Supporting Document

Materials in Contact with Drinking Water: Testing of Final Materials and Conformity Assessment

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This supporting document was prepared by a group of experts representing the EU Member States, the European Drinking Water Industry Initiative (EDW) and the Group of Notified Bodies Drinking Water (NBDW).

It is aimed to update this document regularly to address upcoming questions arising in the implementing process of this new European system. Please provide comments concerning this document to II3.4@uba.de.

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1 Introduction

The nature of materials that come into contact with water intended for human consumption can have an impact on the quality of such water through the migration of potentially harmful substances, by enhancing microbial growth or by influencing the odour, colour or taste of such water. For this reason, Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption already laid down provisions for Member States to take measures to ensure the quality of treatment, equipment and materials in contact with drinking water.

However, the evaluation of the Directive carried out in 2015 as part of the Regulatory Fitness and Performance Programme (REFIT) found that these provisions did not succeed in creating uniform hygiene requirements for products in contact with water intended for human consumption throughout the union since it provided too much flexibility for legal transposition in the Member States. As a result, different national product approval systems are in place across the Union, with requirements differing from one Member State to another. This renders it difficult and costly for manufacturers to market their products throughout the Union and it is also costly for Member States. In addition, it makes it difficult for consumers and water suppliers to know if products meet health requirements.

This was considered in the recast of the Drinking Water Directive and more specific basic minimum hygiene requirements for materials were laid down in Article 11(1) of Directive (EU) 2020/2184 of 16 December 2020. This requires Member States to ensure that materials do not compromise human health either directly or indirectly, adversely affect the colour, odour or taste of the water, enhance microbial growth in the water or cause contaminants to leach into the water at levels that are higher than necessary in view of the intended purpose. These requirements apply to materials intended to be used for the abstraction, treatment, storage or distribution of water intended for human consumption in new installations or in existing installations in the case of repair works or reconstruction.

With regard to uniform application in the sense of a European harmonisation, these basic minimum requirements alone do not represent an improvement on Directive 98/83/EC, as the Member States would still be left with too much flexibility in their implementation. The EU Commission has therefore been empowered to specify and supplement the basic minimum hygiene requirements in accordance with Article 11(1) by means of implementing acts and delegated acts.

In order to ensure their harmonised and coherent application, the legal acts were adopted jointly on 23 January 2024 in a regulatory package of Commission decisions and delegated regulations, after prior involvement of the competent authorities of the Member States and ECHA, and will therefore be binding and directly applicable in all Member States from 31 December 2026.

The regulatory package is comprehensive, including binding positive lists of starting substances, compositions and constituents, testing requirements and acceptance criteria for final materials produced from them, and a product conformity assessment procedure that provides for the mandatory involvement of notified bodies.

This new European system is based on a certification system for products in contact with water intended for human consumption. The certificates are issued by notified and accredited conformity assessment bodies and will be valid for the entire EU market. Probably not all Member States will have notified conformity assessment bodies. The manufacturers have the choice of conformity assessment body and can use any notified conformity assessment body located within the EU.

Products intended to come into contact with water intended for human consumption and to be placed on the EU market have to comply with the European requirements. This will apply from 31 December 2026. For products which are assessed to be in conformity with national hygiene requirements and for which the national conformity certificate is still valid on 31 December 2026, it shall apply from 31 December 2032. Compliance with European requirements is demonstrated by the above-mentioned certificates and the marking with the symbol according to the Annex of CDR (EU) 2024/371 (see section 7.2).

The European system ensures a safe use of the materials in all EU Member States. However, Member States might restrict the use of certain products with certain drinking water compositions due to technical or health reasons. Examples are the use of copper and galvanised steel pipes which are not suitable with all European drinking waters or the use of certain copper alloys in certain products due to technical corrosion issues (e.g. dezincification).

2 Scope

This supporting document is intended to facilitate and support the practical implementation of the procedures and methods for testing and accepting final materials and the conformity assessment procedures according to Article 11 of Directive (EU) 2020/2184, as well as Commission Implementing Decision (EU) 2024/368 and Commission Delegated Regulation (EU) 2024/370.

This supporting document is addressed equally to all stakeholders dealing with the conformity assessment and testing of products in contact with water intended for human consumption as conformity assessment bodies, accreditation bodies, notifying authorities, manufacturers of final products and manufacturers of products in the upstream supply chain. While not legally binding, the guidance given in this document does not conflict with the requirements as set out in the above-mentioned legal acts. It describes in detail relevant aspects for the testing and assessment of final materials as used in products and the corresponding conformity assessment, making it particularly relevant for conformity assessment bodies and test laboratories. The conformity assessment procedure for products in contact with drinking water applies from 31 December 2026 in accordance with CDR 2024/370. In order to ensure sufficient preparation time for implementation by the conformity assessment bodies and industrial companies, the content of this guidance document, which is intended to support this, had to be published as soon as possible. However, due to ongoing interlaboratory tests, standardisation projects and method definitions, it was not possible to conclude on all aspects when drafting this document. Therefore, this document should be considered a living document updated by experts and reviewed by relevant stakeholders.

Due to the wide range of addressees and the level of detail, specific guidance may be needed for special interest groups that lies outside the scope of this document. For this reason, EDW provides practical advice and information for the introduction and implementation of the necessary measures specifically for industrial companies in a separate document, which can be obtained from the initiative's website.

3 Legal Acts and Definitions

3.1 Legal Acts specifying the European system

The following legal acts were adopted to specify the European system for materials in contact with water intended for human consumption according to Article 11 of Directive (EU) 2020/2184:

Abbreviation	Reference
CID (EU) 2024/365	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
CID (EU) 2024/367	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
CDR (EU) 2024/369	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
CID (EU) 2024/368	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
CDR (EU) 2024/370	Commission Delegated Regulation (EU) 2024/370 of 23 January 2024 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down conformity assessment procedures for products that come into contact with water intended for human consumption and the rules for the designation of conformity assessment bodies involved in those procedures
CDR (EU) 2024/371	Commission Delegated Regulation (EU) 2024/371 of 23 January 2024 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by establishing harmonised specifications for the marking of products that come into contact with water intended for human consumption

CID (EU) 2024/367 essentially consists of positive lists that apply to the various material groups. The following positive lists are provided in separate Annexes of CID (EU) 2024/367:

- European positive list of **starting substances for organic materials**
- European positive list of **compositions of metallic materials**
- European positive list of **organic constituents of cementitious materials**
- European positive list of **compositions of enamels, ceramic and other inorganic materials**

All positive list entries include expiry dates (even after the first (re-)evaluation), which means that material manufacturers and/or users must submit applications for renewal of list entries, including toxicological assessments, to the European Chemicals Agency (ECHA). **CID (EU) 2024/365** defines the technical and scientific criteria for testing and accepting starting substances, constituents and compositions for the renewal of positive list entries and the inclusion of new entries. The procedural requirements for the applications for the renewal and the inclusion are provided in **CDR (EU) 2024/369**.

For CID (EU) 2024/365, CID (EU) 2024/367 and CDR (EU) 2024/369 ECHA provides separate guidance documents.

In order to ensure that only materials that do not directly or indirectly compromise the protection of human health are used for the manufacture of products, testing requirements and acceptance

criteria in the form of specific limit values are defined for each type of material in **CID (EU) 2024/368.** These testing requirements and acceptance criteria follow a risk-based approach.

CDR (EU) 2024/370 complements CID (EU) 2024/368 as it specifies the conformity assessment procedure to demonstrate the compliance of products with the requirements of the CID (EU) 2024/368. This procedure always includes the involvement of notified conformity assessment bodies. As for the testing requirements, a risk-based approach is implemented. For products of a higher risk group (RG1 and RG2) the conformity assessment body performs a surveillance of the quality system of the manufacturers. This includes the auditing of the production sites and the withdrawal of products or components as test pieces. For products or components of a lower risk group (RG3 and RG4) internal production control will not be audited by the conformity assessment body.

The manufacturers shall mark the certified products according to the **CDR (EU) 2024/371**. This enables the user to recognise the conformity of the products and represents a considerable simplification for users.

This document gives guidance for CID (EU) 2024/368, CDR (EU) 2024/370 and CDR (EU) 2024/371. In some part of the document these legal acts are quoted 1:1 followed by explanation or further specifications. The quoted text is printed in red.

3.2 Date of application

The new European system applies from 31 December 2026. This means that new products to be placed on the EU market have to comply with the European requirements and have to be certified as described in this document.

The conformity assessment bodies have to be accredited and notified by the national notifying authority.

For products already on the market on 31 December 2026 a transitional period applies:

'However, for products which are assessed to be in conformity with national hygiene requirements for products that come into contact with water intended for human consumption and for which the national conformity certificate is still valid on 31 December 2026, it shall apply from 31 December 2032.'

Member States might further specify the use of these products in this transitional period. The aim of this regulation is that products already on the market that can legally be used in a Member State can be used in this Member State within the transitional period. In this case the national requirements and the national conformity assessment procedure apply.

Spare parts for such products that

- were first placed on the market before the 31 December 2026 and
- have not been assessed according a conformity assessment procedure of CDR 2020/370 and
- meet the national requirements at the date it was placed on the market

can still be used after 31 December 2032 without a certificate of conformity according to CDR 2020/370, provided that the drinking water quality is not deteriorated.

3.3 References

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, official journal of the European Union L 435/1, 23. December 2020

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, Office Journal of the European Union L 218/82, 13 August 2008.

