EUROPEAN
COMMISSION

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ANNEXES 1 to 6

ANNEXES

to the

Commission Implementing Decision

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

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.

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

'organic cementitious constituents' means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

'metallic composition category' means a group of metallic compositions with the same metallic composition constituents and the same behaviour when they come in contact with water intended for human consumption.

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		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		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 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 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.
1.1.6.			Designation: • Standardised material designation number under European standard EN 1412, if available; • Standardised material designation symbol under	Name of material category and name of enamel, ceramic or other inorganic composition.

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
			European Standard ISO 1190-1, if available.	
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	

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
			category and corresponding concentration ranges (minimum and maximum % w/w).	
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 maximum percentage by mass (% 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..		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
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.		
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	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).

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		concentration range (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.		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
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.		
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		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		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		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		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	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

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2023)7003]*.		Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2023)7003]*.
2.2.3.		Surface to volume ratio of the relevant products of intended use.	Percentage of exposed surface of a metallic composition (as indicated by the relevant product group under point 2.2.2.).	Surface to volume ratio of the relevant products of intended use.
2.2.4.		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:**			
2.4.1.		For starting substances for organic materials: Maximum dosage of the starting substance in the formulation to produce the		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		final material.		
2.4.2.		For organic constituents of cementitious materials: • In case of polymers: Dosage of the monomersor 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:**			

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
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.		
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 process type and main processing conditions should be described; • Appropriate manufacturing and processing steps and resulting properties, such as	Processing temperatures of the final material.

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
			‘heat treatment to reduce beta-phase’ or ‘phase distribution in 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:**			
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		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		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		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		appropriate screening method as set out in Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2023)7003]*.		
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		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		(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.		
3.4.3.		Molecular weight distribution for polymerised part below 1000 Da; test report of the molecular weight distribution is required.		

		Starting substance for organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
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.		

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 %

Product group	Examples of metallic products or components	Assumed contact surface "a"
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).	Negligible

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 the starting substance or organic cementitious constituent is set in the corresponding Annex to Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2023)7001]* 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) …/… *[OP: please fill in the reference of C(2023)7002]* 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 10/201[1] for less than 15 years before the submission of an application under Article 3 of Commission Delegated Regulation (EU) …/… *[OP: please fill in the reference of C(2023)7002]*.

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[2] 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 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.

[1] 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).

[2] 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).

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) 1907/2006[3] 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

[3] 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)

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		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.
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

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		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 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, 1.4 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 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	Test method for factory-made products and site applied products made from or incorporating organic materials	(a) All metallic compositions: Test method for dynamic rig test established in standard EN 15664-1 for	Test method for products made from or incorporating glassy (porcelain/vitreous enamel) materials according to the standard

		Starting substance or organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
	methods	according to standards referred to in Annex I to Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2023)7003]*.	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: - Either one of the tests methods referred to in points (a) and (b), as applicable; or - the test method established in standard EN 16058, with 3 tests and 3 test waters.	described in Annex IV Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2023)7003]*.
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 species or elements from migration and/or contact water resulting from migration testing. For surface layers (coatings, platings) this includes relevant species or elements from the surface layer and from the		

		Starting substance or organic materials / organic cementitious constituents	Composition of metallic materials	Composition of enamels, ceramic, or other inorganic materials
		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

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) …/… *[OP: please fill in the reference of C(2023)7003]* may replace testing for a starting substance 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. 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 (Ctap) determination and identification of relevant species has been demonstrated;

(iii) the Ctap and identification of relevant 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 species

1. Relevant 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 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, point 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 5 and have been found to migrate into water intended for human consumption with a concentration at the tap (Ctap) 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 species where either of the following conditions are fulfilled:

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

(b) a MTCtap value for the relevant s species in the applicable material type is set in the corresponding Annex to Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2023)7001]* 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 Commission Delegated Regulation (EU) …/… *[OP: please fill in the reference of C(2023)7002]* and the applicant submits at least any new or updated information available as from the date of the Commission's decision;

(c) the relevant species is classified Regulation (EU) 1272/2008 of the European Parliament and of the Council[4] as one of the following:

i. carcinogenic, mutagenic or reproductive toxicity, categories 1A or 1B or endocrine disruptor for human health category 1;

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 species is identified as a substance of very high concern in the Candidate List established under Article 59 of Regulation (EC) 1907/2006, except those identified on the basis of Article 57(f) of Regulation (EC) 1907/2006 only for the environment;

(e) the relevant species is authorised as an active substance under Regulation (EU) 528/2012 on the basis of an opinion of the Commitee 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 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 Commission Delegated Regulation (EU) …/… *[OP: please fill in the reference of C(2023)7002]* and the information that would otherwise have to be generated under Section 2 of this Annex for the

[4] 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).

corresponding C_{tap} is covered by the scientific opinion underlying that specific migration limit.

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 [5], if applicable.

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 point 1.6.

1.4. A stepwise approach for toxicological testing shall be applied based on the C_{tap} of a relevant 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 species. Any other relevant toxicological information shall be considered in addition.

