) Full transfer calculation, simulating full transfer of substances from the product into the migration water.

### 3.4. Enhancement of Microbial Growth (EMG) testing

For the EMG testing, standard EN 16421:2015 – method 1 or 2 shall be used.

### 3.5. Testing residual content of substances (QM/QMA)

For starting substances with a maximum quantity (QM or QMA) restriction set out in the European positive list of starting substances for organic materials of Annex I of Commission Implementing Decision (EU) 2024/367, its residual content in the product shall be analysed.

## 4. ACCEPTANCE REQUIREMENTS: PASS/FAIL CRITERIA

### 4.1. Formulation

Starting substances of the formulation listed in the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367.

- (a) shall be used according to the technical function specified in the European positive list of starting substances for organic materials;
- (b) shall be used in compliance with conditions of use established under the European positive list of starting substances for organic materials.

### 4.2. Relevant substances, unexpected substances, TOC

#### 4.2.1. Conversion of test results

In accordance with the migration standards EN 12873-1:2014 and EN 12873-2:2021, the test results are expressed as migration rates ( $M$ ) in  $\mu\text{g}/(\text{dm}^2 \cdot \text{d})$ . These results shall be converted to estimate the concentrations at the tap ( $C_{\text{tap}}$ ), defined as  $C_{\text{tap}} = M * CF$ , where  $CF$  is the corresponding conversion factor in  $\text{d}/\text{dm}$ .

The conversion factors for the different product groups are listed in Table 5 to this Annex.

Table 5

**Product groups and their conversion factor (CF)**

<b>Product group</b>		<b>CF (in d/dm)</b>
<b>A</b>	<b>Pipes and pipe linings</b>	
1	ID < 80 mm (domestic installations, buildings) <sup>(1)</sup>	20
2	80 mm ≤ ID < 300 mm (service piping)	10
3	ID ≥ 300 mm (mains piping)	5
<b>B</b>	<b>Fittings, ancillaries</b> <sup>(2)</sup>	
1	ID < 80 mm (domestic installations, buildings)	2
2	80 mm ≤ ID < 300 mm (service piping)	1
3	ID ≥ 300 mm (mains piping)	0,5
<b>C</b>	<b>Components of fittings, ancillaries</b> <sup>(3)</sup>	
1	ID < 80 mm (domestic installations, buildings)	0,2
2	80 mm ≤ ID < 300 mm (service piping)	0,1
3	ID ≥ 300 mm (mains piping)	0,05
<b>D</b>	<b>Small Components of fittings, ancillaries</b> <sup>(4)</sup>	
1	ID < 80 mm (domestic installations, buildings)	0,02
2	80 mm ≤ ID < 300 mm (service piping)	0,01
3	ID ≥ 300 mm (mains piping)	0,005
<b>E</b>	<b>Storage systems (reservoirs)</b>	
1	In domestic installations, buildings, water volume < 10 l	4
2	In domestic installations, buildings, water volume ≥ 10 l	2
3	In water supply	1
<b>F</b>	<b>Components of storage systems</b> <sup>(3)</sup>	
1	In domestic installations, buildings, water volume < 10 l	0,4
2	In domestic installations, buildings; water volume ≥ 10 l	0,2
3	In water supply	0,1
<b>G</b>	<b>Small Components storage systems</b> <sup>(4)</sup>	
1	In domestic installations, buildings; water volume < 10 l	0,04
2	In domestic installations, buildings; water volume ≥ 10 l	0,02
3	In water supply	0,01

<sup>(1)</sup> If from a series of different diameter pipes made from the same pre-product under the same manufacturing process (a so-called product family) the smallest diameter pipe is assessed and approved, then the whole series of different diameter pipes is allowed to be used for all application areas within the product group without further testing.

<sup>(2,3,4)</sup> Components (sum of components made of same main polymer or same composition) of assembled products with a wetted surface fraction

<sup>(2)</sup> ≥ 10 % of the assembled product

<sup>(3)</sup> < 10 % of the assembled product

<sup>(4)</sup> < 1 % of the assembled product

#### 4.2.2. Pass/fail criteria for relevant substances

The following requirements shall apply to the cold water migration test:

- (a)  $C_{\text{tap}} \leq \text{MTC}_{\text{tap}}$  for the 3rd migration period (10th day of testing) or, in case extended testing is needed, at the 9th migration period (31st day of testing);
- (b) there shall be no increasing trend of  $C_{\text{tap}}$  in time.

The following requirements shall apply to the warm/hot water migration test:

- (a)  $C_{\text{tap}} \leq \text{MTC}_{\text{tap}}$  for the 7th migration period (10th day of testing) or, in case extended testing is needed, at the 22nd migration period (31st day of testing);
- (b) there shall be no increasing trend of  $C_{\text{tap}}$  in time.

The measured substance concentrations in the migration water from the successive migration periods shall be used to assess the trend. However, if  $C_{\text{tap}}$  in the relevant migration period is below 1/10 of  $\text{MTC}_{\text{tap}}$ , no trend analysis is required.

For ions, the  $\text{MTC}_{\text{tap,organics}}$  of Table 1 in Annex V to Commission Implementing Decision (EU) 2024/367 shall apply.

#### 4.2.3. Pass/fail criteria for unexpected substances

The following requirement shall apply to the cold water migration test:

- (a)  $C_{\text{tap}} \leq \text{MTC}_{\text{tap}}$  for the 3rd migration period (10th day of testing) or, in case extended testing is needed, at the 9th migration period (31st day of testing).

The  $\text{MTC}_{\text{tap}}$  for the unexpected substances are set out in Table 6.