3.4 Definitions

Source	Definition
CDR (EU) 2024/370	'Accreditation' means accreditation as defined in Article 2, point (10), of Regulation (EC) No 765/2008: 'Accreditation' means an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity
	'Admixture' means a constituent-product (generic constituent) incorporated at the time of mixing of concrete at a dosage ≤ 5% related to the mass of dry cement, to modify the properties of the mixture in the fresh and/or hardened state.
CID (EU) 2024/368 CDR (EU) 2024/370	'Assembled product' means a product that consists of two or more components, that are joined together and function as a whole unit and can be disassembled without destroying the components.
CDR (EU) 2024/370	'Authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on the manufacturer's behalf in relation to specified tasks.
	'Conversion factor' is used to calculate the expected concentration at the tap and is based on worst-case assumptions about contact times of drinking water with the respective products or components and their surface/volume ratios in the drinking water distribution.
CID (EU) 2024/368	'Cementitious material' means a material that contains a hydraulic cement in sufficient proportion to act as the main binder by forming a hydrate structure which governs the performance of the material.
CID (EU) 2024/368	'Ceramic material' means inorganic poly or single crystalline, non-metallic solid materials subjected to high temperature in manufacture.
	'Certificate' means the provision by a notified body of written assurance that the product meets the minimum hygiene requirements.
CID (EU) 2024/368 CDR (EU) 2024/370	'Component' means an identifiable part of an assembled product consisting of one or more materials.

DWD	'Composition' means the chemical composition of a metal, enamel, ceramic or other inorganic material.
CDR (EU) 2024/370	'Conformity assessment body' means a body that performs conformity assessment activities, including testing, certification and inspection.
CDR (EU) 2024/370	'Conformity assessment' means the process demonstrating that a product complies with the minimum hygiene requirements.
CID (EU) 2024/368	'Constituent' means: any of the following: (a) a substance that has been intentionally used to manufacture a cementitious material; (b) an alloying element present in a composition of metallic materials; (c) an element or a combination of elements present in a composition of enamels, ceramic or other inorganic materials; (d) a substance present in a mixture of substances.
	'Constituent product' means a commodity to produce a final cementitious material
	'Curing compound' means a product whose application on concrete or mortar surfaces exposed to atmospheric agents allows to oppose the evaporation of the water contained in the concrete or mortar during the setting phase of hardening.
CID (EU) 2024/368	'Enamel' means a material that is a vitreous material obtained by melting at temperatures higher than 1200°C and fritting of a mixture of inorganic substances. Note: The application temperature of enamels on the substrate (e.g. steel) is less than 1200°C (800°C – 900°C for steel)
CID (EU) 2024/368	'Enhancement of Microbial Growth (EMG)' means the ability of final organic or cementitious materials to enhance the multiplication of micro-organisms under specified conditions.
	'EU declaration of conformity' means the statement issued by the manufacturer in accordance with Article 2 of CDR (EU) 2024/370, declaring that the product fulfils the minimum hygiene requirements set out pursuant to Article 11 of Directive (EU) 2020/2184.
CID (EU) 2024/368 CDR (EU) 2024/370	'Final material' means a material which is subject to testing and acceptance in accordance with the testing requirements and acceptance requirements set out in Commission Implementing Decision (EU) 2024/368
	'Formwork release agent' means a product intended to be applied to the surfaces of molds and forms to facilitate the separation of concrete elements by reducing the adhesion between them.

CID (EU) 2024/368	'Formulation' means the list of all substances or constituents used in the preparation of an organic material or of a cementitious material and their relative quantities.
	'Grinding aid' means a specific organic constituent added to the cement or to the inorganic addition to improve grinding by preventing the particles from coagulating
CDR (EU) 2024/370	'Importer' means any natural or legal person established within the Union who makes available products from a third country on the Union market
	'Intermediate product' means a commodity which undergoes chemical reactions (e.g. curing of rubber, cross linking of plastics) to produce the final material.
CDR (EU) 2024/370	'Making available on the market' means any supply of a product for distribution, consumption or use on the Union market over the course of a commercial activity, whether in return for payment or free of charge;
CDR (EU) 2024/370	'Manufacturer' means any natural or legal person who manufactures products or who has products designed or manufactured, and markets those products under its name or trademark, or who designs and constructs products for its own use
	'Marking' means a marking to be used to indicate that a product has been declared conform to the minimum hygiene requirements of Article 11 of Directive (EU) 2020/2184 under the procedure established by CDR (EU) 2024/370 and consists of the information text and symbol of CDR (EU) 2024/371;
CID (EU) 2024/368 CDR (EU) 2024/370	'Material' means a solid, semi-solid or liquid that is used for the manufacturing of a product that is: (a) an organic composition prepared from one or more starting substances; or (b) a cementitious composition prepared from one or more constituents; or (c) a metallic, enamel, ceramic or other inorganic composition
CID (EU) 2024/368	'Metallic material' means a metal or metal alloy and that is used either in bulk form or as metallic plating.
CID (EU) 2024/368	'Migration water' means the test water that has been in contact with the test piece under the specified conditions set out in the respective Annexes I, II, III and IV of Commission Implementing Decision (EU) 2024/368.
CDR (EU) 2024/370	'Minimum hygiene requirements' means the requirements set out in Commission Implementing Decision (EU) 2024/368.
CID (EU) 2024/368	'Multilayer product' means a product that consist of two or more layers of final materials bonded together and cannot be non-destructively disassembled for the testing.

CDR (EU) 2024/370	'National accreditation body' means national accreditation body as defined in Article 2, point (11), of Regulation (EC) No 765/2008 'national accreditation body' shall mean the sole body in a Member State that performs accreditation with authority derived from the State.
CID (EU) 2024/365	'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.
CDR (EU) 2024/370	'Notified body' means a conformity assessment body that has been notified in accordance with Article 5 *of* Commission Delegated Regulation (EU) 2024/370.
	'Organic addition' means a constituent product which is incorporated into the concrete or mortar and which main constituent is organic and which is used at a dosage > 5% related to the mass of dry cement.
CID (EU) 2024/368	'Organic material' means a material that mainly consists of carbon-based substances (Further specification:) and falls under the following material categories: plastics, rubbers, coatings, lubricants and silicones.
CDR (EU) 2024/370	'Placing on the market' means the first making available of a product on the Union market;
	'Pre-product' means commodity with a specific formulation (polymers, additives and further starting substances) in any commercially available format (e.g. pellets, granules, etc.) that a manufacturer uses in the manufacturing process of a product or a component of an assembled product without undergoing any further chemical reactions.
CID (EU) 2024/368 CDR (EU) 2024/370	'Product' means an object that comes into contact with water intended for human consumption, which is made of final materials and which is intended to be placed on the market.
	'Product type series' means a group of products or components that can be covered by the testing of one representative test piece.
CDR (EU) 2024/370	'Reduced test' means carrying out a test where only a part of the procedures and methods for testing set out in Commission Implementing Decision (EU) 2024/368 are applied on test pieces which have been withdrawn by the notified body during the initial or annual inspection.

	'Relevant substance' means a substance to be analysed in the migration or contact water.
CID (EU) 2024/368	'Site applied material' means a final material to be produced on a construction site.
	'Spare part' means a replaceable component, sub assembly or assembly of a product in use and in contact with water intended for human consumption, which is identical to and interchangeable with the item it is intended to replace.
DWD CID (EU) 2024/368	'Starting substance' means a substance that has been intentionally added in the production of organic materials or of admixtures for cementitious materials.
CID (EU) 2024/368 CDR (EU) 2024/370	'Test piece' means a representative object that is used for the carrying out of testing in accordance with the procedures and methods set out in Implementing Decision (EU) 2024/368.
CID (EU) 2024/368	'Total barrier' means a barrier layer that prevents the diffusion of any substances towards the side of the final material in contact with the water intended for human consumption.
CID (EU) 2024/368	'Unexpected substance' means a substance that has migrated from a product, a final organic material or a final cementitious material into water intended for human consumption, that was not intentionally added during the production process of the material or product, and that was not included in the information provided in the application referred to in Article 11(5) of Directive (EU) 2020/2184.

4 Covered Products

According to Article 11 of Directive (EU) 2020/2184 materials that are intended to be used in new installations or, in case of repair works or reconstruction, in existing installations for the abstraction, treatment, storage or distribution of water intended for human consumption and that come into contact with such water have to comply with the requirements as laid down in the Directive, the specifying Decisions and the supplementing Regulations. As a consequence, all products containing such materials are covered by the new European system independent of the size of the supply system the products are used for.

However, Member States have different definitions for the boundaries of the domestic distribution system for water intended for human consumption. As a consequence, in some Member States certain products (e.g. angle stop valve for toilet flushing or connecting hose of a washing machine) are considered as products in contact with drinking water whereas in other Member States these products are not covered.

Treatment chemicals and filter media are excluded from the European system for materials in contact with water intended for human consumption. This might cause problems as certain

treatment chemicals (e.g. ion exchange resins or sacrificial anodes) or filter media (e.g. filter membranes) are part of devices which are considered as products in contact with water intended for human consumption. For these products the European system still applies and all components in contact with water intended for human consumption (e.g. housing but also the glue for fixing the membranes) excluding the treatment chemicals and filter media have to follow the European requirements. According to Article 12 of Directive (EU) 2020/2184 for the treatment chemicals and filter media included in these products national requirements apply. These products have to be labelled with the European mark followed by national conformity marks for the treatment chemicals and filter media. It is recommended that Member States will refer to the European requirements concerning the materials used as filter media. This is reasonable as the European positive lists probably will cover the required starting substances, compositions and constituents for manufacturing the filter media and a testing according to the test procedures of CID (EU) 2024/368 is possible. This is not the case for ion exchange resins as not all starting substances used for the manufacturing are included in the European positive list of starting substances for organic materials and the testing procedures of CID (EU) 2024/368 are not applicable. For sacrificial anodes a reference to the European system is also not possible.

