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

(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 ([1]), and in particular Article 11(2), point (a), thereof,

Whereas:

(1) Testing and acceptance methodologies should be established for assessing the safe use of starting substances, compositions and constituents.

(2) Inclusion or removal of an entry in a European positive list should be based on the identification of the starting substance, composition or organic cementitious constituent and the identification of its intended use. The physico-chemical properties of the starting substance, composition or organic cementitious constituent necessary for carrying out migration testing should be established. The starting substance, composition or organic cementitious constituent should be tested for migration.

(3) Inclusion or removal of an entry in a European positive list should be based on the identification of chemical species that are relevant for the acceptance methodology, or risk assessment, because they may have an impact on the safe use of a material or product, such as an impurity, the constituent of a starting substance or a degradation product. These relevant chemical species should be determined on the basis of the information on the identification of the starting substance, composition or constituent and on the basis of its intended use as well as the results of migration testing. The toxicological properties of these relevant chemical species should also be identified.

(4) For proportionality and efficiency reasons, testing for physico-chemical properties and toxicological properties as well as risk assessment should be more limited if a similar assessment has already been carried out at Union level within a reasonable period of time or if the substance has a stringent classification in Part 3 of Annex VI of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]) or the applicant proposes such classification. For proportionality reasons, the testing requirements for toxicological properties should be stricter where there is a high exposure to a certain substance through migration.

(5) In order to respect the precautionary principle and in order to cover the potential for significant exposure over a long period of time, the acceptance methodology should be based on a worst-case risk assessment of each relevant chemical species. The risk assessment should consider migration, including release, under the worst foreseeable conditions of use. In particular, the risk assessment should consider the expected long-term exposure to materials or products in contact with water intended for human consumption and, in the case of metallic compositions, the differences in the properties, such as composition and corrosivity, of all water in the Union intended for human consumption.

([1]) OJ L 435, 23.12.2020, p. 1.

([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(6) Economic operators and relevant authorities should be allowed sufficient time to adapt their national methodologies to the methodologies set out in this Decision. 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,

HAS ADOPTED THIS DECISION:

Article 1

Definitions

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

(1) 'non-intentionally added species' means either one of the following:

(a) an impurity of a starting substance or organic cementitious constituent or composition;

(b) a reaction product or a degradation product of a starting substance or organic cementitious constituent that forms during the processing or use of the material;

(c) a reaction product or a degradation product of a starting substance or organic cementitious constituent that forms in contact with water during the use of the material;

(2) 'nanoform' means a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm–100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm. For the purpose of this definition:

(a) 'particle' means a minute piece of matter with defined physical boundaries;

(b) 'aggregate' means a particle comprising strongly bound or fused particles;

(c) 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

(3) 'migration' means transfer of substances from a material into water intended for human consumption.

Article 2

Testing and acceptance of starting substances, compositions and constituents

1. The methodologies referred to in Article 11(2), point (a), of Directive (EU) 2020/2184 shall apply to the following:

(a) starting substance for organic materials;

(b) organic constituent of cementitious materials;

(c) composition of metallic materials;

(d) composition of enamels, ceramic and other inorganic materials.

2. Where a polymer is intended for use in an organic material or a cementitious material, the testing and acceptance methodologies shall be applied to the monomer, pre-polymer or polymer in accordance with the rules set out in points v to viii of Annex I and points iii and iv of Annex III to Commission Implementing Decision (EU) 2024/367 ([3]).

([3]) 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, 23.04.2024, ELI: http://data.europa.eu/eli/dec_impl/2024/367/oj).

Article 3

Testing methodology

1. Starting substances, compositions and organic cementitious constituents shall be identified in accordance with the requirements set out in Annex I.

2. The intended use of starting substances, compositions, constituents, as well as materials and products shall be specified in accordance with the requirements set out in Annex II.

3. The physico-chemical properties of the relevant chemical species shall be determined in accordance with the requirements set out in Annex III.

4. Migration into water intended for human consumption shall be determined in accordance with the requirements set out in Annex IV.

5. The relevant chemical species shall be identified in accordance with Section 3 of Annex IV.

6. The toxicological properties of the relevant chemical species referred to in paragraph 5 shall be determined in accordance with the requirements set out in Annex V.

Article 4

Acceptance methodology in the European positive lists

1. Starting substances, compositions and constituents shall be accepted in accordance with Annex VI on the basis of an assessment of the risks raised by the relevant chemical species identified for the corresponding starting substance, composition or organic cementitious constituent.

2. Starting substances and organic cementitious constituents which have a biocidal function and which are subject to Regulation (EU) No 528/2012 of the European Parliament and of the Council ([4]) shall only be accepted if they belong to product-type 6 (preservatives for products during storage) as set out in Annex V to that Regulation.

Article 5

Entry into force

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

([4]) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

ANNEX I

IDENTIFICATION OF STARTING SUBSTANCES, COMPOSITIONS AND CONSTITUENTS

Sufficient information to enable the identification of starting substances, compositions and constituents and characterisation of nanoforms shall be generated, including the information set out in the Table. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items referred to in the table, the reasons shall be clearly stated.

Table

Standard information and testing with regard to the identification of a starting substance, a composition or a constituent

		Starting substance for organic materials/ organic cementitious constituents	**Composition of metallic materials**	**Composition of enamels, ceramic, or other inorganic materials**
	Standard information and testing			
1.1.	**Name or any other identifier:**			
1.1.1.		Name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature and/or other international chemical names, if available.		
1.1.2.		Other names (e.g., usual name, trade name, abbreviation) (if available).		
1.1.3.		European Inventory of Existing Commercial Chemical Substances (Einecs), European List of Notified Chemical Substances (Elincs) or No-Longer Polymer (NLP) number, or the number assigned by ECHA under Regulation (EC) No 1907/2006, if available.	European Inventory of Existing Commercial Chemical Substances (Einecs), European List of Notified Chemical Substances (Elincs) or the number assigned by the Agency under Regulation (EC) 1907/2006, if available.	
1.1.4.		Chemical Abstracts Service (CAS) name and CAS number, if available.		
1.1.5.		European Union Positive List number, if available.	European Union Positive List number, if available.	European Union Positive List number, if available.

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
1.1.6.			Designation: • Standardised material designation number under European standard EN 1412, if available; • Standardised material designation symbol under international standard ISO 1190-1, if available.	Name of material category and name of enamel, ceramic or other inorganic composition.
1.1.7.			Identity of existing metallic composition category that the composition belongs to.	
1.1.8.			Identity and designation of new metallic composition category that the composition belongs to.	
1.1.9.			Identity of metal constituents of the new metallic composition category and corresponding concentration ranges (minimum and maximum % w/w).	
1.1.10.			Identity of metal impurities of the new metallic composition category present above 0,02 % w/w concentration in the composition and corresponding maximum percentage by mass (% w/w).	
1.1.11.			Identity of metal constituents of the reference material for the new metallic composition category and corresponding concentration ranges (minimum and maximum % w/w).	