Table 6

#### **$\text{MTC}_{\text{tap}}$ for unexpected substances <sup>(1)</sup>**

Parameter	$\text{MTC}_{\text{tap}}$
Identified substances with a known $\text{MTC}_{\text{tap}}$	$\text{MTC}_{\text{tap}}$ of the substance
Identified substance without a known $\text{MTC}_{\text{tap}}$	1,0 µg/l
Unidentified substances	1,0 µg/l per unidentified substance <sup>1</sup> 5,0 µg/l for the sum of the unidentified substances

<sup>(1)</sup> Based on the response of the closest internal standard.

#### 4.2.4. Pass/fail criteria for TOC

The following requirements shall apply to the cold water migration test:

- (a)  $C_{\text{tap}} \leq 0,5 \text{ mg/l}$  for the 3rd migration period (10th day of testing) or,  $C_{\text{tap}} \leq 0,5 \text{ mg/l}$  for the 9th migration period (31st day of testing) and  $C_{\text{tap}} \leq 2,0 \text{ mg/l}$  for the 3rd migration period (10th day of testing);
- (b) there shall be no increasing trend of  $C_{\text{tap}}$  in time.

The following requirements shall apply to the warm/hot water migration test:

- (a)  $C_{\text{tap}} \leq 0,5 \text{ mg/l}$  for the 7th migration period (10th day of testing) or,  $C_{\text{tap}} \leq 0,5 \text{ mg/l}$  for the 22nd migration period (31st day of testing) and  $C_{\text{tap}} \leq 2,0 \text{ mg/l}$  for the 7th migration period (10th day of testing);
- (b) there shall be no increasing trend of  $C_{\text{tap}}$  in time.

The measured TOC in the migration water from the successive migration periods shall be used to assess the trend. However, if the TOC in the relevant migration period is below 0,2 mg/l no trend analysis is required.

### 4.3. Odour, flavour, colour and turbidity

#### 4.3.1. Pass/fail criteria for TON, TFN

(i) Pass/fail criteria for TON and TFN for pipes with internal diameter (ID) < 80 mm:

The following requirements shall apply to the cold water migration test:

- (a) TON, TFN  $\leq 8,0$  for the 3rd migration period (10th day of testing); or
- (b) TON, TFN  $\leq 8,0$  for the 9th migration period (31st day of testing) and TON, TFN  $\leq 16$  for the 3rd migration period (10th day of testing).

The following requirements shall apply to the warm/hot water migration test:

- (a) TON, TFN  $\leq 8,0$  for the 7th migration period (10th day of testing); or
- (b) TON, TFN  $\leq 8,0$  for the 22nd migration period (31st day of testing) and TON, TFN  $\leq 16$  for the 7th migration period (10th day of testing).

(ii) Pass/fail criteria for TON and TFN for all other products:

The following requirements shall apply to the cold water migration test:

- (a) TON, TFN  $\leq 2,0$  for the 3rd migration period (10th day of testing); or
- (b) TON, TFN  $\leq 2,0$  for the 9th migration period (31st day of testing) and TON, TFN  $\leq 4,0$  for the 3rd migration period (10th day of testing).

The following requirements shall apply to the warm/hot water migration test:

- (a) TON, TFN  $\leq 2,0$  for the 7th migration period (10th day of testing); or
- (b) TON, TFN  $\leq 2,0$  for the 22nd migration period (31st day of testing) and TON, TFN  $\leq 4,0$  for the 7th migration period (10th day of testing).

#### 4.3.2. Pass/fail criteria for colour

The acceptance criterion for colour is  $\leq 5$  mg/l Pt/Co.

The criterion shall be met for the 3rd migration period for cold water migration testing / 7th migration period for warm/hot water testing (10th day of testing) or, in case of extended testing, for the 9th migration period for cold water migration testing / 22nd migration period for warm/hot water testing (31st day of testing).

#### 4.3.3. Pass/fail criteria for turbidity

The acceptance criterion for turbidity is  $\leq 0,5$  NFU.

The criterion shall be met for the 3rd migration period for cold water migration testing / 7th migration period for warm/hot water testing (10th day of testing) or, in case of extended testing, for the 9th migration period for cold water migration testing / 22nd migration period for warm/hot water testing (31st day of testing).

### 4.4. Enhancement of Microbial Growth (EMG)

The pass/fail criteria for the parameter Enhancement of Microbial Growth (EMG) are listed in Table 7.

Additionally, the surface of the products or components shall not have any biocidal effects on water intended for human consumption. Therefore, test pieces without surface colonisation (comparison of contact culture/test sample smear with that of the negative control) do not satisfy this requirement.

Table 7  
Acceptance criteria for EMG

Standard			Non-elastomers	Elastomers (CF > 1 d/dm)	Elastomers (1 d/dm ≥ CF > 0,1 d/dm)	Elastomers (CF ≤ 0,1 d/dm)
EN 16421	Method 1	Biomass production potential (BPP) in pg ATP/ cm <sup>2</sup>	≤ 1 000	≤ 1 000	≤ 1 000	≤ 1 000
EN 16421	Method 2	V <sub>biofilm</sub> in ml/800 cm <sup>2</sup>	≤ 0,05 ± 0,02	≤ 0,05 ± 0,02	≤ 0,12 ± 0,03	≤ 0,20 ± 0,03

#### 4.5. Pass/fail criteria for residual content of substances (QM and QMA)

The maximum quantity (QM and QMA) limits of the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367 shall apply independently of the product group of final organic materials.