Sliding or fitting lubricants, metal machining lubricants and other lubricants used during the assembling process are not covered, if they are completely removed before the final product or system is in use.

Pre-products, intermediate products and constituent products are no final materials and not covered by CDR (EU) 2024/370. However, the risk-based approach of CID (EU) 2024/368 allows for certain risk groups the testing of test pieces of the formulation. Although not covered by CDR (EU) 2024/370 and excluded from marking according to CDR (EU) 2024/371 the certification of pre-products, intermediate products and constituent products based on the testing of a test sample of a final material manufactured from the pre-product, intermediate products or constituent products is possible. It can be regarded as a pre-assessment for the assessment of products or components made of the final materials. This approach simplifies the conformity assessment for a lot of products. A recognition of certificates for pre-products, intermediate products constituent products and formulations by another notified conformity assessment body is strictly recommended, if

- formulation review, testing and assessment of the test pieces was performed according to CID (EU) 2024/368 and
- the production of the test pieces was audited by a notified conformity assessment body and
- the certificate of the pre-product, intermediate product, constituent product or formulation was issued by a notified conformity assessment body and
- the pre-product, intermediate product, constituent product or formulation was tested and/or assesses according to this supporting document and the certificates includes the information as specified in Annexes 10 -13 and
- the certificates are covered by the accreditation of the conformity assessment body.

Site applied products are neither excluded from CID (EU) 2024/368 nor from CDR (EU) 2024/370. However, a conformity assessment of each individually manufactured product (e.g. tank or the lining of a tank) on each construction site according to CDR (EU) 2024/370 is not feasible in all cases (especially for repair work or smaller products). For site applied products Member States can rely on certificates issued for intermediate products and constituent products and might define the testing of the water intended for human consumption exposed to the site applied products for certain parameters.

5 Conformity Assessment

5.1 Principles

Notified bodies perform the conformity assessment for the products to be placed on the market.

These products can be made of one final material (e.g. certain pipes) or of more than one final material. If these materials can be non-destructively disassembled the product is an assembled product (e.g. taps or valves) made of components in the other case it is a multilayer product (e.g. certain pipes). However, if components are glued or combined in this way, that the components are still in direct contact with drinking water and cannot be non-destructively disassembled it is not considered as a multilayer product and the assessment has to be performed as an assembled product. Pipes or hoses with a peelable protective cover layer are formally no multilayer products (the protective layer can be removed without destroying the components), but a migration of substances of the protective layer into the drinking water is to be expected as the layers are in contact with each other. These products have to be considered as multilayer products.

The materials are classified in four different types:

- organic materials
- metallic materials
- cementitious materials
- enamels, ceramic materials and other inorganic materials.

The assessment of the final materials as used in the products is material specific and has to be performed on the level of the components of the assembled product. The corresponding testing might be performed either for each component or for the complete assembled product. However, at the moment no European testing standards (EN) for testing of the complete assembled products are available. For this reason, CID (EU) 2024/368 and this version of this guidance document is limited to the description that each component, which can be disassembled from the assembled product, has to be tested and assessed separately. A standard for testing a complete assembled product is in development at CEN level.

The conformity assessment bodies can issue certificates covering one product, a product type series or components (for further details see section 5.4)

The conformity assessment and the testing follow a risk-based approach. As a consequence, the requirements for the conformity assessment and the testing are less demanding for products or components of products with a minor impact on the drinking water quality.

In most cases the manufacturer of the (assembled) products will not be able to assess the compliance of the products with the requirements. The main obstacle for this is that the manufacturer of the (assembled) product will not have access to the full formulation as this includes all formulation details of pre-products, intermediate products and starting substances to be provided by suppliers and their sub-suppliers. This is one reason for the requirement to use a conformity assessment body for the assessment of the products. Another reason is that the use of a third party gives a higher confidence in the consistency of quality of the product. Especially, when the conformity assessment body additionally inspects the production sites, assesses the quality system of the manufacturer and withdraws the test samples at the production sites. This high level of the conformity assessment is justified as products once installed cannot be exchanged any more easily and are to be used for decades.

Finally, the manufacturer, or its authorised representative (in case of a manufacturer outside of the EU market), shall draw up an EU declaration of conformity based on the certificate issued by the conformity assessment body and mark the product to be placed on the market with the symbol according to the Annex of CDR (EU) 2024/371(see section 7.2).

5.2 Risk-based Approach

5.2.1 Aim

The risk-based approach is a fundamental principle and implemented for testing (CID (EU) 2024/368) and conformity assessment (CDR (EU) 2024/370). In the following this basic principle is explained.

Products or components of assembled products are classified in risk groups according to their risk to contaminate water intended for human consumption.

For non-metallic materials:

For the determination of the conformity assessment procedure and testing for each product or component (see Annexes 1 - 4) the conformity assessment body has to:

1. determine the product group of the product or component and the associated conversion factor (CF) (5.2.2.2 and 5.2.2.3),
2. determine the associated risk group according to the CF (6.1.2.1, 6.3.2.1, 6.4.2.1),
3. determine the conformity assessment procedure (5.3.1) and testing requirements (6.1.2.1, 6.3.2.1, 6.4.2.1)according to the risk group.

For metallic materials:

The product group (5.2.2.1) is directly used to determine the required conformity assessment procedure (5.3.1).

In the following the concept of the product groups, conversion factors and risk groups is explained.

5.2.2 Product groups and conversion factors

5.2.2.1 Metallic Materials

Metallic materials are only classified by the product groups according to the potential impact on the quality of the water intended for human consumption. These product groups are defined in CID (EU) 2024/365 Annex 2 Table 2:

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 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 treatments works as described for product group C subcategory 2 above.	< 0,1 %

Fittings and ancillaries that are used in building installations shall be classified in product group B.

The restriction for components in product group C1 from the above table is to be understood as follows:

The total wetted surface fraction of components of fittings and ancillaries in building installations made of materials that are only accepted for product group C must be less than 10% of the total product surface in contact with drinking water. If the total surface fraction of all these components is 10% or more, metallic materials accepted for product group B have to be used for individual (or all) components. The same applies for components of fittings and ancillaries of product group D. If the sum of the wetted surfaces fraction of these components is 10 % or more, metallic materials accepted for product group C have to be used for individual (or all) components.

The assumed contact surface "a" is used for the assessment of metallic compositions to be listed in the European positive list of compositions for metallic materials. The accepted product groups are provided for each entry of this positive list. The compositions are only accepted for the use in products as specified by the product groups in this positive list.

5.2.2.2 Non-metallic materials

For the determination of the risk group of an individual product or component the product group and the corresponding conversion factor have to be identified as a first step. In the following paragraph the meaning of the conversion factors and the product groups are described.

Migration testing is performed according to European standards (EN). In most cases the migration waters obtained from these testing procedures will display higher concentrations of released substances than found in real use. This is achieved by long migration periods (up to 3 days) and by a large surface exposed to a relatively small test water volume (high S/V ratio). The reason for this test design is to ensure sufficiently high substance concentrations for reliable analytical results for substances to be identified in migration waters. As a consequence, the test results are reported as migration rates (M) in µg/(dm²*d) and not as concentrations in µg/l.

For the estimation of the expected concentrations at the tap (c_{tap}), these test results have to be converted according to S/V ratio and contact time:

$$c_{tap} = M * CF = c_{measured} \frac{CF}{S/V * t}$$

M: Migration rate according to EN 12873-1 (or -2) or EN 14944 series in µg/(dm²*d)

CF: Conversion factor according to Table 1 in d/dm

$c_{measured}$: concentration measured in the migration water in µg/l

S/V: Ratio of wetted surface of the material to the volume of the test water in dm^{-1} (test condition)

t: contact time of the migration period in d (test condition)

The conversion factors are defined for products and components of assembled products with similar properties. These are summarized in product groups (see Table 5 of Annex I of CID (EU) 2024/368; Table 1 includes further details for the definition of the product groups).

The starting point for the definition of the product groups and the corresponding conversion factors are **pipes (A)** (see Table 1). These are differentiated according to their inner diameter (ID). The uses 'domestic installations', 'service piping' and 'mains' as provided in the brackets in the table are examples only. Pipes with an ID < 80 mm are commonly used in domestic installation systems in

buildings and are classified in one product group A1. The next group of pipes (80 mm ≤ ID < 300 mm) (A2) are commonly used for service pipes, and pipes with an ID ≥ 300 mm (A3) are commonly used as water mains. The conversion factors of these product groups are derived from the highest S/V ratio of the group (F_g) (corresponds to the S/V of the smallest ID, for pipes < 80 mm this is ID = 10 mm) and an assumed contact time (F_O). For pipes with an ID < 80 mm commonly used in domestic installations the assumed contact time is 12 hours as worst case, for service pipes 2 days and for water mains 4 days. In water mains the water can be transported over long distances causing a relative long contact time.

For pipes with a specific ID not used in the commonly assumed application, the conversion factor for this ID applies.

For products where the ID of the connected piping system cannot be clearly identified (e.g. pumps, water meters, etc), the specification of the manufacturer for the use of the products are used to identify the piping system with the smallest ID the product might be installed.