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
1.1.12.			Identity of metal impurities of the reference material for the new metallic composition category that are present above 0,02 % w/w concentration in the composition and their corresponding concentration ranges (minimum and maximum, % w/w).	
1.2.	**Information related to molecular and structural formula or crystal structure:**			
1.2.1.		Molecular formula and structural formula (including IUPAC International Chemical Identifier (InChI), Simplified Molecular Input Line Entry System (SMILES) notation and other representation, if available).	Description of crystal structures, including crystalline phases, if available..	Description of crystal structures, including crystalline phases, if available..
1.2.2.		Information on optical activity and typical ratio of (stereo)isomers, if available.		
1.2.3.		Molecular weight or molecular weight range, if available.		
1.3.	**Chemical characterisation. Where it covers a nanoform, this nanoform shall be characterised pursuant to point 1.4.:**			
1.3.1.		Degree of purity (%), i.e., typical concentration and concentration range (in percentage, minimum and maximum) of substance constituents.		

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
1.3.2.		Names (EC, CAS numbers, and other identifiers, if available) of substance constituents present above 0,02 % w/w concentration in the formulation and at concentration ≥ 0,1 % w/w in the substance (taking into account information submitted under points 1.1.1, 1.1.2 and 1.1.3 above and Table 1, point 2.4.1 of Annex II). For each of these, typical concentration and concentration range (minimum and maximum % w/w).	Names (and other identifiers e.g. EC, CAS numbers) of constituents of the composition, i.e., the elements in any form (e.g., bound or unbound) and corresponding concentration ranges (minimum and maximum % w/w).	Names (and other identifiers e.g. EC, CAS numbers) of constituents of the composition, i.e., the elements in any form (e.g., bound or unbound) and corresponding concentration ranges (minimum and maximum % w/w).
1.3.3.		Names (and other identifiers e.g. EC, CAS numbers) of impurities present above 0,02 % w/w concentration in the formulation of the final material and at concentration ≥ 0,1 % w/w in the substance (taking into account information submitted under points 2.4.1. and 2.4.2. of Table 1 of Annex II). For each of these, typical concentration and concentration range (minimum and maximum % w/w).	Names (and other identifiers e.g. EC, CAS numbers) of impurities present above 0,02 % w/w concentration in the composition and corresponding maximum percentage by weight (% w/w).	• Names (and other identifiers e.g. EC, CAS numbers) of impurities, other than cadmium (Cd) and lead (Pb) present above 0,02 % w/w concentration in the composition and corresponding maximum percentage by weight (% w/w); • Information on the maximum percentage by weight (% w/w) for cadmium (Cd) and lead (Pb).
1.3.4.		All necessary qualitative and quantitative analytical data specific for the identification of the substance, such as ultraviolet, infra-red, nuclear magnetic resonance, mass spectrum, chromatographic, titrimetric, elemental analysis and/or diffraction data.	All necessary qualitative and quantitative analytical data specific for the identification of the composition and constituents of the composition, such as elemental analysis, Inductively Coupled Plasma Mass Spectrometry, Atomic Absorption Spectroscopy, Ion Chromatography, titrimetric and/or diffraction data (e.g., X-Ray Fluorescence (XRF) or X-Ray Powder Diffraction (XRD).	

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
1.3.5.		Description of the analytical methods or the appropriate bibliographical references that are necessary for the identification of the starting substance, organic cementitious constituent (including the identification and quantification of impurities and substance constituents), metallic composition constituent, and enamel, ceramic, or other inorganic composition constituent. The description shall consist of the experimental protocols followed and the relevant interpretation of the results reported under points 1.3.1. to 1.3.4. This information shall be sufficient to allow the methods to be reproduced.		
1.4.	**Characterisation of a nanoform:**			
1.4.1.		Names or other identifiers of the nanoform of the starting substance or organic cementitious constituent, if applicable.		
1.4.2.		Number based particle size distribution with indication of the number fraction of nanoform particles in the size range 1 nm – 100 nm.		
1.4.3.		Description of surface functionalisation or treatment and identification of each agent including IUPAC name and CAS or EC number.		
1.4.4.		Shape, aspect ratio and other morphological characterisation: crystallinity, information on assembly structure, including e.g., shell like structures or hollow structures, if available.		
1.4.5.		Surface area (specific surface area by volume, specific surface area by mass or both).		
1.4.6.		Description of the analytical methods or the appropriate bibliographical references for the information elements in point 1.4. This information shall be sufficient to allow the methods to be reproduced.		

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
1.5.	**Additional information required for starting substances and organic cementitious constituents which are (a) polymers or (b) pre-polymers**:			
1.5.1.		Name (and other identifiers e.g. EC, CAS numbers) of monomers and other reactants from which the substance is produced.		
1.5.2.		Manufacturing process description (including information on the use of monomers and reactants as well as their ratio).		
1.5.3.		Additives to the (pre-)polymer.		
1.5.4.		Structure information of the (pre-)polymer.		
1.5.5.		Molecular mass distribution; test report of the molecular mass distribution is required.		
1.5.6.		Number averaged molecular mass.		
1.5.7.		Molecular mass range (minimum and maximum).		
1.5.8.		Identities of the substance constituents with molecular weight < 1000 Da and their percentage by weight (% w/w).		
1.5.9.		Residual monomers and their concentrations (%).		
1.5.10.		Viscosity		
1.5.11.		Melt flow index		

ANNEX II

INTENDED USE

Sufficient information on the intended use of starting substances, compositions, constituent as well as of final materials and products shall be generated, including the information set out in Table 1.

Table 1

Standard information and testing with regard to intended use

		Starting substance for organic materials/ organic cementitious constituents	**Composition of metallic materials**	**Composition of enamels, ceramic, or other inorganic materials**
	Standard information and testing			
2.	**Use:**			
2.1.	**Material type, category and sub-category:**	Identification of the material type, material category and material sub-category.		
2.2.	**Identity and use of final material and product:**			
2.2.1.		Specification of the product/component. Definition of area of uses: domestic vs. non-domestic installations.		
2.2.2.		Relevant product groups for organic materials or cementitious materials (refer to Table 5 of Annex I to Commission Implementing Decision (EU) 2024/368 [1].	Relevant product groups for metallic compositions (refer to Table 2 of this Annex).	Relevant product groups for enamel, ceramic or other inorganic materials (refer to Table 5 of Annex IV to Commission Implementing Decision (EU) 2024/368.
2.2.3.		Cold (≤ 25 °C)/warm (25 – 65 °C) or hot (≥ 65 °C) water use.	Cold (≤ 25 °C)/warm (25 – 65 °C) or hot (≥ 65 °C) water use.	Cold (≤ 25 °C)/warm (25 – 65 °C) or hot (≥ 65 °C) water use.
2.3.	**Technical function:**	Specification of the technical function.		
2.4.	**Conditions of use of the starting substance, composition or organic cementitious constituent; of the final material; and of the product:**			

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
2.4.1.		For starting substances for organic materials: Maximum dosage of the starting substance in the formulation to produce the final material.		
2.4.2.		For organic constituents of cementitious materials: • In case of polymers: Dosage of the monomers or other reactants to produce the polymers • Maximum dosage of the constituent (polymer) to produce a generic constituent. • Maximum dosage of the generic constituent used in the formulation to produce the final material.		
2.4.3.		Proposed restrictions or other conditions of use for the inclusion of the starting substance, composition or constituent on the European positive list.		
2.5.	**Information on the processing and internal structure of the material, final material and product:**			
2.5.1.		Information on the processing of the material, final material and product, including treatment of material, final material or product prior to use.		