#### 4.6. Purity pass/fail criteria for pigments, colorants and fillers

Pigments, colorants and fillers shall comply with the purity requirements according to Table 8, if the corresponding substances were not analysed as relevant substances in the migration waters. The extraction with 0,1 N hydrochloric acid shall be performed according to the procedure described in Council of Europe resolution AP(89)1 on the use of colourants in plastic materials coming into contact with food.

Table 8  
Requirements on purity of pigments, colorants and fillers

#### Pigments and colorants

Colorants and pigments shall comply with the following purity requirements:

<p>a) When extracted with 0,1 N hydrochloric acid, the following elements may dissolve from the colorant or pigment up to the maximum amount, based on the colorant or pigment:</p> <ul style="list-style-type: none"> <li>— antimony 0,05 %</li> <li>— arsenic 0,01 %</li> <li>— barium 0,01 %</li> <li>— cadmium 0,01 %</li> <li>— chromium 0,1 %</li> <li>— lead 0,01 %</li> <li>— mercury 0,005 %</li> <li>— selenium 0,01 %</li> </ul>	<p>b) The content of primary aromatic amines soluble in 1 M hydrochloric acid shall not exceed 0,05 % (calculated as aniline). This limit does not apply to primary aromatic amines containing carboxyl- or sulfo-groups, or When extracted with 2 N ethanolic hydrochloric acid, a maximum of 0,05 % aromatic amines (based on the colorant or pigment) may dissolve from the colorant or pigment.</p>
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#### Fillers

Fillers can be contaminated with impurities. For mineral fillers, the following specification applies:

After solution in 0,1 N hydrochloric acid, the concentration of the following elements shall not exceed the maximum amount, based on the filler:

— antimony	0,005 %
— arsenic	0,01 %
— barium	0,01 %
— cadmium	0,01 %
— chromium	0,1 %
— lead	0,01 %
— mercury	0,0005 %
— selenium	0,01 %

## ANNEX II

## FINAL METALLIC MATERIALS

**1. GENERAL PROCEDURE FOR TESTING AND ACCEPTING FINAL METALLIC MATERIALS AS USED IN A PRODUCT.**

The procedure for testing and accepting final metallic materials as used in a product includes the following steps:

**Step 1 – Identification of relevant substances and relevant other parameters depending on:**

1. Metallic compositions of the final materials
2. Composition of applied platings

**Step 2 – Performance of tests:**

1. Testing of the composition
2. Testing of the release of relevant substances

**Step 3 – Compliance with pass/fail criteria****2. IDENTIFICATION OF RELEVANT SUBSTANCES AND RELEVANT OTHER PARAMETERS****2.1. Composition review***2.1.1. Required information*

For the composition review of a metallic product or an assembled product containing metallic components the following information is required:

- (a) list of all metallic components including the composition of the bulk material as range for all constituents exceeding 0,02 % (m/m), details about the processing to obtain the final metallic materials and the wetted surface fraction of the components in relation to the wetted surface of the assembled product;
- (b) list of solders applied including details about the soldering process;
- (c) detailed description of applied plating processes;
- (d) detailed description of applied impregnations or organic coatings;
- (e) any other information considered relevant for the assessment of the composition of the final metallic material.

*2.1.2. Accepted compositions*

The compositions of the final metallic materials and platings shall comply with compositions listed in the European positive list of compositions for metallic materials in Annex II of Commission Implementing Decision (EU) 2024/367 established in accordance with Article 11(2) (b) of the Directive and fulfil the limitations set out in the European positive list in respect of their use for certain product groups and the use of these products.

Categorisation of products in product groups for metallic materials is set out in Table 2 of Annex II to Commission Implementing Decision (EU) 2024/365<sup>(1)</sup>. Applied organic impregnations and coatings shall comply with the requirements of Annex I.

#### 2.1.3. *Relevant substances*

For plated products, relevant substances shall be identified based on the composition of the plating listed in the European positive list of compositions of metallic compositions in Annex II of Commission Implementing Decision (EU) 2024/367.

### 3. TESTING REQUIREMENTS

#### 3.1. Composition testing

An analysis of the composition of the final metallic materials shall be performed to verify compliance with the compositional requirements of metallic materials included in the European positive list of metallic compositions in Annex II of Commission Implementing Decision (EU) 2024/367. The methods of analysis shall be validated and documented in accordance with EN ISO/IEC 17025:2017 or other equivalent standards accepted at international level.

#### 3.2. Testing of release of relevant substances from plated products

Plated products should be tested for the residues on the surface according to indications in the European positive list of metallic compositions in Annex II of Commission Implementing Decision (EU) 2024/367. A suitable test should simulate metallic element release into drinking water at the consumers tap. The methods of analysis shall be validated and documented in accordance with EN ISO/IEC 17025:2017 or other equivalent standards accepted at international level.

The testing of the release of organic substances used in the plating process shall be performed in accordance with the requirements set out in Annex I.

### 4. ACCEPTANCE REQUIREMENTS: PASS/FAIL CRITERIA

#### 4.1. Compliance with the European positive list of metallic compositions

The analysed composition of final metallic materials shall comply with the compositional requirements and other limitations specified in the European positive list of metallic compositions in Annex II of Commission Implementing Decision (EU) 2024/367.

#### 4.2. Pass/fail criteria for relevant substances

The requirement  $C_{\text{tap}} \leq \text{MTC}_{\text{tap,metallics}}$  shall apply where  $\text{MTC}_{\text{tap,metallics}}$  is listed in the Table 1 of Annex V to Commission Implementing Decision (EU) 2024/367, where in the calculation of  $C_{\text{tap}}$  the stagnation time and the sampling volume are taken in due consideration.