Table 1: Product groups and their conversion factor (CF)

	Product group	CF (in d/dm)	F_g = S/V (in dm^{-1})	F_o = t (in days)
A	**Pipes and pipe linings**			
1	ID < 80 mm (domestic installations, buildings) [1]	20	40	0.5
2	80 mm ≤ ID < 300 mm (service piping)	10	5	2
3	ID ≥ 300 mm (mains piping)	5	1.25	4
B	**Fittings, ancillaries [2]**			
1	ID < 80 mm (domestic installations, buildings)	2	4	0.5
2	80 mm ≤ ID < 300 mm (service piping)	1	0.5	2
3	ID ≥ 300 mm (mains piping)	0.5	0.125	4
C	**Components of fittings, ancillaries [3]**			
1	ID < 80 mm (domestic installations, buildings)	0.2	0.4	0.5
2	80 mm ≤ ID < 300 mm (service piping)	0.1	0.05	2
3	ID ≥ 300 mm (mains piping)	0.05	0.0125	4
D	**Small Components of fittings, ancillaries [4]**			
1	ID < 80 mm (domestic installations, buildings)	0.02	0.04	0.5
2	80 mm ≤ ID < 300 mm (service piping)	0.01	0.005	2
3	ID ≥ 300 mm (mains piping)	0.005	0.00125	4
E	**Storage systems (reservoirs)**			
1	In domestic installations, buildings, water volume < 10 l	4	4	1
2	In domestic installations, buildings, water volume ≥ 10 l	2	2	1
3	In water supply	1	0.25	4
F	**Components of storage systems [3]**			
1	In domestic installations, buildings, water volume < 10 l	0.4	0.4	1
2	In domestic installations, buildings; water volume ≥ 10 l	0.2	0.2	1
3	In water supply	0.1	0.025	4
G	**Small Components storage systems [4]**			
1	In domestic installations, buildings; water volume < 10 l	0.04	0.04	1
2	In domestic installations, buildings; water volume ≥ 10 l	0.02	0.02	1
3	In water supply	0.01	0.0025	4

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

[2,3,4] Components (sum of components made of the same main polymers or the same compositions) of assembled products with a wetted surface fraction

[2] **≥ 10 %** of the assembled products

[3] **< 10 %** of the assembled products

[4] **< 1 %** of the assembled products

Based on the product groups for pipes (A1-A3), the product groups for fittings, ancillaries and their components are derived (B1-B3, C1-C3, D1-D3). **Fittings and ancillaries** are all products that are installed in a piping system (e.g. pipe connectors, valves, taps, pumps, water meters, instantaneous water heaters). These products are covered in one group as similar or identical materials might be used and the same substances might be released into the water intended for human consumption. It is assumed that the wetted surface of the fittings and ancillaries in the piping system is 10% of the wetted surface of the complete piping system. This can be considered as a worst-case assumption, as the fraction calculated as average for one system will be normally less than 10%, but for the last metres of the domestic installation system a surface fraction of 10% can be exceeded. The conversion factor of these product groups (B1-B3) corresponds to the conversion factor of the corresponding piping systems (A1-A3) multiplied by 0.1. The corresponding product group is derived from the size of the connector of the fitting or ancillary with the piping system and expressed by the ID of the piping system.

For **components of fittings and ancillaries** two main product groups are defined: C and D. For an assembled product the wetted surfaces of all components have to be determined. In case the wetted surface fraction of the component is larger than 10 % of the wetted surface of the assembled product, product groups B apply; in case the wetted surface fraction is between 1 % and 10 %, product groups C apply; and in case the wetted surface fraction is less than 1 %, product groups D apply. If components are made of the same main polymer(-s) or the same compositions, the respective surfaces are added to determine the product group (see 5.2.2.3). The conversion factors of product groups C and D consider the reduced surface fraction.

Fittings and ancillaries sold as spare part of assembled products are categorised as components of the assembled product.

For **storage systems** (e.g tanks) separate product groups (E1-E3) apply. Similar to the components of fittings and ancillaries, also for storage systems product groups for components (F1-F3) and small components (G1-G3) are defined.

5.2.2.3 Summation of fraction of wetted surfaces in assembled products

The fractions of wetted surfaces of materials used for components of an assembled product shall be summed in order to determine product group of components.

The summation is material specific (see Table 2).

Table 2: Summation of wetted surfaces to determine the product group

Type of Material	Legal text	Interpretation
Metallic materials	Prerequisute for product group C1: 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. (CID (EU) 2024/365 Annex 2 Table 2)	All components made of metallic materials classified in the same product group have to be considered. The summation is used to check the pass/fail criteria regarding the accepted product group.

Organic materials	If an assembled product consists of components made of the **same main polymer**, then the surface fraction of these components shall be cumulatively added for the determination of the product group… (CID (EU) 2024/368 Annex I 2.1)	Main polymer means that in case of organic materials consisting of different polymers only the main polymer is relevant. Same (main) polymer means that the polymers are made of the same monomers (e.g. PE, PVC, POM, PA) The summation is used to determine the product and risk group of the components.
Cementitious materials	If an assembled product consists of components made of the **same final material**, then the surface fraction of these components shall be cumulatively added for the determination of the product group… (CID (EU) 2024/368 Annex III 2.1)	Same final material means that the components are produced with the same formulation (same constituents according to the European positive list of organic constituents of cementitious materials are used)
Enamels, ceramic materials	If an assembled product consists of components made of the **same final material**, then the surface fraction of these components shall be cumulatively added for the determination of the product group… (CID (EU) 2024/368 Annex IV 2.1)	Same final material means compositions of the same entry of the European positive list of compositions of enamels, ceramic materials and other inorganic materials.

See Annex 7 for examples of the summation of wetted surface fractions.

In the case that the assembled product integrates treatment chemicals (e.g. ion exchange resins, sacrificial anodes) or filter media (e.g. filter membranes) according to DWD Article 12, these components and the respective surfaces shall not be considered for the total wetted surface of the complete product.

In special cases of ancillaries, the functionality of the main component inherently requires a large wetted surface area (e.g. heat exchangers). In order to obtain a device ready for operation, the main components will come along with other connected parts which in turn may have considerable wetted surface areas. If the total wetted surface area of the ancillary including its main component would be considered for calculation of the relative wetted surface proportion and thus the risk group of the other components, these would be assigned an inappropriately low risk group. As a result, components with potentially relevant possible influence on drinking water quality would not be tested and evaluated properly. Subsequently, the wetted surfaces of all other (remaining) parts and components are summed up and classified into corresponding product groups according to their respective relative surface fraction. For this classification step the surface of the main component is not considered.

If a pipe or a fitting is placed on the market it shall be classified in product group A or B, respectively. Pipes and fittings as components of an assembled product are considered as components and classified accordingly.

In case of lubricants, the manufacturer shall declare the maximum wetted surface fraction in contact with drinking water of the assembled product(s).

Connecting hoses, shower hoses and pull-out hoses are regarded as pipes and have to comply with the requirements for pipes.

For products at the point of use of the water (e.g. taps, hydrants, etc) all wetted surfaces shall be considered in all positions open and closed.

5.2.3 Risk groups

5.2.3.1 Purpose

Risk groups are defined to determine

- the testing requirements of the individual products or components according to CID (EU) 2024/368 and
- the procedure of the conformity assessment according to CDR (EU) 2024/370 (modules B and D or modules B and C according to Annex II of Decision No 768/2008/EC).

The reason for introducing the risk groups is that for minor components (small wetted surface and low contact time of the water with the component) the influence on the drinking water quality might be minor or neglectable and testing can be reduced or might not be necessary.

For products and components made of all materials except metallic materials four risk groups (RG) are defined.

The risk groups are determined by the conversion factor. Products and components for which a high conversion factor (≥ 4 d/dm) has to be applied will cause a higher impact on the quality of the water intended for human consumption. These products are categorized in risk group 1 (RG1) requiring the most extensive testing and the most extensive procedure for the conformity assessment.

In practice, the procedure for determining the risk group is as follows: For the products or components of assembled products first the product group is determined according to CID (EU) 2024/368 Annex I Table 5. This yields the conversion factor which is then used for the determination of the risk group according to CID (EU) 2024/368 material corresponding Annex Table 1. Annex 1 – 4 provide a summary of theses tables including the required conformity assessment procedures.

5.2.3.2 Organic materials

The risk groups for products or components made of organic materials specify the parameters to be tested and the type of test piece(s) to be used for testing. Three different types of test pieces are distinguished:

- **(assembled) product**,
- **component** or
- **test piece of the formulation**.

For certain risk groups and certain parameters, only the testing of the (assembled) product or of the component is possible.

Testing of **(assembled) product** means that the actual product of one manufacturer has to be tested. For the specific manufacturer it is possible that one product is tested covering a product type series (see 5.4.3).

So far, no European testing standard for assembled products is available. This means that only products made of one material, multilayer products (which cannot be disassembled) and the components of assembled products can be tested.

Testing of **component** means also that the actual component has to be tested. But compared with the requirement to test the product a wider grouping (product type series) is possible. A component can be tested representing a variety of components used in one assembled product, in different assembled products and also in assembled products of different manufacturers (see 5.4.4). To make this effective it is necessary that the certification of components is possible. This allows that the total number of required tests is reduced.

Testing of **test piece of the formulation means** that the testing of a test piece made of a final material produced from a specific formulation under well-defined conditions represents all components made from this formulation independent from the production site and the actual manufacturer of the final material. To make this effective the certification of pre-products is required (see 5.4.5). This approach allows that for components of assembled products classified in RG3 and RG4 and no further testing is required. For RG1 and RG2, some tests are required on the level of product or component and other tests are also accepted on the level of test pieces of the formulation. In this case the certificate of the pre-product covers the tests required on the level of test pieces of the formulation and allows a significantly reduced testing of these components or products.

5.2.3.3 Metallic materials

Metallic materials are not categorized in risk groups. Compositions of metallic materials are intensively tested in the process of the assessment for the acceptance in the European positive list. The conformity assessment is limited to the testing of the composition. For this reason, the risk based approached is limited to the procedure for the conformity assessment, which is determined by the product group directly.

5.2.3.4 Cementitious materials

For cementitious materials there is no difference in the testing requirements for RG 1 – RG 3. Only for small components classified in RG 4 a reduced testing is possible.