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
2.5.2.		Processing temperatures of the final material.	• Description of the manufacturing and processing steps used to produce the final material. For bulk materials this includes description of any processing such as mechanical (forming), thermal (heat treatment) affecting crystallography, grain morphologies (size and shape), phase structure, impurities and their distribution, residual stresses, microstructure and/or surface condition. For specifically produced surface layers, platings, the applied surface of the plating, process type and main processing conditions as well as plating properties should be described; • Appropriate manufacturing and processing steps and resulting properties, such as 'heat treatment to reduce beta-phase' or 'phase distribution in the final material'.	Processing temperatures of the final material.
2.5.3.		Information on the internal structure of the final material.		
2.6.	**Union and national level assessments and authorisations:**			
2.6.1.		Details of any authorisation, risk assessment and other relevant regulation at the European Union or national level for use in final materials or materials coming into contact with water intended for human consumption.		
2.6.2.		Details of any authorisation, risk assessment and other relevant regulation at the European Union or national level for use in final materials or materials coming into contact with food.		
2.7.	**EU authorisation of biocidal active substances:**			

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
2.7.1.		Approval/assessment status of the starting substance or organic cementitious constituent under Regulation (EU) No 528/2012.		
2.7.2.		Product-type relevant to the starting substance or organic cementitious constituent under Regulation (EU) No 528/2012.		
2.7.3.		Approval start date under Regulation (EU) No 528/2012.		
2.7.4.		Approval end date under Regulation (EU) No 528/2012.		
3.	**Identification of non-intentionally added species other than impurities:**			
3.1.		Evaluation on the presence of non-intentionally added species other than impurities and substance constituents migrating from the material taking into account at least the following: (a) physico-chemical properties; (b) technical functions; (c) interaction with the matrix; (d) water characteristics; (e) results of analysis of testing waters by applying an appropriate screening method as set out in Commission Implementing Decision (EU) 2024/368		

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
3.2.		Reactions of the starting substance or organic cementitious constituent occurring during the processing of the material and final material and reaction or degradation products formed (also taking into account the thermal stability as demonstrated by a mandatory thermal stability test, of the substance)		
3.3.		Reactions of the starting substance or organic cementitious constituent occurring during the use of the final material in contact with water intended for human consumption and reaction or degradation products formed (also taking into account hydrolysis as demonstrated by a mandatory hydrolysis study of the substance).		
3.4.	**Identification of other substances that may migrate into the drinking water when using starting substances and organic cementitious constituents which are monomers or other reactants:**			
3.4.1.		Evaluation of the presence of any polymerised part below 1000 Da that is relevant to the use of the starting substance or organic cementitious constituent.		
3.4.2.		Description of process that leads to the formation of the polymerised part below 1000 Da.		

		Starting substance for organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
3.4.3.		Molecular weight distribution for polymerised part below 1000 Da; test report of the molecular weight distribution is required.		
3.4.4.		Number averaged molecular weight of polymerised part below 1000 Da.		
3.4.5.		Molecular mass range (min and max) of polymerised part below 1000 Da.		
3.4.6.		Residual polymerised part below 1000 Da and its concentration (%).		
3.5.		Name (and other identifiers e.g. EC, CAS numbers) of non-intentionally added species identified under points 3.1.–3,4.		

(1) 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 (OJ L, 2024/368, 23.04.2024, ELI: http://data.europa.eu/eli/dec_impl/2024/368/oj).

Table 2

Product groups for metallic compositions

Product group	Examples of metallic products or components	Assumed contact surface 'a'
A	Pipes.	100 %
B	Fittings, ancillaries in buildings installations.	10 %
C	1. Components of products of Product Group B. The sum of the surfaces in contact with water intended for human consumption of all these components shall be less than 10 % of the total wetted surface of the product. 2. Fittings, ancillaries in water mains and water treatment works with permanent flow.	1 %
D	Components of fittings and ancillaries in water mains and in water treatment works as described for product group C subcategory 2 above).	< 0,1 %

ANNEX III

PHYSICO-CHEMICAL PROPERTIES

Section 1. No standard information or testing requirement

No standard information or testing shall be required for starting substances and organic cementitious constituents where either of the following conditions are fulfilled:

(a) a parametric value for the starting substance or organic cementitious constituent is set under Annex I to Directive (EU) 2020/2184;

(b) a Maximum Tolerable Concentration at the tap (MTC_{tap}) value for the starting substance or organic cementitious constituent is set in the corresponding Annex to Commission Implementing Decision (EU) 2024/367 ([1]) following a decision by the Commission on an application for a starting substance, composition or organic cementitious constituent that has been submitted to ECHA under Article 3 of Commission Delegated Regulation (EU) 2024/369 ([2]) and the applicant submits at least any new or updated information available as from the date of the Commission's decision;

(c) a specific migration limit is set under Commission Regulation (EU) No 10/2011 ([3]) for less than 15 years before the submission of an application under Article 3 of Delegated Regulation (EU) 2024/369.

Section 2. Standard information or testing required

2.1. Testing under this Section shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC of the European Parliament and of the Council ([4]) or other international standards recognised as being equivalent to Directive 2004/10/EC by the Commission or ECHA.

2.2. Testing under this Section shall be carried out in compliance with the test method as determined and specified by ECHA and published on its website, taking into account in particular the requirements set out in point 2.5.

2.3. Column 1 of Table 1 establishes the required standard information and testing for a starting substance or organic cementitious constituent.

Column 1 of Table 1, points 4.7 and 4.8 establish the required standard information and testing for relevant chemical species other than a starting substance or organic cementitious constituent.

Column 1 of Table 1, points 4.1.3, 4.2 and 4.4 establish the required standard information and testing for a metallic, enamel, ceramic or other inorganic composition.

([1]) 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, 23.04.2024, ELI: http://data.europa.eu/eli/dec_impl/2024/367/oj).

([2]) Commission Delegated Regulation (EU) 2024/369 of 23 January 2024 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down the procedure regarding inclusion in or removal from the European positive lists of starting substances, compositions and constituents (OJ L, 2024/369, 23.04.2024, ELI: http://data.europa.eu/eli/reg_del/2024/369/oj).