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<sup>(1)</sup> Commission Implementing Decision (EU) 2024/365 of 23 January 2024 laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards methodologies for testing and accepting starting substances, compositions and constituents to be included in the European positive lists (OJ L, 2024/365, 2024.04.23, ELI: [http://data.europa.eu/eli/dec\\_impl/2024/365/oj](http://data.europa.eu/eli/dec_impl/2024/365/oj)).



## ANNEX III

## FINAL CEMENTITIOUS MATERIALS

**1. GENERAL PROCEDURE FOR TESTING AND ACCEPTING FINAL CEMENTITIOUS MATERIALS AS USED IN A PRODUCT.**

The procedure for testing and accepting final cementitious materials as used in a product includes the following steps:

**Step 1 – Identification of relevant substances and relevant other parameters depending on:**

1. Categorisation of products or components into risk groups and corresponding testing requirements.
2. Formulation review.

**Step 2 – Performance of tests**

1. Migration test for:
  - (a) Relevant substances
  - (b) Unexpected substances
  - (c) Odour and flavour
  - (d) Colour and turbidity
  - (e) Total Organic Carbon (TOC)
2. Testing for enhancement of microbial growth (emg)

**Step 3 – Compliance with pass/fail criteria****2. IDENTIFICATION OF RELEVANT SUBSTANCES AND RELEVANT OTHER PARAMETERS****2.1. Categorisation of products into risk groups and corresponding testing requirements**

The applicable testing procedure of final cementitious materials results from the use of these materials in products.

In accordance with Table 5 of Annex I, a product group and a corresponding conversion factor (CF) shall be determined for the product or the component. Based on the determined CF, the product or component is categorised in a risk group (RG). In accordance with Table 1 of this Annex, the categorisation in a RG determines the corresponding testing requirements and relevant other parameters.

For an assembled product, the components shall be determined. For each component in an assembled product, a product group shall be determined. If an assembled product consists of components made of the same final materials, then the surface fraction of these components shall be cumulatively added for the determination of the product group in accordance with Table 5 of Annex I.

The testing shall be performed on the final materials as used in products in contact with water intended for human consumption.

Minor components are considered to be components categorised in risk group 4 (RG4) and for which reduced testing requirements, as set out in Table 1, may apply in comparison with the testing requirements for the risk group 1, 2 or 3 (RG1, RG2, RG3).

Table 1

**Risk-based testing requirements for products or components of assembled products**

Risk Group	CF in d/dm	Formulation review	Relevant substances	Screening for unexpected substances	TOC	TON <sup>(1)</sup> , TFN <sup>(2)</sup> , colour, turbidity	EMG
RG1	≥ 4	Yes	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used	Yes, on product or test piece	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used
RG2	≥ 0,4 and < 4						
RG3	≥ 0,04 and < 0,4						
RG4	< 0,04	No	No	No	Yes, on product or test piece	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used

<sup>(1)</sup> Threshold odour number

<sup>(2)</sup> Threshold flavour number

## 2.2. Formulation review

A formulation review shall be performed in accordance with the requirements in Table 1.

### 2.2.1. Required Information

The following information in the formulation review is required for each final cementitious material:

- list of all constituents (including information on their impurities) used to produce the final cementitious material;
- the respective percentage by mass (m/m %) of constituents with respect to cement content used to produce the final cementitious material;
- any other information considered relevant for the assessment of the formulation of the final cementitious material.

The cut-off value, below which details of the formulation of the final material are not required, expressed as mass percentage in the formulation is 0,02 % (w/w) related to the cement content for one constituent.

The formulation shall be evaluated and compared with the accepted constituents of the European positive list of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 and with the accepted starting substances of the European positive list for organic materials, when relevant in accordance with Table 1 of Annex III to Commission Implementing Decision (EU) 2024/367. The evaluation shall define the relevant substances that shall be analysed in the migration water.

### 2.2.2. Relevant substances

The relevant substances to be analysed in the migration water are:

- (1) Organic cementitious constituents used in the formulation of the final cementitious material, listed in the European positive list of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 or listed in the European positive list of starting substances for organic materials, of Annex I to Commission Implementing Decision (EU) 2024/367 and for which an  $MTC_{\text{tap}}$  applies;
- (2) Impurities, degradation or reaction products specified in the condition of use of the European positive list of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 or specified in the condition of the use of the European positive list of starting substances for organic materials, of Annex I to Commission Implementing Decision (EU) 2024/367 used in the formulation;
- (3) Organic cementitious constituents used in the formulation, their impurities, degradation and reaction products not listed in the European positive list of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 or in the European positive list of starting substances for organic materials, of Annex I to Commission Implementing Decision (EU) 2024/367, but accepted under section 2.2.3 of this Annex;
- (4) Metals for which  $MTC_{\text{tap,cementitious}}$  exist according to Table 1 in Annex V to Commission Implementing Decision (EU) 2024/367;
- (5) Primary aromatic amines (PAA) if organic pigments or colorants are used in the formulation not complying with the purity requirements according to section 4.6 of Annex I or when purity testing was not performed.

### 2.2.3. Accepted constituents

Final cementitious materials shall only contain organic cementitious constituents listed in the European positive list of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 and in the European positive list of starting substances for organic materials as further specified in Table 1 of Annex III to Commission Implementing Decision (EU) 2024/367.