Cementitious materials are mainly used for water abstraction, distribution of raw water, in water treatment works and in the water distribution system of the water supplier. The products made of cementitious materials are quite large and testing of the actual products is not possible and specifically produced test pieces (e.g. prisms or test plates) have to be used.

The testing of final cementitious materials can be reduced when the constituent products are certified (see 5.4.7).

5.2.3.5 Enamels, ceramic materials and other inorganic materials

For enamels, ceramic materials and other inorganic materials there is no difference in the testing requirements for RG 1 – RG 3. Only for small components classified in RG 4 a reduced testing is possible.

Enamelled products (e.g. tanks, large valves for the distribution system) are in most cases quite large and testing of the actual product is not possible. For this reason, enamelled plates made of steel are used as test pieces. For products or components classified in RG 1 – RG 2 these test pieces have to be produced at the production site of the respective product. For products or components classified in RG 3 the test pieces might be produced by any manufacturer. For this risk group the testing covers the use of the respective enamel by any enameller.

5.3 Conformity assessment procedures

5.3.1 Modules

The procedure for the conformity assessment follows also a risk-based approach.

In all cases the conformity assessment body has to perform a type examination according to module B ‘type examination’ of Annex II to Decision no 768/2008/EC. For this an examination of a test piece (production type) is required.

For products categorised in RG1 and RG2 (product groups A & B for metallic materials) the conformity assessment body has to assess and survey the quality assurance of the production process (module D ‘Conformity to type based on quality assurance of the production process’ of Annex II to Decision no 768/2008/EC) additionally. This includes periodic audits at the production sites. The certificates issued for these types of products have to be based on both modules B & D and are issued by one conformity assessment body.

For products or components falling in RG3 and RG4 (product groups C & D for metallic materials) the manufacturer has to use an internal production control (module C ‘Conformity to type based on internal production control’ of Annex II to Decision no 768/2008/EC), which is not audited or surveyed by the conformity assessment body. For these types of products, the certificates issued are limited to module B ‘type examination’.

5.3.2 Single material or multilayer products

The manufacturer has to provide a detailed technical documentation of the product to the conformity assessment body. This technical documentation has to include:

- a general description of the product
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the products,
- Specification including
    - type of material(s) (e.g. PE-Xa, POM, CW511L),
    - the production site(s),
    - formulation or composition as known
    - suppliers of the starting substances, pre-products, intermediate products, compositions or constituents
    - certificates available for the pre-products, intermediate products, formulations, compositions or constituents (if applicable)
- wetted surface area of the product,
- if the product is no pipe the ID of the piping system the product is intended to be installed and
- any other relevant information for the assessment of the product

If the application is made for a product type series the information has to be provided for all products or components of the type series.

Additionally, the manufacturer has to provide a written declaration that the same application has not been lodged with any other notified body.

The conformity assessment body has to define the risk group of the product based on the product group (see 5.2.3).

5.3.3 Assembled products

The manufacturer of an assembled product has to provide a detailed technical documentation of the assembled product to the conformity assessment body. This technical documentation has to include:

- a general description of the product
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the products,
- Specification for each component including
    - type of material (e.g. PE-Xa, POM, CW511L),
    - the wetted surface area,
    - the manufacturer(s) or suppliers of the component and alternative suppliers,
    - the production site(s),
    - formulation or composition as far as is known
    - suppliers of the starting substances (if used directly to produce components of the assembled product), pre-products, intermediate products, compositions or constituents
    - certificates available for the components, pre-products, intermediate products, formulations, compositions or constituents
- wetted surface area of the complete assembled product
- ID of the piping system the product is intended to be installed and
- any other relevant information for the assessment of the product

If the application is made for a product type series the information has to be provided for all products or components of the type series.

Additionally, the manufacturer has to provide a written declaration that the same application has not been lodged with any other notified body.

Where the product is an assembled product, the applicable conformity assessment procedure shall be determined by the individual component with the highest risk group categorisation (RG1 is the highest risk group, RG4 is the lowest risk group) under Implementing Decision (EU) 2024/368 or, in the case of metallic compositions, the highest categorised product group in Table 2 'Product group for metallic compositions' of Annex II to Implementing Decision (EU) 2024/365. (CDR (EU) 2024/370 Article 2 Paragraph 3)

For an assembled product, the risk group of each individual component (for the summing of surfaces see 5.2.2.3) shall be determined in order to determine the component categorized in the highest risk group categorization (for non-metallic material) or the highest product group categorization (metallic material). In most cases the complete assembled product will exhibit the highest risk group and will determine the conformity assessment procedure. However, in some specific cases components might be classified in a higher risk category (RG 2) than the assembled product in which it is incorporated (e.g. metallic product with a high organic wetted surface > 10% intended to be used in the distribution system). In this case the manufacturer of the assembled product is assessed according to RG2 but the audit will focus only on this specific component.

The applicable conformity assessment procedure for the manufacture of an individual component of an assembled product shall be determined by the risk group of that individual component under Implementing Decision (EU) 2024/368 or, in the case of metallic compositions, the product group of the individual component in Table 2 'Product group for metallic compositions' of Annex II to Implementing Decision (EU) 2024/365. (CDR (EU) 2024/370 Article 2 Paragraph 4)

Components of assembled products are dealt according to the respective risk groups. This means that for small components (e.g. O-rings) falling in RG3 and RG4 module D does not apply and the

conformity assessment body does not survey the quality assurance system of the production process of these components. This applies for components when assembled products are certified but might also apply to the certification of components.

For the identification of the risk group of the components the summation of wetted surfaces of components made of the same main polymer or the same composition applies (see 5.2.2.3).

For components made of organic materials: If the wetted surface fraction of all components of the same main polymer is ≥ 10 % of an assembled product, the conformity assessment procedure according to module combination B and D (as set out in Annex II to Decision No 768/2008/EC) is not generally and mandatorily applicable for all components if it can be demonstrated during the type examination for all components (e.g. by a pre-product certificate) that the test requirements and acceptance criteria according to RG 2 are fulfilled, whereby the conversion factor of the corresponding product group must be applied.

If the wetted surface fraction is < 10% for all individual components, the conformity assessment procedure according to module combination B and D has only to be applied for the component with the largest wetted surface fraction. An Example for this case is given in Annex 7 of this document.

If the wetted surface fraction of one or more components is ≥ 10%, the conformity assessment procedure according to module combination B and D has to be applied for these components, but not for components with a wetted surface fraction of < 10%. The surface fraction of elastomer gap or ring seals is summed up independently of other components made of the same base polymer (e.g. expansion membranes). Although in very rare cases the sum of the surface fractions of gap and ring seals in an assembled product can result in a surface fraction of > 10 %, in these cases only the requirements of product group C and risk group 3 apply.

Only for components classified in RG1 or RG2 the conformity assessment body has to withdraw test pieces for testing.

If components are already certified according to the correct risk group no further testing of these components are required. In this case, the surveillance of the conformity assessment body is limited to check that the correct components are used for the production of the assembled product.

5.3.4 Type examination (Module B)

For the type examination the product has to be tested for all parameters according to CID (EU) 2024/368. The testing might be reduced due to the risk-based approach for testing. Certificates issued for components reduce the testing requirements for assembled products. Certificates issued for pre-products or intermediate product reduce testing requirements for the final product.

The conformity assessment body has to define the detailed testing requirements including parameters based on the formulation review for organic and cementitious materials, the composition review for metallic materials, enamels, ceramic materials, the identified risk groups and the provided certificates for components, pre-products, intermediate products, constituent products and formulations.

For products and components classified in RG1 and RG2 (product groups A & B for metallic materials) it is important, that the test pieces used for testing are withdrawn by the conformity assessment body at the production site and that the test pieces are products as placed on the market. The conformity assessment body has to ensure that no additional post-treatment or cleaning process, deviating from the regular production process, is applied to improve the test pieces. If the products cannot be tested due to size or the testing procedure specially produced test pieces (test plates) can

be used for testing. In this case the conformity assessment body has to audit the production of the test pieces.

For products of RG3 and RG4 (product groups C & D for metallic materials) the manufacturer can send the test pieces to the conformity assessment body or the corresponding test laboratory. The tests should be performed after the conformity assessment body set the testing requirements.

If the tests are not carried out by the conformity assessment body the tests shall be performed by test laboratories. The certification body shall inform the manufacturer in advance of outsourcing activities, in order to provide the client with an opportunity to object (see EN ISO/IEC 17065).

The tests as required according to CID (EU) 2024/368 have to be performed on behalf of the conformity assessment body. For the assessment of other requirements originating from the European Positive Lists (e.g. purity or molecular mass distribution of a starting substance) the applicant or the respective suppliers might provide test reports or declarations of conformity.

The type examination has to be repeated after 5 years.

5.3.5 RG1 & RG2: Quality assurance of the production process (Module D)

For product or components of RG1 & RG2 (product groups A & B for metallic materials) module D according to Decision No 768/2008/EC applies. This means that manufacturers shall operate a quality system for **production**, **final product inspection** and **testing of the products**. This system has to address specifically the requirements according to CID (EU) 2024/368 and has to be approved by the conformity assessment body that carries out the type examination. The agreed quality system shall include the frequencies of monitoring, inspections and testing. The quality system by the manufacturer has to address the material specific properties. Table 3 gives details for the material specific elements of the quality system, which have to be further specified for the individual quality system and might be completed by other measures.