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.

[5] 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).

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.	**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 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.
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 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

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		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 speciesnor 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 7 and 8**	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 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

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		dose toxicity study with the reproduction/developmental toxicity screening test is available showing severe toxicity effects according to the criteria for classifying the relevant 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 uncertainty 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 species and route of administration were used; (c) the relevant 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/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 species and route of administration were used; (b) the relevant 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

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		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 species and its metabolites are absent in urine or bile.
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 8**	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 species.
8.2.	**Repeated dose toxicity:**	
8.2.1.	Long-term repeated dose toxicity (≥ 12 months)	This study does not need to be conducted if a combined long-term repeated dose/carcinogenicity study is undertaken
8.3.	**Reproductive toxicity:**	The studies do not need to be conducted where the relevant species is of low toxicological activity (no evidence of toxicity seen in any of the tests available, in which a sufficiently

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		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 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 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 species and/or any of its metabolites will reach a steady state in the test animals only after an extended exposure; (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:

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		(a) existing information on the relevant 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 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 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 species is justified to be more appropriate, oral route of administration	
8.3.3.	Further pre-natal developmental toxicity study, in a second species, oral route of administration or mechanistic study	A decision on the need to perform additional studies on a second 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).

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
8.4.	**Carcinogenicity:**	
8.4.1	Carcinogenicity study, in rat, oral route of administration See 8.4.2 for new study requirements	The study does not need to be conducted where all of the following conditions are fulfilled: (a) no genotoxic potential is identified in genotoxicity tests; (b) the sub-chronic andlong-term (≥ 12 months) toxicity studies show no evidence of toxicity at the limit dose level.
8.4.2	Combined carcinogenicity study and long-term repeated dose toxicity	
8.5.	**Additional toxicity properties:**	If there is an indication for one or more mechanisms/modes of action of the relevant 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 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 speciesmay 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 species may

	Column 1 Standard information and testing	Column 2 Specific rules for adaptation of the standard information and testing
		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) 1907/2006 shall apply *mutatis mutandis* with the exception set out in point 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) 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. Section 2 shall not apply to a relevant 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) carcinogenic, mutagenic or reproductive toxicity, categories 1A or 1B, (ii) endocrine disrupter for human health category 1, (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 (EU) 1272/2008; or

(b) identified as a substance of very high concern under the Candidate List established under Article 59 of Regulation (EC) 1907/2006, except those identified on the basis of Article 57(f) of Regulation (EC) 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 species is:

a non-intentionally added species, or

substance constituent, or

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

(b) Ctap is lower than the generic limit of 0,1 µg/l or the relevant MTCtap 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 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).

2. Part 2 of Section 2 shall not apply in the case of any concern that a relevant 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 species, besides exposure via material used in products in contact with water intended for human consumption.

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

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

(b) a MTCtap value for the relevant species in the applicable material type is set under the corresponding Annex of Commission Implementing Decision (EU) …/… *[OP: please fill in the reference of C(2023)7001]* 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) …/… *[OP: please fill in the reference of C(2023)7002]*, in which case that MTCtap 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) 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) 10/2011 in less than 15 years from the date of submission of the application under Article 4 of Commission Delegated Regulation (EU) …/… *[OP: please fill in the reference of C(2023)7002]* and that specific migration limit was derived based on the same data as required under Annex V considering the Ctap of the corresponding relevant species, in which case that specific migration limit divided by 20 l/kg shall be used for the purpose of Part 4 of Section 2.

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

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

(b) the available information for the relevant species is sufficient to exclude genotoxicity but does not fulfil the information requirements set out in Tables 2 and 3 of Annex V, or is not sufficient for DNEL derivation in accordance with Part 2 of Section 2, in which case the generic limit MTCtap of 2,5 µg/l shall apply for the purpose of Part 4 of Section 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 (MTCtap) for each relevant species;

(b) ensuring that Ctap for each relevant species is lower than its MTCtap.

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 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 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 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) 1907/2006.

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

2.4.1 If the C_{tap} < 2,5 µg/l and screening genotoxicity tests are negative: MTC_{tap} = 2,5 µg/l.

As an exception, if duly justified and the application fulfils the requirements of Table 2 of Annex V, Section 2.4.2 may apply.

2.4.2 If the C_{tap} is equal or above 2,5 µg/l but below 250 µg/l: 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 species, besides exposure via material used in products in contact with water intended for human consumption. The MTC_{tap} shall not be higher than 250 µg/l.

$$\mathbf{MTC_{tap}\ (\mu g/l)} = \frac{\mathbf{DNEL\ (mg/kg/d) \times 60\ (kg) \times 1000\ (\mu g/mg)}}{\mathbf{2\ (l/d)}} \times \boldsymbol{ALF}$$

2.4.3. If the C_{tap} is above 250 µg/l: the MTC_{tap} shall be set in accordance with the equation above.

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 species.

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, point 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) MTCtap values are met for all analysed elements;

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