The use of the following additional constituents is allowed:

- (a) Inorganic constituents;
- (b) Organic cementitious constituents for which there is no possibility that they, including their reaction products, migrate at levels exceeding 0,1 µg/l in water intended for human consumption. This only applies to substances that do not belong to either one of the following categories:
  - (i) Substances classified as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B, endocrine disrupters (ED) for human health category 1, persistent, bioaccumulative and toxic substances (PBT) or very persistent and very bioaccumulative substances (vPvB) in accordance with Regulation No. 1272/2008 (CLP); or being included in the candidate list as substances of very high concern (SVHC) under Regulation (EC) No 1907/2006; and (REACH) for their ED, PBT or vPvB properties;
  - (ii) Substances intentionally added in nanoform.

The relevant notes of Annex III to Commission Implementing Decision (EU) 2024/367 establishing the European Positive List of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 shall be considered in the acceptance of constituents of cementitious materials.

#### 2.2.4. Material-specific requirements

If used, pigments and colorants shall comply with purity criteria as defined in Table 8 of Annex I, and not migrate at levels exceeding 0,1 µg/l.

### 3. TESTING REQUIREMENTS

#### 3.1. Migration testing

Testing of organic coatings with inorganic fillers should be performed according to section 3.1 of Annex I. If pH > 9.5 in the final migration water, the test should be considered invalid and the product should be evaluated as a cementitious product and testing will be performed according to section 3.1 of Annex III.

##### 3.1.1. Specifications for testing final cementitious materials for migration of organoleptic parameters (odour, flavour, colour and turbidity), TOC, relevant and unexpected substances

###### (a) Test pieces

For a product or a component of which the size does not allow the practical application of the testing, a representative test piece for the testing shall be provided.

Special attention shall be given to the production of the test piece.

###### (b) Preconditioning of test pieces

Test pieces shall be preconditioned by immersion in demineralised water containing anhydrous calcium chloride ((222 ± 2) mg CaCl<sub>2</sub> L<sup>-1</sup>) and sodium hydrogen carbonate ((336 ± 2) NaHCO<sub>3</sub> mg L<sup>-1</sup>) adjusted to a pH of (7.4 ± 0,1) by air or CO<sub>2</sub> bubbling.

Test pieces shall be preconditioned at (23 ± 2) °C in three successive periods of (24 ± 1) h followed by one period of (72 ± 1) h and one period of (24 ± 1) h. After each period the water is discarded and the test piece is not rinsed. If the pH of the last preconditioning water exceeds 9,5 then the preconditioning shall be repeated with new test pieces.

After the fifth preconditioning the test piece shall immediately be subjected to the migration test.

###### (c) Migration test

Test pieces shall be immersed in migration test water with a specified temperature and for a specified period of time.

###### (i) Migration test water for odour, flavour, colour, turbidity and TOC

Non-chlorinated migration test water shall be natural water without gas or demineralised water containing anhydrous calcium chloride ((222 ± 2) mg CaCl<sub>2</sub> L<sup>-1</sup>), sodium hydrogen carbonate ((482 ± 2) NaHCO<sub>3</sub> mg L<sup>-1</sup>) and sodium silicate ((71 ± 1) Na<sub>2</sub>SiO<sub>3</sub>·9·H<sub>2</sub>O mg L<sup>-1</sup>). It shall have a pH of (7.4 ± 0,1) by air or CO<sub>2</sub> bubbling, a conductivity of (500 ± 50) µS cm<sup>-1</sup>, an alkalinity of (350 ± 50) mg HCO<sub>3</sub><sup>-</sup> L<sup>-1</sup>, a concentration of calcium of (80 ± 10) mg L<sup>-1</sup> and a concentration of silica of (15 ± 5) mg SiO<sub>2</sub> L<sup>-1</sup>. Non-chlorinated migration test water shall have no odour (< 2 TON), flavour (< 2 TFN), colour (< 0,1 m<sup>-1</sup>), turbidity (< 0,1 FNU) and TOC (< 0,2 mg C L<sup>-1</sup>).

Chlorinated migration test water shall consist of non-chlorinated test water containing (1,0 ± 0,2) mg L<sup>-1</sup> of free chlorine.

###### (ii) Migration test water for migration of relevant and unexpected substances

Non-chlorinated migration test water shall be demineralised water containing anhydrous calcium chloride ((110 ± 1) mg CaCl<sub>2</sub> L<sup>-1</sup>), sodium hydrogen carbonate ((140 ± 1) NaHCO<sub>3</sub> mg L<sup>-1</sup>) and sodium silicate ((48 ± 1) Na<sub>2</sub>SiO<sub>3</sub>·9·H<sub>2</sub>O mg L<sup>-1</sup>). It shall have a pH of (7,0 ± 0,1) by air or CO<sub>2</sub> bubbling.

Chlorinated migration test water shall consist of non-chlorinated test water containing (1,0 ± 0,2) mg L<sup>-1</sup> of free chlorine.

###### (iii) Migration test water temperature

All products shall be tested at 23 °C ± 2 °C (cold water test condition).

Additionally, products that are normally used for warm or hot applications shall be tested at 60 °C ± 2 °C or 85 °C ± 2 °C, respectively. For this purpose, warm water corresponds to normal operating temperatures between 30 °C and 70 °C and hot water corresponds to operating temperatures exceeding 70 °C.

(iv) Duration of migration test periods

The test piece for cold water application shall be in contact with test water for  $72 \text{ h} \pm 1 \text{ h}$ . The test piece for elevated temperature applications shall be in contact with water for 24h. The test shall be repeated at least two more times using fresh test water each time. For cold water tests, the migration samples of the 1st, 2nd and 3rd migration period shall be analysed. The compliance with the pass/fail criteria shall be assessed at the 3rd migration period. If the pass/fail criteria (see sections 4.2 and 4.3) are not met at the 3rd migration period the testing can be extended and the 5th, 7th and 9th period shall be analysed additionally. In this case the pass/fail criteria shall be assessed at the 9th migration period.