Table 3: Material specific elements of the quality system by the manufacturer

Material	Production	Final product inspection	Testing of the products
Organic	Monitoring system of: • Material flow in the manufacturing process. • Critical process parameters (e.g. temperature and pressure of injection moulding)	No specific requirements – final product inspection might be visual or by other means to ensure a constant quality of the final material.	For pipes: Migration testing and analysis of TON or alternative parameter (e.g. analysis of specific substances known to cause the relevant odour) For other products: No requirements for testing according to CID (EU) 2024/368.
Metallic	Monitoring system of: • Material flow in the manufacturing process. • Critical process parameters (e.g. temperature of post treatment to reduce β-phases)	See testing	<u>For cast materials</u>: Composition testing in the production and/or for final product inspection required <u>For wrought materials:</u>

			Composition testing for the incoming goods or acceptance test certificate 3.1 acc. EN 10204 by the supplier
Cementitious	Monitoring system of: • Material flow in the manufacturing process.	No specific requirements – final product inspection might be visual or by other means to ensure a constant quality of the final material.	No requirements for testing according to CID (EU) 2024/368.
Enamels, ceramic and other inorganic	Monitoring system of: • Material flow in the manufacturing process. • Critical process parameters	No specific requirements – final product inspection might be visual or by other means to ensure a constant quality of the final material.	No requirements for testing according to CID (EU) 2024/368.

The conformity assessment body surveys the quality system. For this it carries out an initial inspection and annual inspections of the production site. Further details for these inspections are provided in Annex 5.

The conformity assessment body has to survey the used starting substances, pre-products, intermediate products, compositions or constituents in the course of the audit. For this reason, the auditing team needs to have access to the formulation of the organic and cementitious materials (at least to the list of pre-products and intermediate products provided to the conformity assessment body for the respective production site) and the compositions declared for the type examination.

During the yearly inspection the conformity assessment body withdraws test samples. However, a complete testing of the samples according to CID (EU) 2024/368 is only required every 5th year. In-between this period a reduced testing shall be performed according to Table 4. For organic and cementitious materials still a migration test according to CID (EU) 2024/368 is required. However, the migrations waters only have to be analysed for TON, TFN, colour, turbidity and TOC. The analysis is only required when a corresponding test is also required for the type examination.

Table 4: Material specific reduced testing by the conformity assessment body

Material	Testing
Organic	Analysis of the migration waters for TON, TFN, colour, turbidity and TOC
Metallic	Testing of composition
Cementitious	Analysis of the migration waters for TON, TFN, colour, turbidity and TOC
Enamels, ceramic and other inorganic	Testing of composition

The conformity assessment body issues a certificate for the product based on the type examination and of the surveillance of the quality system.

5.3.6 RG3 & RG4: Internal production control (Module C)

For products or components classified in RG3 and RG4 (product groups C & D for metallic materials) the manufacturer shall make use of an internal production control according to module C as set out in Annex II to Decision No 768/2008/EC.

This system is not surveyed by the conformity assessment body. The internal production control (Module C) is not covered by the certificate issued by the conformity assessment body. The certificates issued for products falling in RG3 and RG4 are limited to Module B. The manufacturer declares the use of an internal production control by means of the declaration of conformity.

5.4 Type of certificates

5.4.1 Overview

The conformity assessment bodies can issue the following types of certificates.

Table 5: *Type of certificates*

Certificate issued for	EU marking	Notes
Product	Yes	• Covers a single product (can be an assembled product) • Certificate has to clearly specify the covered product and all production site(s) • Certificate has to specify the assessed product group and the applied conformity assessment procedure (modules B & D or module B)
Product type series	Yes	• Covers a group of (assembled) products (see 5.4.3) • Certificate has to list the covered products and all production site(s) • Certificate has to specify the assessed product group and the applied conformity assessment procedure (modules B & D or module B)
Component(s)	Yes[1]	• Covers a group of components (see 5.4.4) • Certificate has to list the covered components and all production site(s) • Certificate has to specify the assessed product group and the applied conformity assessment procedure (modules B & D or module B)
Pre-product	No	• Issued for pre-products • Certificate is issued for a pre-assessment and is based on the testing of test pieces made of the final material • Certificate has to specify the assessed product group • Certificate has to make a reference to the production conditions to be applied
Intermediate product	No	• Issued for intermediate products (e.g. coatings, adhesives, polymers to be cross-linked, ready-to-used cementitious product (Type 2))

[1] In certain cases (see 7.2.2) the symbol does not have to be affixed on the component, even when the component is certified according to CDR (EU) 2024/370

		• Certificate is issued for a pre-assessment and is based on the testing of test pieces made of the final material • Certificate has to specify the assessed product group • Certificate has to make a reference to the production conditions to be applied. • For the assessment of final organic material classified in RG2 this certificate covers only the formulation review and EMG. • This certificate is important for site applied products
Constituent product	No	• Issued for constituent products used for manufacturing of cementitious materials • Certificate is issued for a pre-assessment and is based on the testing of the constituent product in a standardized cementitious matrix as a test piece of a final material • Certificate has to specify the assessed product group and its maximum authorized concentration in the formulation (concentration which has been tested)
Formulation	No	• Certificate has to specify clearly that the certificate only covers the formulation review and that no further testing was performed. • Certificate has to include the information that the conformity assessment body will provide the identity or the number of relevant substances to be analysed in the migration waters to other conformity assessment bodies. • Certificate only becomes effective when identity of relevant substances can be disclosed to other conformity assessment bodies.

Some of the certificates are not issued for products made of final materials. These certificates are issued as a pre-assessment for certain final materials and are not issued according to CDR (EU) 2024/370. The products covered by these certificates must not be marked according to CDR (EU) 2024/371. It is recommended to issue certificates for pre-products, intermediate products, constituent products and formulations because this simplifies the assessment of products. Conformity assessment bodies should acknowledge these certificates issued by another notified conformity assessment body for their assessment of products or components made of final materials.

It is important that the title of the issued certificate clearly indicates the type of the certificate. For some certificates (see Table 3) the assessed product group and the applied conformity assessment procedure (modules B & D or module B) have to be clearly specified on the front page of the certificate. The certificate shall contain:

- Name and address of the manufacturer
- Conclusion of the conformity assessment
- Any conditions for the certificate depending on the type of certificate
- Necessary data for identification of the approved type depending on the type of certificate
- Product group and applied conversion factor for the assessment
- Approved temperatures (23°C / 60°C / 85°C)

Annexes 8 -13 provide templates for different certificates. The information provided in these templates should be included on the front page of the issued certificates.

One manufacturer might have several production sites. If the production sites are under the same entity, with same quality management system and with same quality assurance of the production process, products manufactured at these different sites can still be covered by one certificate.

The use of alternative suppliers of pre-products, starting substances, constituents or compositions has to be considered for the assessment and might require additional testing. For example, for the use of granulated polymers obtained from different suppliers to manufacture pipes or other products a testing of the products manufactured by using the alternatives is required, if the pre-products are not certified.

5.4.2 Product

5.4.2.1 Pipes and other single material or multilayer products

A certificate issued for a single product made of one single material or a multilayer material is straightforward.

Products made of organic materials with variations of the formulation (e.g. colour) cannot be covered by one certificate. However, tests performed for certain parameters might be considered for the conformity assessment of the modified product (see 6.1.2.2.2).

5.4.2.2 Assembled products

In the best case for all components of the assembled product valid certificates are available. This can be certificates for the component or certificates issued for the corresponding pre-product.

For the validity check of the certificates the conformity assessment bodies have to check:

- The certificates cover the correct product group and risk group of the component in the assembled product.
- The certificates were issued by notified conformity assessment bodies.
- The certificates are not expired at the date the certificate of the assembled product is issued.

If for all components valid certificates are available no further testing is required and the audit at the production site is limited to the check that the correct components are used.

A pre-product certificate does not cover all testing requirements for a component classified in RG2, even when the certificate is issued for the corresponding product group of the component. In this case a migration test of test pieces withdrawn at the production site by the conformity assessment body has to be performed and the migration waters have to be analysed for TOC, TON, TFN, colour and turbidity. Additionally, for this component Module D of Annex II of Decision No 768/2008/EC for the conformity assessment procedure applies, which is also not covered by the pre-product certificate.

An intermediate product certificate only covers components classified in RG3 & RG4. For components classified in RG2 only the formulation review and EMG testing might be recognized for the assessment of the final materials.

The testing requirements for components made of metallic materials are limited and a certificate issued for these components might not be necessary, as testing of the composition will be required additionally for the certification of the assembled product.

5.4.3 Product type series

5.4.3.1 Pipes and other single material or multilayer products

Pipes and other mono-material or multilayer products with different dimensions

- made of the same starting substances (formulation) in case of organic materials, same constituents in case of cementitious materials or metallic compositions,
- by applying the same production process and
- produced by the same manufacturer

can be considered as one product type series (for pipes also known as product family) and can be covered by one certificate for a product type series.

The products may fall in different risk group or product groups. The product classified in the highest risk group or in the product group with the highest conversion factor within the product type series is used as representative for the entire product type series.

It is sufficient that only one size of the pipes or product is tested. For pipes made of organic materials this shall be the pipe with the smallest ID. If this is not possible (e.g. due to non-availability or for the purpose of audit testing) and a pipe with another ID is tested, the conversion factor according to the available smallest ID has to be applied for the calculation of c_{tap}.

The certificate has to include a list with all products covered.

5.4.3.2 Assembled products

Assembled products might also be grouped in a product type series. Examples for assembled product type series are:

- Taps of different geometries but similar components made of the same final materials
- Water dispensers in different sizes with customer specific accessories
- Circulation pumps in different sizes
- Borehole pumps in different sizes, where additional equipment or accessories could be installed (e.g. motor cooling), or where customer specific technical requirements apply (cable length)
- Water heating systems e.g. with different tank sizes or customer specific accessories
- Instantaneous water heaters in different sizes

The approach for the assessment of this kind of product type series follows the approach for the assessment of a single assembled product, but has to cover the whole range of products. When the wetted surfaces of certain components used in different assembled products belonging to the product type series will result in different risk groups, the assessment of this component has to be performed for the highest identified risk group.