([3]) 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).

([4]) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

Column 2 of Table 1 establishes specific rules according to which the standard information and testing of column 1 may be omitted, replaced by other information, or adapted in another way.

2.4. Any other relevant physico-chemical information shall be identified and considered in addition.

2.5. Where a test method offers flexibility in the determination or choice of the study design, including by not prohibiting certain specifications, the chosen study design shall ensure that the data generated are adequate for migration testing and risk assessment.

2.6. The general rules for adaptations set out in Sections 1 and 2 of Annex XI to Regulation (EC) No 1907/2006 ([5]) shall apply *mutatis mutandis*.

Table 1

Standard information and testing, and specific rules for the adaptation of such information and testing, with regard to physico-chemical properties

	Column 1 **Standard information and testing**	**Column 2** **Specific rules for adaptation of the standard information and testing**
4.1.	Appearance at 20 °C and 101,3 kPa	
4.1.1.	Physical state	
4.1.2.	Aggregate state (e.g., viscous, crystalline, powder)	
4.1.3.	Colour	
4.1.4.	Odour	
4.2.	Melting/freezing point	No need to provide information below a lower limit of – 20 °C.
4.3.	Boiling point	No need to provide information for the following: (a) gases; (b) solids which either melt above 300 °C or decompose before boiling, in which case the boiling point under reduced pressure may be estimated or measured; (c) substances which decompose before boiling (e.g. auto-oxidation, rearrangement, degradation, decomposition, etc.).
4.4.	Density	The study for density does not need to be conducted in the following cases: (a) the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent, in which case an indication of whether the solution density is higher or lower than the solvent density is sufficient; (b) the substance is a gas, in which case an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.

([5]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1-849).

	Column 1 **Standard information and testing**	**Column 2** **Specific rules for adaptation of the standard information and testing**
4.5.	Vapour pressure	No need to provide information if the melting point is above 300 °C. If the melting point is between 200 °C and 300 °C, a limit value based on measurement or a recognised calculation method is sufficient.
4.5.1.	Henry's law constant must always be stated for solids and liquids if it can be calculated.	
4.6.	Surface tension of an aqueous solution	The information need only be provided in the following cases: (a) based on structure, surface activity is expected or can be predicted; (b) surface activity is a desired property of the material; If the water solubility is below 1 mg/l at 20 °C, the test does not need to be conducted.
4.7.	Water solubility	No need to provide information in the following cases: (a) the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours); (b) the substance is readily oxidisable in water. If the substance appears 'insoluble' in water, a limit test up to the detection limit of the analytical method shall be performed. For metals and sparingly soluble metal compounds, information on transformation/dissolution in aqueous media shall be provided.
4.8.	Partition coefficient (*n*-octanol/water) and its pH dependency	No need to provide information if the substance is inorganic. If the test cannot be performed (e.g., the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for the partition coefficient as well as details of the calculation method shall be provided.
4.9.	Granulometry	The study does not need to be conducted if the substance is marketed or used in a non-solid or non-granular form.
4.10.	Dissociation constant	No need to provide information in the following cases: (a) the substance is hydrolytically unstable (half-life less than 12 hours) or is readily oxidisable in water; (b) it is scientifically not possible to perform the test, for instance if the analytical method is not sensitive enough; (c) based on the structure, the substance does not have any chemical group that can dissociate.

ANNEX IV

MIGRATION AND CONFIRMATION OF RELEVANT CHEMICAL SPECIES

Section 1. General requirements, standard information and testing for the determination of migration

1.1. Any testing under this Section shall be carried out in compliance with the principles of good laboratory practice provided for in standard EN ISO/IEC 17025 or other international standards recognised as being equivalent by the Commission or ECHA.

1.2. Any testing or modelling shall follow the appropriate test method determined by ECHA and published on its website or identified below. Such testing or modelling shall also follow the specifications determined by ECHA and published on its website to ensure adequate and reliable conclusion on migration, taking into account the requirement for migration determination based on worst foreseeable conditions of use.

1.3. Any testing or modelling under this Section shall be carried out on the basis of the intended use for the starting substance, composition or constituent and the test piece shall be representative of worst foreseeable conditions of use.

1.4. Sufficient information on the determination of the migration of all the following substances, at least including the information set out in Table 1, shall be generated:

(a) the starting substance, organic cementitious constituent, substance constituent, and each non-intentionally added species identified in accordance with points 1.3 and 1.5, in the table of Annex I and point 3 in Table 1 of Annex II as well as any starting substance or an organic cementitious constituent which functions as a monomer or other reactant of a main polymer in the material;

(b) each metallic composition constituent and impurity identified in accordance with points 1.3.2 and 1.3.3 in the table of Annex I, unless:

(i) the metallic composition constituent is phosphorus, silicon, sulfur or tin; or

(ii) the metallic composition impurity is aluminium, iron, manganese, phosphorus, silicon, tin or zinc;

(c) each inorganic composition constituent and impurity identified in accordance with points 1.3.2 and 1.3.3 in the table of Annex I, unless the inorganic composition constituent is carbon, calcium, fluorine, iron, magnesium, nitrogen, phosphorus, potassium, silicon, sodium, tin or zinc.

1.5. In case of starting substances which are metals or alloys that are not included in the European positive list of compositions as metallic materials, the migration waters resulting from testing of a representative test piece of the final material shall be analysed in accordance with the rules set out in point Section 1.4(b).

1.6. Any other relevant migration information that is available shall be identified and considered.

Table 1

Standard information and testing with regard to migration

		Starting substance or organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
5.	**Migration:**			
5.1.	Test pieces			
5.1.1.		Detailed description of the test pieces including dimensions, the production of the test pieces and the storage of the test pieces between the production and the sampling including the name of the producer of the test pieces.		
5.1.2.		Dosage of the starting substance/organic cementitious constituent to produce the test pieces.		
5.1.3.		Concentration of the starting substance/ organic cementitious constituent in the test pieces.		
5.1.4.			Composition of the test pieces.	Composition of the test pieces.
5.1.5.			Roughness of the inner surface of the test pieces.	
5.2.	Testing for hygienic safety via migration methods or electrochemical methods of the substances as specified in Annex IV Section 1.4.	Test method for factory-made products and site applied products made from or incorporating organic materials according to standards referred to in Annex I to Commission Implementing Decision (EU) 2024/368.	(a) All metallic compositions: Test method for dynamic rig test established in standard EN 15664-1 for assessment of metal release. (b) Metallic compositions which exhibit passive behaviour in contact with water intended for human consumption: Test method established in standard EN 16056 to evaluate the passive behaviour of stainless steels and other passive metallic compositions. (c) Platings: • Tests method referred to in point (a); or	Test method for products made from or incorporating glassy (porcelain/vitreous enamel) materials according to the standard described in Annex IV Commission Implementing Decision (EU) 2024/368.