For warm or hot water tests the migration samples of the 1st, 6th and 7th migration period shall be analysed. The compliance with the pass/fail criteria shall be assessed at the 7th migration period. If the pass/fail criteria (see sections 4.2 and 4.3) are not met at the 7th migration period the testing can be extended and 12th, 17th and 22nd period shall be analysed additionally. In this case the pass/fail criteria shall be assessed at the 22nd migration period.

(v) Surface-to-volume ratio (S/V)

The largest S/V representative of the product group shall be selected.

(vi) Additional specifications

For further details on testing organoleptic parameters, TOC, relevant and unexpected substances relevant European standards or, in the absence thereof, an internationally recognised methods shall be used.

Cold water test ( $23 \text{ °C} \pm 2 \text{ °C}$ ) shall be performed with chlorinated and non-chlorinated test water. In case a warm or a hot water test is required, the test shall only be performed with non-chlorinated test water.

### 3.2. Analysis of migration waters

#### 3.2.1. Relevant substances

The relevant substances defined in section 2.2.2 shall be analysed in the migration waters.

The methods for analysis of relevant substances in migration waters shall be validated and documented in accordance with EN ISO/IEC 17025:2017 or other equivalent standards accepted at international level.

#### 3.2.2. Unexpected substances

For the identification and semi-quantitative analysis of unexpected substances a GC-MS screening or screening by other analytical techniques can be used.

Unexpected substances are only determined in the migration waters of the cold water test.

#### 3.2.3. Relevant other parameters

The methods for analysis of relevant other parameters in migration waters shall be validated and documented in accordance with EN ISO/IEC 17025:2017 or other equivalent standards accepted at international level.

### 3.3. Mathematical modelling

Where generally recognised diffusion models exist on the basis of experimental data, mathematical modelling for estimation of migration levels may be used as alternative to the migration testing of relevant substances for certain types of final cementitious materials.

If these recognised diffusion models predict that the migration of the substance complies with the maximum tolerable concentration at the tap ( $MTC_{\text{tap}}$ ), migration testing for these substances is not necessary. For the assessment of some parameters and for modelling, the content of the respective substances in the final material shall be determined.

If compliance is not shown by using the models, migration testing shall be performed.

Only validated mathematical models applicable to cementitious materials shall be used to determine the concentration of a relevant substance in migration water.

### 3.4. Enhancement of Microbial Growth (EMG) testing

Tests for Enhancement of Microbial Growth shall be performed if organic constituents are used according to the formulation. For the Enhancement of Microbial Growth testing, standard EN 16421:2015 – method 1 or 2 shall be used.

## 4. ACCEPTANCE REQUIREMENTS: PASS/FAIL CRITERIA

### 4.1. Formulation

Organic cementitious constituents of the formulation listed in the European positive list of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 and in the European positive list of starting substances for organic materials as further specified in Table 1 of Annex III to Commission Implementing Decision (EU) 2024/367 shall be used:

- (a) in accordance with the technical function specified in the relevant European positive lists;
- (b) in compliance with conditions of use established under the relevant European positive lists.

### 4.2. Relevant substances, unexpected substances

#### 4.2.1. Conversion of migration test results

The migration test results are expressed as migration rates (M) in  $\mu\text{g}/(\text{dm}^2\text{d})$ . These results shall be converted to estimate the concentrations at the tap ( $C_{\text{tap}}$ ), defined as  $C_{\text{tap}} = M * \text{CF}$ , where CF is the corresponding conversion factor in d/dm.

The conversion factors for the different product groups are listed in Table 5 to Annex I.

#### 4.2.2. Pass/fail criteria for relevant substances

The following requirements shall apply to the cold water migration test:

- (a)  $C_{\text{tap}} \leq \text{MTC}_{\text{tap}}$  for the 3rd migration period or, in case extended testing is needed, at the 9th migration period;
- (b) there shall be no increasing trend of  $C_{\text{tap}}$  in time.

The following requirements shall apply to the warm/hot water migration test:

- (a)  $C_{\text{tap}} \leq \text{MTC}_{\text{tap}}$  for the 7th migration period or, in case extended testing is needed, at the 22nd migration period.
- (b) there shall be no increasing trend of  $C_{\text{tap}}$  in time

The measured substance concentrations in the migration test water from the successive migration periods shall be used to assess the trend. However, if the  $C_{\text{tap}}$  in the relevant migration period is below 1/10th of the  $\text{MTC}_{\text{tap}}$ , then no trend analysis is required.

For metals,  $\text{MTC}_{\text{tap,cementitious}}$  of Table 1 in Annex V to Commission Implementing Decision (EU) 2024/367 shall apply.

#### 4.2.3. Pass/fail criteria for unexpected substances

The following requirement shall apply to the cold water migration test:  $C_{\text{tap}} \leq \text{MTC}_{\text{tap}}$  for the 3rd migration period or, in case extended testing is needed, at the 9th migration period.

The  $\text{MTC}_{\text{tap}}$  for the unexpected substances are set out in Table 6 of Annex I. For certain cementitious products the S/V ratio does not allow to meet the limit of  $\text{MTC}_{\text{tap}} = 1 \mu\text{g/L}$  as established for organic materials.

In this case  $\text{MTC}_{\text{tap}} < \text{Limit of Quantification}$  for the highest S/V ratio shall apply.