The product type series might cover different accessories or alternative components of the assembled products.

The certificate has to clearly specify the covered products including a list of all products with all accessories or alternative components if relevant.

5.4.4 Components

5.4.4.1 General

Components (including lubricants and greases) of assembled products can be regarded as products and can also be certified according to the CDR (EU) 2024/370. The use of certificates for components simplifies the conformity assessment procedure of assembled products. In the best case for all components of an assembled product certificates exist so that no further testing for the conformity assessment of the assembled product is required. It is important that the conformity assessment

bodies acknowledge certificates of products / components issued by another conformity assessment body for their conformity assessment of assembled products.

In most cases certificates issued for components will cover a type series. This means that 5.4.3 additionally applies. The components may fall in different risk or product groups. The component classified in the highest risk group or in the product group with the highest conversion factor within the product type series is used as representative for the entire product type series. The testing has to be performed with a representative component identified by the conformity assessment body. If yearly testing is required the tested components shall vary among the components.

Certificates might be issued for single material components but also for assembled components (e.g. mixture cartridge for taps).

The certificate has to clearly specify the covered components (in case of a type series a list of all covered components has to be included) and the production site(s).

5.4.4.2 Single material components

Case 1: **The manufacturer of the component applies for certification**

Components

- made of the same starting substances (formulation) in case of organic materials, same constituents in case of cementitious materials or same metallic compositions,
- by applying the same production process and
- produced by the same manufacturer

can be covered by one certificate, even when these components are used for different assembled products or assembled products of different manufacturers.

If the certificates are issued for RG2 the required audit will take place at the production sites of the components.

Case 2: **The manufacturer of the assembled product applies for certification**

Components

- made of the same starting substances (formulation) in case of organic materials, same constituents in case of cementitious materials or metallic compositions,
- by applying the same production process defined by the manufacturer of the assembled product,
- produced by different manufacturer as a specified order of the manufacturer of the assembled product and
- used in one or more assembled product

can be covered by one certificate.

The manufacturer of the assembled product shall define the used pre-products, starting substances, constituents or compositions and the production process including production parameters.

The initial testing can be limited to components made by one manufacturer. For the re-testing the conformity assessment body should aim to withdraw components produced by a different manufacturer for testing.

If the conformity assessment procedure requires an inspection of the production site of the component (e.g. RG2), the inspection can be limited to the manufacturer of the assembled product.

In this case the manufacturer of the assembled product has to request a documentation to ensure that the quality assurance of the production process is fulfilled by the manufacturer of the component and make it available for the conformity assessment body. This documentation includes process parameters (e.g. pressures and temperatures) applied for the individual lots delivered by the supplier and all documentation as detailed in Annex 5. Depending on the available documents the conformity assessment body will decide if an audit is necessary at the component production site.

5.4.4.3 Assembled components

Conformity assessment bodies can issue certificates for an assembled component (also called pre-assemblies, e.g. mixer cartridge) analogue to 5.4.2.2 or for a product type series of assembled components analogue to 5.4.3.2.

For assembled components the certificate has to specify the total wetted surface of each complete assembled component and the maximum wetted surface fraction of the assembled component in the final assembled product, which was used for the assessment of the assembled component. For the assessment of the final assembled product only the wetted surface of the complete assembled component has to be considered. The surfaces of the components of the assembled component do not have to be considered for the summation of the surfaces to define the product groups of the other components of the assembled product.

5.4.5 Pre-product

The DWD introduces the term “final material” to clearly specify that the testing has to be performed on the level of the final materials as used in products. Production processes like injection moulding potentially have an influence on the characteristics of the final materials. For this reason, the type and manufacturing conditions of the production processes have to be considered for the conformity assessment and it is important that the products or components as used are tested.

The risk-based approach for testing allows that the testing of test pieces representing the final material covers a variety of products or components. To this end, the test pieces have to correspond with the final materials as used for products. It is important that the production process of the final materials is clearly defined and that testing covers only those products or components that are produced according to this process. This approach becomes very effective and reduces the tests required in total significantly when pre-products are certified. This is especially of advantage as the time consuming and difficult formulation review will have to be performed only once and not for all products and components.

As pre-products do not correspond to final materials, formally a certification according to CDR (EU) 2024/370 is not possible. However, the notified conformity assessment bodies can issue certificates for pre-products, which can be used as a pre-assessment of the conformity assessment of products made of final materials.

To accomplish this voluntary certification, testing has to be performed on test pieces made of the final material (not on the pre-product e.g. granulate). As the production process may have an impact on the characteristics of the final material, the manufacturers of the pre-products have to specify conditions of the production process of the final materials. The conformity assessment body has to audit the production of the test pieces and to withdraw the test pieces for testing.

Testing shall include all parameters that apply for the products to be made out of the pre-product, taking the intended use into account. This includes parameters that may need to be tested ‘on product’ or ‘on component’, to show that a fully compliant product can be made out of the pre-product. Any parameter that needs to be tested ‘on product’ or ‘on component’ will also need to be tested on the final product.

Only pre-products that comply with all applicable test requirements can be certified.

The issued certificate is limited to the specific production process of the final materials and has to be specified in the certificate (e.g. by making a reference to production conditions specified by the manufacturer of the pre-product). The issued certificate also needs to state for which intended use the pre-product was assessed.

NOTE: As testing for pipes made of organic materials shall mainly be performed 'on product' and production processes often differ from those for fittings and ancillaries, the benefit of certifying pre-products for intended use as pipes is limited.

Certified pre-products must not be marked according to CDR (EU) 2024/371. However, notified conformity assessment bodies shall acknowledge certificates of pre-products (resulting from such a pre-assessment) issued by another notified conformity assessment body for their subsequent conformity assessments of products made of final materials. The pre-product certificate must cover the use of the product, including temperature, intended use and production conditions. A higher intended use (e.g. fittings, ancillaries) covers a lower intended use (e.g. component of fittings, ancillaries). Annex 14 provides a template for an annex of a pre-product certificate indicating the coverage of the certificate.

5.4.6 Intermediate products

Intermediate products (e.g. commodity to produce an organic coating) are used for the manufacturing of factory-made products but also to produce site-applied products**.** Like pre-products these commodities cannot be certified according to CDR (EU) 2024/370 and cannot be marked according to CDR (EU) 2024/371 as these are no final materials.

A certification of these intermediate products reduces the extent of the assessment of final materials and is an effective approach for site-applied products. However, as the curing of this intermediate products is of importance for the characteristics of the final material the scope of these certificates is more limited than the scope for pre-products. For products and components made of organic materials and classified in RG1 and RG2 an intermediate certificate can only be used for demonstrating the formulation review and EMG testing of the final product. All other parameters will have to be re-tested for products or components produced by the manufacturer of the final material.

Nonetheless, for issuing an intermediate product certificate testing shall include all parameters that apply for the products to be made of the intermediate product, taking the intended use into account, even when a re-testing of these parameters for the certification of the final product is required.

The testing has to be performed for a final material. For example, for the testing of a commodity to produce organic coatings test plates have to be coated as test pieces. The conformity assessment body has to audit the production of the test pieces and to withdraw the test pieces for testing.

The issued certificate is limited to the specific production process of the final materials and has to be specified in the certificate (e.g. by making a reference to production conditions specified by the manufacturer of the intermediate product).

Annex 15 provides a template for an annex of an intermediate product certificate indicating the coverage of the certificate as pre-assessment for final products or final components.

5.4.7 Constituent products

The use of constituent products is common to produce factory-made and site-applied products made of cementitious materials. A constituent product is a specific good of one supplier, which is placed on the market. Examples for constituent products are:

- Specific cement grade of one supplier
- Specific aggregate grade of one supplier
- Specific mortar grade of one supplier
- Retarder of one supplier

For the testing of constituent products, the test pieces containing a standardized cementitious matrix have to be used. The test pieces can either be produced by the test laboratory or by the manufacturer of the constituent product. The conformity assessment body has to audit the production of the test pieces and to withdraw the test pieces for testing if the test pieces are not produced by the test laboratory.

Constituent products certificates are valid for products and components classified in any risk group. This means if the constituent product is certified by a notified conformity assessment body the formulation of the constituent product does not have to be provided to the conformity assessment body of the final material and no further testing related to this constituent product is required.

Certified constituent products must not be marked according to CDR (EU) 2024/371.

Annex 16 provides a template for an annex of a constituent product certificate indicating the coverage of the certificate as pre-assessment for final products or final components.

5.4.8 Formulations

As the formulation review is a demanding and time-consuming process, the certification of products made of final materials can be accelerated when the formulation review for products made of the same pre-products or for certain commodities (e.g. glass fibres including sizing agents) used in formulations of different final materials is only completed once.

This can be dealt with by an internal process of the conformity assessment body but can also be extended to other conformity assessment bodies. In the latter case certificates for the formulation can be issued.

Based on the formulation review the relevant substances are identified to be analysed in the migration test. As these relevant substances, which are part of the formulation, are in most cases confidential, they cannot be provided on the certificate. However, the certificate should specify that the number or the identity of the substances to be analysed in the migration waters will be provided by the conformity assessment that issued the certificate to another conformity assessment body. This kind of certificates only become effective when the owner of the formulation allows the conformity assessment body of the formulation to provide the identity of the relevant substances to the conformity assessment body assessing the product made of the final material. Alternatively, respective manufacturer provides the identity of the relevant substances to the conformity assessment body assessing the product made of the final material. Certificates issued for formulations give no indication for a compliance of the final material with the requirements. This has to be clearly indicated on the certificate.