		Starting substance or organic materials/ organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
			• The test method established in standard EN 16058, with 3 different test pieces.	
5.3.	Analytical methods and techniques	For testing in accordance with point 5.2. (excluding the test method to evaluate the passive behaviour of stainless steels and other passive metallic compositions): Description and details of analytical methods and techniques used to analyse concentrations of potentially relevant chemical species or elements from migration and/or contact water resulting from migration testing. For surface layers (coatings, platings) this includes relevant chemical species or elements from the surface layer and from the substrate. The methods and techniques shall be validated and shall comply with minimum performance criteria. The description shall consist of the experimental protocols followed and the relevant interpretation of the results. This information shall be sufficient to allow the methods to be reproduced.		

Section 2. General rules for adaptation of information and testing with regard to the migration

2.1. A prediction of migration in organic materials using mathematical modelling in accordance with the migration testing standard set out in Annex I of Commission Implementing Decision (EU) 2024/368 may replace testing for a substances as specified in Annex IV, Section 1.4 used in an organic material where, on the basis of a scientific explanation, any of the following conditions is met:

(a) testing is demonstrated to be not technically possible;

(b) testing would require a concentration of the substance in water below the limit of quantification, using the best available technique;

(c) the test substance rapidly degrades in water.

2.2. Physical testing of a metallic composition may be waived if its migration is likely to be similar, as a result of compositional and structural similarities, to another metallic composition and the following conditions are met:

(a) For ferrous compositions, the compositions are used under permanent water flow and the supporting explanation takes into account water compositions and, in particular, oxygen concentration;

(b) For copper alloys:

(i) the alloys have similar corrosion behaviour;

(ii) the representative test piece belongs to the same metallic composition category;

(iii) the alloys have identical alloying elements, impurities and microstructure;

(iv) the constituents and impurities of the similar metallic composition have MTC_{tap} values higher than 100 µg/l.

(c) For both ferrous compositions and copper alloys (a) and (b):

(i) an adequate and reliable migration test for the similar metallic composition has been carried out;

(ii) adequacy for the purpose of concentration at the tap (C_{tap}) determination and identification of relevant chemical species has been demonstrated;

(iii) the C_{tap} and identification of relevant chemical species of that similar metallic composition have been used.

In all cases, adequate and reliable documentation of the applied method shall be provided. Such documentation shall include an explanation why the migration of the metallic composition may be determined based on the information on the similar metallic composition and supporting information to scientifically justify such explanation.

Section 3.Criteria for the identification of relevant chemical species

Relevant chemical species are those that are covered by the requirements set out in Annex V in order to demonstrate that the starting substance, composition or constituent meets the acceptance criteria set out in Annex VI. Relevant chemical species include the following:

(a) starting substances and organic cementitious constituents which function as a monomer or other reactant of a main polymer in the material;

(b) starting substances, organic cementitious constituents, substance constituents and non-intentionally added species originating from the starting substance or organic cementitious constituent which show one of the human health hazards referred to in Section 1.1 of Annex VI irrespective of their levels of migration;

(c) starting substances, organic cementitious constituents, substance constituents and non-intentionally added species originating from a starting substance or organic cementitious constituent which do not fall under point (a) or (b) and which have been tested in accordance with Table 1 and have been found to migrate into water intended for human consumption with a concentration at the tap (C_{tap}) exceeding 0,1 µg/l;

(d) metallic composition constituents or impurities, which have been tested in accordance with Table 1;

(e) enamel, ceramic or other inorganic composition constituents or impurities of an enamel, ceramic or other inorganic composition which have been tested in accordance with Table 1.

ANNEX V

TOXICOLOGICAL PROPERTIES

Section 1. No standard information or testing

1.1. No standard information or testing is required for a relevant chemical species where either of the following conditions are fulfilled:

(a) a parametric value for the relevant chemical species is set under Annex I to Directive (EU) 2020/2184;

(b) a MTC_{tap} value for the relevant chemical species in the applicable material type is set in the corresponding Annex to Implementing Decision (EU) 2024/367 following a decision by the Commission on an application for a starting substance, composition or constituent that has been submitted to ECHA under Article 4 of Delegated Regulation (EU) 2024/369 and the applicant submits at least any new or updated information available as from the date of the Commission's decision;

(c) the relevant chemical species is classified in Regulation (EC) No 1272/2008 of the European Parliament and of the Council [1] as one of the following:

(i) Category 1A or 1B for carcinogenicity, mutagenicity or reproductive toxicity or Category 1 for endocrine disruption for human health;

(ii) persistent bioaccumulative and toxic;

(iii) very persistent and very bioaccumulative;

(iv) persistent mobile and toxic;

(v) very persistent and very mobile;

(d) the relevant chemical species is identified as a substance of very high concern in the Candidate List established under Article 59 of Regulation (EC) No 1907/2006, except those identified on the basis of Article 57(f) of Regulation (EC) No 1907/2006 only for the environment;

(e) the relevant chemical species is authorised as an active substance under Regulation (EU) No 528/2012 on the basis of an opinion of the Committee of the Risk Assessment of ECHA setting a defined safety threshold for the oral route and used as such in materials in contact with water under Product-type 6.

1.2. No standard information or testing is required for a relevant chemical species, to the extent that a specific migration limit is set under Commission Regulation (EU) No 10/2011 for less than 15 years from the date of submission of the application under Article 3 of Delegated Regulation (EU) 2024/369.

Section 2. Standard information or testing required

Part 1. General and specific rules

1.1. Testing under this Section shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or ECHA and with the provisions of Directive 2010/63/EU of the European Parliament and of the Council [2], if applicable.

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

[2] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010. on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

1.2. Any applicant shall ensure that testing on vertebrate animals is carried out only when no alternative methods, identified under this Section, is available. If testing on vertebrate animals is unavoidable, such testing shall be designed, where appropriate, by taking into account the possibility to explore several parameters within the framework of one study (e.g. kinetic data generation, micronucleus formation, neurotoxicity, immunotoxicity) or to combine two studies (e.g. long-term toxicity study and carcinogenicity study) to the extent permitted by the corresponding test method.

1.3. Testing under this Section shall be carried out in compliance with the appropriate test guideline determined and specified by ECHA and published on its website, taking into account in particular the requirements set out in Section 1.6.

1.4. A stepwise approach for toxicological testing shall be applied based on the C_{tap} of a relevant chemical species in water intended for human consumption. For the lowest migration concentration band, the standard information is set out in Table 1, and every time a new migration band is reached, the standard information set out in the corresponding Tables 2 and 3 shall be added.

Column 1 of Tables 1, 2 and 3 establishes the standard information for relevant chemical species.

Column 2 of Tables 1, 2 and 3 lists specific rules according to which the standard information and testing may be omitted.

Standard information and testing may be adapted according to the general rule set out in Part 2.

1.5. Any other relevant toxicological information that is available shall be identified and considered.

1.6. Where a test method offers flexibility in the determination or choice of the study design, including by not prohibiting certain study specifications, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physico-chemical properties or biological effects of the test substance, the applicant shall provide a scientifically robust justification.