#### 4.2.4. Pass/fail criteria for Total Organic Carbon (TOC)

The following requirements shall apply to the cold water migration test:

- (a)  $C_{\text{tap}} \leq 0,5 \text{ mg/l}$  for the 3rd migration period or  $C_{\text{tap}} \leq 0,5 \text{ mg/l}$  for the 9th migration period and  $C_{\text{tap}} \leq 2,0 \text{ mg/l}$  for the 3rd migration period;
- (b) there shall be no increasing trend of  $C_{\text{tap}}$  in time.

The following requirements shall apply to the warm/hot water migration test:

- (a)  $C_{\text{tap}} \leq 0,5 \text{ mg/l}$  for the 7th migration period or  $C_{\text{tap}} \leq 0,5 \text{ mg/l}$  for the 22nd migration period and  $C_{\text{tap}} \leq 2,0 \text{ mg/l}$  for the 7th migration period.
- (b) there shall be no increasing trend of  $C_{\text{tap}}$  in time.

The measured TOC in the migration water from the successive migration periods shall be used to assess the trend. However, if the TOC in the relevant migration period is below 0,2 mg/l no trend analysis is required.

### 4.3. Odour, flavour, colour and turbidity

#### 4.3.1. Pass/fail criteria for TON, TFN

The following requirements shall apply to the cold water migration test:

- (a) TON, TFN  $\leq 2,0$  for the 3rd migration period; or
- (b) TON, TFN  $\leq 2,0$  for the 9th migration period and TON  $\leq 4,0$  for the 3rd migration period.

The following requirements shall apply to the warm/hot water migration test:

- (a) TON, TFN  $\leq 2,0$  for the 7th migration period; or
- (b) TON, TFN  $\leq 2,0$  for the 22nd migration period and TON, TFN  $\leq 4,0$  for the 7th migration period.

#### 4.3.2. Pass/fail criteria for colour

The acceptance criterion for colour is  $\leq 5 \text{ mg/l Pt/Co}$

The criterion shall be met for the 3rd migration period for cold water migration testing / 7th migration period for warm/hot water testing or in case of extended testing for the 9th migration period for cold water migration testing / 22nd migration period for warm/hot water testing.

#### 4.3.3. Pass/fail criteria for turbidity

The acceptance criterion for turbidity is  $\leq 0,5 \text{ NFU}$

The criterion shall be met for the 3rd migration period for cold water migration testing / 7th migration period for warm/hot water testing or in case of extended testing for the 9th migration period for cold water migration testing / 22nd migration period for warm/hot water testing.

### 4.4. Enhancement of Microbial Growth (EMG)

The pass/fail criteria for Enhancement of Microbial Growth (EMG) for method 1 (EN 16421:2015) is  $< 1\ 000 \text{ pg ATP/ cm}^2$  and for method 2 (EN 16421:2015) is  $\leq (0,05 \pm 0,02) \text{ ml/800 cm}^2$ .

Additionally, the surface of the products or components shall not have any biocidal effects on water intended for human consumption. Therefore, test pieces without surface colonisation (comparison of contact culture/test sample smear with that of the negative control) do not satisfy this requirement.

## ANNEX IV

**FINAL ENAMELS, CERAMIC MATERIALS AND OTHER INORGANIC MATERIALS (INCLUDING GLASS)****1. GENERAL PROCEDURE FOR TESTING AND ACCEPTING**

The procedure for testing and accepting final enamels, other glass materials, ceramic materials and other inorganic materials as used in a product includes the following steps:

**Step 1 – Identification of relevant substances and relevant other parameters depending on:**

1. Categorisation of products or components into risk groups and corresponding testing requirements.
2. Composition review

**Step 2 – Performance of tests**

1. Testing of composition
2. Migration test for relevant substances

**Step 3 – Compliance with pass/fail criteria****2. IDENTIFICATION OF RELEVANT SUBSTANCES AND RELEVANT OTHER PARAMETERS****2.1. Categorisation of products or components into risk groups and corresponding testing requirements.**

For each product or component of an assembled product, a product group and a corresponding conversion factor (CF) shall be determined in accordance with Table 5 of Annex I. Based on the determined CF, the product or component is categorised in a risk group (RG) in accordance with Table 1.

The categorisation in a RG determines the corresponding testing requirements including the relevant other parameters. The applicable testing procedure of final materials results from the use of these materials in products or components of assembled products.

Minor components are considered to be components categorised in risk group 4 (RG4) and for which reduced testing requirements, as set out in Table 1, may apply in comparison with the testing requirements for the risk group 1, 2 or 3 (RG1, RG2, RG3).

For an assembled product the components shall be determined. For each component in an assembled product, a product group shall be determined. If an assembled product consists of components made of the same final material, then the wetted surface fraction of these components shall be cumulatively added for the determination of the product group in accordance with Table 5 of Annex I.

The testing shall be performed on the final materials as used in products in contact with water intended for human consumption.



Table 1

**Risk-based testing requirements for products or components of assembled products**

<b>Risk group</b>	<b>Conversion factor CF in d/dm</b>	<b>Composition review &amp; testing</b>	<b>Specific migration testing</b>
RG 1	$\geq 4$	Yes	Yes, on product or component. Enamels: test piece(s) produced by enameller
RG 2	$\geq 0,4$ and $< 4$		
RG 3	$\geq 0,04$ and $< 0,4$	Yes	Yes, on product or component. Enamels: test pieces(s) produced by enamel manufacturer
RG 4	$< 0,04$	Yes	No

**2.2. Composition review***2.2.1. Required information*

For the final materials the complete composition with the range for all constituents exceeding 0,02 % (m/m) is required. The content of lead and cadmium shall be declared.