Table 1

Standard information and testing – C_{tap} below 2,5 µg/l

	Column 1 **Standard information and testing**	**Column 2** **Specific rules for adaptation of the standard information and testing**
6.1.	**Genotoxicity/Mutagenicity:**	
6.1.1.	*In vitro* genetic toxicity	
6.1.1.1.	*In vitro* gene mutation study in bacteria	The *in vitro* gene mutation study in bacteria does not need to be conducted if this test is not applicable for the relevant chemical species. In this case, the applicant shall provide a justification and perform an *in vitro* study referred to in point 6.1.1.3. The study does not need to be conducted for nanoforms where it is not appropriate. In this case, other studies involving one or more *in vitro* mutagenicity studies in mammalian cells shall be provided.

	Column 1 **Standard information and testing**	**Column 2** **Specific rules for adaptation of the standard information and testing**
6.1.1.2.	*In vitro* mammalian chromosomal aberration study or *in vitro* mammalian micronucleus study	The study does not need to be carried out if an adequate data from an *in vivo* cytogenicity test is available.
6.1.1.3.	*In vitro* gene mutation test in mammalian cells	The study shall be carried out in the following cases: (a) there are negative results in both *in vitro* studies referred to in points 6.1.1.1. and 6.1.1.2.; (b) the *in vitro* study referred to in point 6.1.1.1. is inapplicable to the relevant chemical species. The study does not need to be carried out if there are adequate data from a reliable *in vivo* mammalian gene mutation test.
6.1.2.	*In vivo* genetic toxicity	
6.1.2.1.	An appropriate *in vivo* mammalian somatic cell genotoxicity study	The study shall be carried out if there is a positive result in any of the *in vitro* genotoxicity study referred to in point 6.1.1. which gives rise to a concern. The study shall address the chromosomal aberration concern or the gene mutation concern or both, as appropriate.
6.1.2.2.	An appropriate *in vivo* mammalian germ cell genotoxicity study	The study shall be carried out if there is a positive result in an available *in vivo* mammalian somatic cell genotoxicity study, which gives rise to concern. The study shall address the chromosomal aberration concern or the gene mutation concern or both, as appropriate. The study does not need to be conducted if there is clear evidence that neither the relevant chemical species nor its metabolites reach the germ cells.
6.2.	**Appropriate toxicokinetic and metabolism studies in mammals, appropriate repeated dose toxicity study, appropriate reproductive toxicity study, appropriate carcinogenicity study or appropriate additional studies referred to in Tables 2 and 3**	The study shall be carried out if there is any of the information available, raises a concern for at least one of the following hazard classes defined in Annex I to Regulation (EC) No 1272/2008: Specific Target Organ Toxicity – Repeat Exposure (STOT RE), Carcinogenicity, Mutagenicity or Reprotoxicity (CMR) or endocrine disruption for human health. The study shall address each of the concerns identified.

Table 2

Standard information and testing – C_{tap} equal to or above 2,5 µg/L and below 250 µg/L

	Column 1 **Standard information and testing**	**Column 2** **Specific rules for adaptation of the standard information and testing**
7.1.	**Toxicokinetics and metabolism studies in mammals:**	
7.1.1.	Data to demonstrate the absence of potential for accumulation in human	
7.2.	**Repeated dose toxicity:**	
7.2.1.	Sub-chronic repeated dose toxicity study (90-days) in one animal species (rodents), male and female, via oral route of administration	The study does not need to be conducted where any of the following conditions are fulfilled: (a) a reliable short-term toxicity study (28 days) or a repeated dose toxicity study with the reproduction/developmental toxicity screening test is available showing severe toxicity effects according to the criteria for classifying the relevant chemical species as STOT RE (Regulation (EC) No 1272/2008), for which the observed No Observed Adverse Effect Level (NOAEL)-28 days, with the application of an appropriate assessment factor allows the extrapolation towards the NOAEL-90 days for the same route of exposure; (b) a reliable chronic toxicity study is available, in which an appropriate animal species and route of administration were used; (c) the relevant chemical species is unreactive, insoluble, not bioaccumulative and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test'.
7.3.	**Reproductive toxicity:**	
7.3.1.	Reproduction/Developmental toxicity screening study	The study does not need to be conducted where any of the following conditions are fulfilled: (a) a reliable extended one-generation reproductive toxicity study is available, in which an appropriate animal species and route of administration were used; (b) the relevant chemical species is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via the oral route of exposure, e.g., plasma/blood concentrations below detection limit using a sensitive method and the relevant chemical species and its metabolites are absent in urine or bile.

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
7.4.	**Appropriate toxicokinetic and metabolism studies, appropriate repeated dose toxicity study, appropriate reproductive toxicity study, appropriate carcinogenicity study or appropriate additional studies referred to under Table 3**	The study shall be carried out if any information available raises a concern for at least one of the following hazard classes defined in Annex I to Regulation (EC) No 1272/2008: STOT RE or CMR or endocrine disruption for human health. The study shall address each of the concerns identified.

Table 3

Standard information and testing – C_{tap} equal or above 250 µg/L

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
8.1.	**Toxicokinetics and metabolism studies in mammals:**	
8.1.1.	Study on absorption, distribution, metabolism and excretion	
8.1.2.	Considerations on the potential need for additional toxicokinetic information	Additional information might be needed based on the outcome of the toxicokinetic and metabolism study conducted in rats or based on the evaluation of the toxicological and physicochemical profile of the relevant chemical species.
8.2.	**Repeated dose toxicity:**	
8.2.1.	Long-term repeated dose toxicity (≥ 12 months), oral route of administration	This study does not need to be conducted if the combined chronic toxicity/carcinogenicity study referred to in point 8.4.1. is provided.
8.3.	**Reproductive toxicity:**	The studies do not need to be conducted where the relevant chemical species is of low toxicological activity (no evidence of toxicity seen in any of the tests available, in which a sufficiently comprehensive and informative dataset has been used), it can be proven from toxicokinetic data that no systemic absorption occurs via the oral route of exposure, e.g., plasma/blood concentrations below detection limit using a sensitive method and the relevant chemical species and its metabolites are absent in urine or bile.
8.3.1.	Extended one-generation reproductive toxicity study, oral route of administration	An Extended One-Generation Reproductive Toxicity Study with the extension of cohort 1B to include the F2 generation where any of the following conditions are met: (a) the relevant chemical species displays genotoxic effects in somatic cell mutagenicity tests *in vivo* which could lead to its classification as mutagen category 2; (b) there are indications that the internal dose for the relevant chemical species and/or any of its metabolites will reach a steady state in the test animals only after an extended exposure;

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		(c) there are indications of one or more relevant modes of action related to endocrine disruption from available *in vivo* studies or non-animal approaches. An Extended One-Generation Reproductive Toxicity Study including cohorts 2A/2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) shall be included in case of particular concerns on (developmental) neurotoxicity or (developmental) immunotoxicity justified by any of the following: (a) existing information on the relevant chemical species itself derived from relevant available *in vivo* or non-animal approaches (e.g., abnormalities of the central nervous system (CNS), evidence of adverse effects on the nervous or immune system in studies on adult animals or animals exposed prenatally); (b) specific mechanisms/modes of action of the relevant chemical species with an association to (developmental) neurotoxicity and/or (developmental) immunotoxicity (e.g., cholinesterase inhibition or relevant changes in thyroidal hormone levels associated to adverse effects); (c) existing information on effects caused by substances analogous to the relevant chemical species being studied, suggesting such effects or mechanisms/modes of action. Two-generation reproductive toxicity studies that were initiated before 13 May 2015 shall be considered appropriate to address this standard information requirement.
8.3.2.	Prenatal developmental toxicity study, in rat, unless another animal species is justified to be more appropriate, oral route of administration	
8.3.3.	Further pre-natal developmental toxicity study, in a second animal species, oral route of administration or mechanistic study	A decision on the need to perform additional studies on a second animal species or mechanistic studies shall be based on the outcome of the first test (point 8.3.2.) and all other relevant available data (in particular rodent reproductive toxicity studies).
8.4.	**Carcinogenicity:** See 8.4.1 for new study requirements	The study does not need to be provided where all of the following conditions are fulfilled: (a) no genotoxic potential is identified in genotoxicity tests; and

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		(b) the sub-chronic and long-term (≥ 12 months) toxicity studies show no evidence of toxicity at the limit dose level.
8.4.1	Combined Chronic Toxicity/Carcinogenicity study oral route of administration	The study does not need to be conducted if adequate data from a reliable carcinogenicity study, oral route of administration is available: in such circumstances the long term repeated dose toxicity study referred to in point 8.2.1. must be provided.
8.5.	**Additional toxicity properties:**	If there is an indication for one or more mechanisms/modes of action of the relevant chemical species with an association to (developmental) neurotoxicity and/or endocrine disruption and/or (developmental) immunotoxicity, corresponding additional data shall be generated in accordance with this point, unless already fully covered by the information under point 8.3.1.
8.5.1.	Appropriate neurotoxicity information or study, including developmental neurotoxicity, in rat, unless another animal species is justified to be more appropriate (e.g. adult hen for delayed neurotoxicity study), oral route of exposure	If anticholinesterase activity is detected, a test for response to reactivating agents shall be generated.
8.5.2.	Appropriate information or study on endocrine disruption, oral route of exposure if relevant	This standard information or study shall be generated if there is any evidence from *in vitro* studies or from repeated dose or reproduction toxicity studies, that the relevant chemical species may have endocrine disrupting properties for human health, in order to elucidate the mode/mechanism of action and provide sufficient evidence for relevant adverse effects.
8.5.3.	Appropriate immunotoxicity information or study, including developmental immunotoxicity	This standard information or study shall be generated if there is any evidence, from skin sensitisation, repeated dose or reproductive toxicity studies, that the relevant chemical species may have immunotoxic properties, in order to elucidate the mode/mechanism of action and provide sufficient evidence for relevant adverse effects.
8.5.4.	Appropriate mechanistic data or studies	This standard information or testing shall be generated if necessary to clarify any effects reported in toxicity studies.

Part 2. General rules for adaptation of Column 1 of Tables 1, 2 and 3

2.1. The general rules for adaptation set under Sections 1 and 2 of Annex XI to Regulation (EC) No 1907/2006 shall apply *mutatis mutandis* with the exception set out in Section 2.2.

2.2. The general rules for adaptation under Sections 1.3 (Qualitative or Quantitative structure-activity relationship ((Q)SAR)) and 1.5 (Grouping of substances and read-across approach) of Annex XI to Regulation (EC) No 1907/2006 shall apply to the standard information and testing referred to in Table 1, point 6.1.1., only in the case of a substance constituent or a non-intentionally added species for which experimental testing is not technically possible (e.g., it cannot be isolated and tested as such).

ANNEX VI

ACCEPTANCE METHODOLOGY

Section 1. Limited acceptance methodology

1.1. Section 2 shall not apply to a relevant chemical species which is a starting substance, or an organic cementitious constituent, or a substance constituent or a non-intentionally added species where such substance or constituent is:

(a) classified as (i) Category 1A or 1B for carcinogenicity, mutagenicity or reproductive toxicity; (ii) Category 1 for endocrine disruption for human health; (iii) persistent bioaccumulative and toxic; (iv) very persistent and very toxic; (v) persistent mobile and toxic; or (vi) very persistent and very mobile under Regulation (EC) No 1272/2008; or

(b) identified as a substance of very high concern under the Candidate List established under Article 59 of Regulation (EC) No 1907/2006, except those identified on the basis of Article 57(f) of Regulation (EC) No 1907/2006 only for the environment.

In either case, the starting substances or organic cementitious constituents referred to in the first paragraph shall be accepted in the European positive list under the following conditions of use:

(a) The relevant chemical species is:

(i) a non-intentionally added species, or

(ii) substance constituent, or

(iii) starting substance or organic cementitious constituent which is monomer of a main polymer of the contact material.

(b) C_{tap} is lower than the generic limit of 0,1 µg/l or the relevant MTC_{tap} calculated from a parametric value set under Annex I to Directive (EU) 2020/2184 by application of an appropriate allocation factor (ALF) to take into account multiple routes of exposure to the relevant chemical species, besides exposure via materials used in products in contact with water intended for human consumption;

(c) The concentration of the starting substance, organic cementitious constituent, substance constituent or non-intentionally added species in the final material is lower than 0,1 % (weight/weight), except if physical migration testing is uncertain in which case the concentration in the final material is lower than 0,02 % (weight/weight).

1.2. Part 2.4 of Section 2 shall not apply in the case of any concern that a relevant chemical species which is a starting substance, or an organic cementitious constituent, or a substance constituent, or a non-intentionally added species may have genotoxicity, carcinogenicity or endocrine disruption properties for human health with non-threshold mode of action.

In such case, the starting substances or organic cementitious constituents referred to in the first paragraph may be accepted in the European positive list if C_{tap} is lower than a generic limit of 0,1 µg/l or the relevant MTC_{tap} value calculated from a parametric value set under Annex I to Directive (EU) 2020/2184 by application of an appropriate ALF to take into account multiple routes of exposure to the relevant chemical species, besides exposure via material used in products in contact with water intended for human consumption.