*2.2.2. Accepted compositions*

The compositions of the final materials shall comply with compositions listed in the European positive lists of compositions of enamels, ceramics and other inorganic materials set out in Table 1 of Annex IV of Commission Implementing Decision (EU) 2024/367, and fulfil the limitations set out in this European positive list in respect of their use for certain product groups and the use of these products.

The content of lead and cadmium shall be less than 0,02 % (m/m).

*2.2.3. Relevant substances*

The relevant substances to be analysed in migration waters are specified for each composition set out in the Annex IV to Commission Implementing Decision (EU) 2024/367.

**3. TESTING REQUIREMENTS****3.1. Testing of the composition**

An analysis of the composition of the final materials shall be performed to verify compliance with the compositional requirements of compositions of enamels, ceramics or other inorganic materials included in the Annex IV to Commission Implementing Decision (EU) 2024/367.

**3.2. Migration testing***3.2.1. Standards*

For testing the release of relevant substances, the following standard shall be used to obtain the migration waters: EN 12873-1:2014.

The following sections 3.2.2, 3.2.3, 3.2.4 and 3.2.5 substantiate this standard.

*3.2.2. Test piece*

Special attention shall be given to the production of the test piece. The respective component or product is to be used as test piece(s).

A specifically produced test piece shall only be used if the product cannot be tested.

### 3.2.3. Temperature of testing

All products shall be tested at  $23\text{ °C} \pm 2\text{ °C}$  (cold water test condition).

Additionally, products that are normally used for warm or hot applications shall be tested at  $60\text{ °C} \pm 2\text{ °C}$  or  $85\text{ °C} \pm 2\text{ °C}$ , respectively. For this purpose, warm water corresponds to normal operating temperatures between  $30\text{ °C}$  and  $70\text{ °C}$  and hot water corresponds to operating temperatures exceeding  $70\text{ °C}$ .

For materials that can be subjected to high temperature variation (for example, in solar water heaters), the test should be carried out at  $85\text{ °C}$ .

### 3.2.4. Type of test water

Cold water test ( $23\text{ °C} \pm 2\text{ °C}$ ) shall be performed with non-chlorinated test water. In the case PAH analysis is required the test shall be performed with chlorinated test water additionally.

In case a warm or a hot water test is required, the test shall only be performed with non-chlorinated test water.

### 3.2.5. Migration periods

For cold water tests the migration samples of the 1st, 2nd and 3rd migration period according to standards shall be analysed. The compliance with the pass/fail criteria shall be assessed at the 3rd migration period (10th day of testing). If the pass/fail criteria (see 4.2 and 4.3) are not met at the 3rd migration period, testing can be extended and the 5th, 7th and 9th period shall be analysed additionally. In this case the pass/fail criteria shall be assessed at the 9th migration period (31st day of testing).

For warm or hot water tests the migration samples of the 1st, 2nd, 3rd and 7th, migration period shall be analysed. The compliance with the pass/fail criteria shall be assessed at the 7th migration period (10th day). If the pass/ fail criteria (see 4.2 and 4.3) are not met at the 7th migration period, testing can be extended and the 12th, 17th and 22nd period shall be analysed additionally. In this case the pass/fail criteria shall be assessed at the 22nd migration period (31st day).

## 3.3. Analysis of migration waters

### 3.3.1. Relevant Substances

The methods for analysis of relevant substances in migration waters shall be validated and documented in accordance with EN ISO/IEC 17025:2017 or other equivalent standards accepted at international level.

## 4. ACCEPTANCE REQUIREMENTS: PASS/FAIL CRITERIA

### 4.1. Composition

The analysed composition of the final material shall comply with the compositional requirements and other limitations specified in the respective European positive list of compositions.

### 4.2. Relevant substances

#### 4.2.1. Conversion of test results

In accordance with the standard EN 12873-1:2014, the test results are expressed as migration rates (M) in  $\mu\text{g}/(\text{dm}^2 \cdot \text{d})$ . These results shall be converted to estimate the concentrations at the tap ( $C_{\text{tap}}$ ), defined as  $C_{\text{tap}} = M * \text{CF}$ , where CF is the corresponding conversion factor in  $\text{d}/\text{dm}$ .

The conversion factors for the different product groups are listed in Table 5 of Annex I.

#### 4.2.2. Pass/fail criteria for relevant substances

The following requirements shall apply to the cold water migration test:

- (a)  $C_{\text{tap}} \leq \text{MTC}_{\text{tap}}$  for the 3rd migration period (10th day of testing) or, in case extended testing is needed, at the 9th migration period (31st day of testing);

(b) there shall be no increasing trend of  $C_{\text{tap}}$  in time.

The following requirements shall apply to the warm/hot water migration test:

(a)  $C_{\text{tap}} \leq \text{MTC}_{\text{tap}}$  for the 7th migration period (10th day of testing) or, in case extended testing is needed, at the 22nd migration period (31st day of testing);

(b) there shall be no increasing trend of  $C_{\text{tap}}$  in time.

The measured substance concentrations in the migration water from the successive migration periods shall be used to assess the trend. However, if  $C_{\text{tap}}$  in the relevant migration period is below 1/10 of  $\text{MTC}_{\text{tap}}$ , no trend analysis is required.

The  $\text{MTC}_{\text{tap, inorganic}}$  to be applied are defined in the Annex IV and Table 1 of Annex V to Commission Implementing Decision (EU) 2024/367.

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