1.3. Part 2 of Section 2 shall not apply to a relevant chemical species in any of the following cases:

(a) a parametric value for the relevant chemical species in the applicable material type is set under Annex I to Directive (EU) 2020/2184, in which case the MTC_{tap} value shall be calculated by application of an appropriate ALF to take into account multiple routes of exposure to the relevant chemical species, besides exposure via material used in products in contact with water intended for human consumption, in which case that MTC_{tap} value shall be used for the purpose of Part 4 of Section 2;

(b) a MTC_{tap} value for the relevant chemical species in the applicable material type is set under the corresponding Annex of Commission Implementing Decision (EU) 2024/367 following a decision by the Commission on an application for a starting substance, composition or organic cementitious constituent that has been submitted to ECHA under Article 4 of Commission Delegated Regulation (EU) 2024/369, in which case that MTC_{tap} value may be used for the purpose of Part 4 of Section 2 provided that it may not be impacted by information not included in the previous application for the concerned starting substance, composition or organic cementitious constituent;

(c) an authorisation for an active substance has been granted under Regulation (EU) No 528/2012 on the basis of an ECHA opinion setting a defined safety threshold for the oral route and used as such in material in contact with water under product-type 6, in which case that safety threshold shall be used for the purpose of Part 4 of Section 2;

(d) a specific migration limit has been set under Commission Regulation (EU) No 10/2011 in less than 15 years from the date of submission of the application under Article 4 of Commission Delegated Regulation (EU) 2024/369, in which case that specific migration limit divided by 20 l/kg shall be used for the purpose of Part 4 of Section 2.

1.4. Part 2.4 of Section 2 shall not apply in the following cases:

(a) the available information for the relevant chemical species is insufficient to exclude genotoxicity, in which case the generic limit MTC_{tap} of 0,1 µg/l shall apply for the purpose of Part 4 of Section 2;

(b) the available information set out in Tables 1, 2 and 3 of Annex V for the relevant chemical species is sufficient to exclude genotoxicity but does not allow to conclude on toxic effects listed under Part 2.1.2 of Section 2. In such case the generic limit MTC_{tap} of 2,5 µg/l shall apply for the purpose of Part 4 of Section 2. Such generic limit cannot be applied for the toxic effects for human health with non-threshold mode of action referred to in the first paragraph of Section 1.2.

Section 2. Comprehensive acceptance methodology

Part 1. Introduction

1.1. The acceptance methodology for starting substances, compositions and constituents shall be based on a risk assessment. Such risk assessment shall result in:

(a) determining the maximum tolerable concentration at tap water (MTC_{tap}) for each relevant chemical species;

(b) ensuring that C_{tap} for each relevant chemical species is lower than its MTC_{tap}.

1.2. In addition to the information required under Annexes I, II and III, a risk assessment shall take into account any other relevant technical or scientific information which is available addressing worst foreseeable conditions of use. Where appropriate, conditions of use shall be implemented.

1.3. The information provided in the risk assessment shall allow the Committee for Risk Assessment of ECHA to evaluate and reach an opinion on whether the starting substance, composition or constituent complies with the criteria set out under Article 11(1) of Directive (EU) 2020/2184.

Part 2. Hazard assessment

2.1. Principles

2.1.1. For accepting a starting substance, composition or constituent, the hazard assessment process, in relation to human health shall entail assessment of effects, comprising the following steps:

(a) hazard identification: identification of the adverse effects which the relevant chemical species have an inherent capacity to cause;

(b) hazard characterisation: dose (concentration) – response (effects) assessment: estimation of the relationship between dose, or level of exposure to the relevant chemical species, and the incidence and severity of an effect, where appropriate.

2.1.2. The hazard assessment for human health shall address the following potential toxic effects for the general human population and exposure by the oral route:

(a) mutagenicity;

(b) systemic (target-organ) toxicity after repeated dose administration;

(c) toxicity for reproduction;

(d) carcinogenicity;

(e) neurotoxicity;

(f) immunotoxicity;

(g) endocrine disruption for human health.

2.1.3. The hazard identification shall address the properties and potential adverse effects of the relevant chemical species that migrate from the material.

2.2. Dose-response assessment

2.2.1. The establishment of a quantitative dose (concentration)-response (effect) relationship is required and, where possible, a no observed adverse effect level (NOAEL) shall be identified. If it is not possible to identify a NOAEL, the lowest observed adverse effect level (LOAEL) shall be identified. Where appropriate, other dose-effect descriptors may be used as reference values.

2.2.2. When carrying out the hazard assessment, special consideration shall be given to toxicity data derived from observations of human exposure where such data are available, e.g. information gained from manufacture, from poison centres or epidemiology surveys.

2.3. Derived no effect level

2.3.1. The derivation of a derived no effect level (DNEL) shall be carried out in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006.

2.4. Maximum Tolerable Concentration at the tap (MTC_{tap})

2.4.1. Subject to Part 2.4.2, the MTC_{tap} is equal to a value calculated on the basis of the safe oral dose (DNEL), the body weight (60 kg), the drinking water ingestion rate of 2 l (litres) per day and an appropriate ALF (expressed as a percentage) to take into account multiple routes of exposure to the relevant chemical species, besides exposure via material used in products in contact with water intended for human consumption.

$$\mathbf{MTC_{tap}\ (\mu g/l)} = \frac{DNEL\ (mg/kg/d) \times 60\ (kg) \times 1\ 000\ (\mu \mathbf{g}/\mathbf{mg})}{2\ (l/d)} \times ALF$$

2.4.2. By way of exception to Part 2.4.1:

(a) If the C_{tap} < 2,5 µg/l and genotoxicity tests are negative: MTC_{tap} shall (1) not be lower than 0,1 µg/l for an organic cementitious constituent; and (2) not be higher than 2,5 µg/l, unless duly justified and the application fulfils the requirements of Table 2 of Annex V, in which case point (b) below applies.

(b) If the C_{tap} is equal or above 2,5 µg/l but below 250 µg/l, the MTC_{tap} shall not be higher than 250 µg/l.

Part 3. Migration assessment

3.1. The C_{tap} to be compared against the MTC_{tap} value shall be determined based on the worst foreseeable conditions of use, including in terms of representativeness of the concentration in the material matrix, water, surface area to water volume, and temperature, as determined by ECHA and published on its website for each test method taking into account, in particular, the requirements for determination based on the worst foreseeable conditions of use and the appropriate EN standard.

Part 4. Risk acceptance

4.1. Risk acceptance for starting substances for organic materials, organic cementitious constituents and compositions for enamels, ceramic and other inorganic materials

The starting substance, composition or constituent shall be accepted if C_{tap} < MTC_{tap} for each relevant chemical species on the 10th day of testing according to point 5.2 in Table 1 of Annex IV.

4.2. Risk acceptance for metallic materials

For the assessment of the test rig results (according to standard EN 15664-1) the arithmetic mean of the equivalent pipe concentrations $MEP_n(T)$ analysed from relevant contact waters (see Annex IV, Section 1.1) shall be considered.

The composition can be accepted for a product group with the assumed contact surface a (see Table 2 of Annex II), if the following criteria are met for all required test waters:

(a) MTC_{tap} values are met for all analysed elements starting week 16 of testing;

(b) Analysed metal concentrations are not showing increasing trend.