Pre-product and intermediate certificate except issued for components classified in RG4 include a formulation review. If these certificates are used for products or components classified in a risk group requiring the testing of relevant substances for the product or component, the identity of the relevant substances has to be submitted to the other conformity assessment body in the same way as for formulation certificates.

5.4.9 Validity of certificates

All certificates issued by the conformity assessment bodies are valid for 5 years.

At the date of issue, the formulation and compositions have to comply with the European Positive List. This is important as all positive list entries have an expiry date.

If certificates issued for components, pre-products, intermediate products and formulations are used for the assessment of products these certificates have to be valid at the date of issue of the certificate of the products. Also in this case, the conformity assessment bodies can issue a certificate for the final product with a validity of 5 years, but should check the status of the underlaying certificates in the progress of the annual inspection.

6 Testing & Assessment

6.1 Organic Materials

6.1.1 General procedure for testing and accepting final organic materials as used in a product (Chapter 1 of Annex I of CID (EU) 2024/368)

The testing requirements are subject to a risk-based approach (5.2.3.2). This approach ensures proportionate testing in relation to the human health risk of the final material.

As described before (see 5.1) the testing and assessment has to be carried out on the level of the components of assembled products. Only for single material products or multilayer products (e.g. pipes) the testing is performed on the level of the product to be certified.

The procedure for testing and accepting final organic materials as used in a product includes three main steps.

Step 1– Identification of relevant substances and relevant other parameters

For the identification of the required testing the risk group of the product or component has to be determined.

Based on the identified risk groups a formulation review is required (RG1 -RG3). In most cases the formulation review is a quite complex task as the conformity assessment body will have to contact suppliers and upstream suppliers. As a result of the positive formulation review the relevant substances to be analysed in the migration waters will be identified.

Step 2 – Performance of tests

Two different types of migration testing are required. For the parameters TOC, relevant substances and unexpected substance a migration testing according to EN 12873-1/2 has to be performed. For the parameters odour, flavour, colour and turbidity the migration test has to be performed according to EN 1420. For relevant substances modelling of the migration can be used instead of testing.

Testing for the Enhancement of the Microbial Growth (EMG) according to EN 16421 is carried out independently of the migration testing. It might even be performed by a different testing laboratory.

If the formulation review reveals that for certain starting substances QM or QMA restrictions apply the residual content of these substances in the final materials has to be determined.

Step 3 – Compliance with pass/fail criteria

Finally, the conformity assessment body has to check the test results for compliance with the pass/fail criteria. In case of the migration testing for TOC, relevant substances and unexpected substances a conversion of the test results to calculate the concentration expected at the tap (c_{tap}) has to be made (see 5.2.2.2).

6.1.2 Identification of relevant substances and relevant other parameters (Chapter 2 of Annex I of CID (EU) 2024/368)

This is step 1 of the procedure for testing and accepting final organic materials.

6.1.2.1 Categorisation of products or components into risk groups and corresponding testing requirements (Chapter 2.1 of Annex I of CID (EU) 2024/368)

For each product or component of an assembled product, a product group and a corresponding conversion factor (CF) shall be determined in accordance with Table 5 (of Annex I of CID (EU) 2024/368). Based on the determined CF, the product or component is categorised in a risk group (RG) in accordance with Table 1 (of Annex I of CID (EU) 2024/368).

Table 1 (of Annex I of CID (EU) 2024/368): Risk-based testing requirements for products or components of assembled products.

Risk group	Conversion factor (CF)	Formu-lation review	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG
RG1	≥ 4	Yes	Yes, on product	Yes, on product	Yes, on product	Yes, on product	Yes, on product for pipes with CF > 10 d/dm or test piece of the formulation
RG2	≥ 0.4 and < 4	Yes	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product or component	Yes, on (assembled) product or component	Yes, on component or test piece of the formulation
RG3	≥ 0.04 and < 0.4	Yes	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on component or test piece of the formulation
RG4	< 0.04	No	No	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on component or test piece of the formulation

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

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

For an assembled product, the components shall be determined. For each component in an assembled product, a product group shall be determined. If an assembled product consists of components made of the same main polymer, then the surface fraction of these components shall be cumulatively added for the determination of the product group in accordance with Table 5 (of Annex I of CID (EU) 2024/368).

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

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

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

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

For further explanation see 5.2.

6.1.2.2 Formulation review (Chapter 2.2 of Annex I of CID (EU) 2024/368)

A formulation review is required in accordance with the requirements in Table 1 (of Annex I of CID (EU) 2024/368).

The formulation review is a very important step of the assessment and has to be performed by the notified conformity assessment body. It results in the identification of the relevant substances to be analysed in the migration waters. In most cases the formulation review is quite complex and time demanding, as suppliers and sub-suppliers need to be involved and details of the formulation (e.g. impurities) need to be specified.

The complete formulation has to be disclosed to the conformity assessment body. In most cases the manufacturer of the final material is not able to provide the full formulation as he may only be aware of the pre-products or intermediate products he is using. For this reason, the respective conformity assessment body has to approach the suppliers (e.g. of the granulate) and sub-suppliers (e.g. of stabilizers or solvents used for the production of the granulate). Details of the formulation probably are classified as confidential. As a consequence, the conformity bodies may have to issue non-disclosure agreements to obtain the required information.

The disclosure of the formulation has to address the use of alternative suppliers. The conformity assessment bodies have to approach all alternative suppliers. Only alternative suppliers or manufacturers of single starting substances (no mixture or polymers) do not have to be considered by the conformity assessment body. In this case the manufacturers of the final materials might switch to alternative suppliers or manufacturers of single starting substances, if the purity of the starting substances is the same or higher.

The manufacturers of the final materials including the suppliers and sub-suppliers have to inform the conformity assessment body about modifications of the formulation or the use of alternative suppliers (except of single starting substances with the same or higher purity).

Certificates issued by notified bodies for pre-products (e.g. granulates) or formulations reduce the tasks for the formulation review of the variety of final products. In case of products or components of RG2 and RG3 certificates issued for the pre-products covers the formulation review and most of the testing requirements (expect migration testing for TOC, TON/TFN/colour/turbidity for RG 2). In case of products of RG1 certificates issued for pre-products or for formulations the formulation review can also be recognised. If the conformity assessment body of the product (e.g. pipe) is different from the conformity assessment body of the formulation or of the pre-product then the identity of the relevant substances to be analysed in the migration waters have to be provided by the conformity assessment body of the formulation / pre-product to the conformity assessment body of the final

product. This is only possible if the owner of the specific formulation allows this kind of exchange between the conformity assessment bodies. Alternatively, the conformity assessment body only provides the number of relevant substances to the other conformity assessment body. In this case the identity of the relevant substances is provided to the other conformity assessment body by the manufacturer or the suppliers.

6.1.2.2.1 Required Information (Chapter 2.2.1 of Annex I of CID (EU) 2024/368)

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

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

Independent of the testing procedure (assembled product or component) for all components of an assembled product an individual formulation review is required.

All starting substances and impurities need to be identified, including its percentages of use by mass (m/m %), adding up to 100%. For impurities or intentionally added substances, that are used in a quantity less than 10 ppm (0,0010%) it is allowed to state the amount in the formulation expressed as “mg/kg “.

Solvents have to be declared in the formulation, but are not considered for the quantification of the final material. It can be assumed that most of the mass of the used solvents will disappear in the production process.

In most cases the conformity assessment body will have to approach different suppliers and sub-suppliers to obtain the formulation on basis of starting substances. When the stage of the starting substances is reached the following information has to be provided for each starting substance:

- chemical name(s)
- brand name
- CAS number
- technological function
- quantities (m/m %) used in the production of the final material (or of the pre- or intermediate product)
- purity and impurities including quantities of the impurities (safety data sheet might include this information)
- suppliers

The conformity assessment body has to check the formulation for plausibility. If the provided formulation does not include all expected information (e.g. no information about catalysts or initiators for the production of polymers is provided) the conformity assessment body has to contact the manufacturer or supplier and ask for clarification.

Concerning general purity requirements for starting substances, the manufacturers have a specific responsibility. In view of their knowledge on the composition of substances and mixtures the manufacturer must be aware of possible health risks and must eliminate them if such risks occur.

The manufacturer shall provide the following information concerning impurities for all starting substances to the conformity assessment body:

- all impurities with relative mass percentages above 1 %, and
- all substances that are classified under CLP Regulation No 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction, with relative mass percentages above 0.1 %.

The notified conformity assessment body can omit asking for this information on the identity of the impurities provided the percentage of the impurities is below the respective cut-off value.

Additionally, the manufacturer of the starting substance has to confirm that the substance or mixture is suitable for the manufacture of drinking water contact materials.

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

(a) for one substance: 0,02% for RG1, 0,05 % for RG2 and 0,1 % for RG3 materials; and

(b) for the sum of all such substances: 0,1 % for RG1, 0,2 % for RG2 and 0,5 % for RG3.

The mass percentage is calculated in relation to the mass of the final material (excluding the dosage of solvents).

The cut-off values can only be applied by the conformity assessment body, as in most cases several suppliers will have to provide details for the formulation of the final material. These suppliers are not aware of the dosage for the production of the final material and whether the sum of all such substances is exceeded. As a consequence, the manufacturer and the suppliers will have to declare all intentionally added starting substances to the conformity assessment body.

The cut-off value can be applied to starting substance listed in the EU positive list of starting substances and for non-listed substances. If this is applied to listed substances these substances need not be analysed in the migration water independent of an existing MTC_{tap}. When the criterion for the sum of all such substances (0,1 % for RG1, 0,2 % for RG2 and 0,5 % for RG3) is exceeded, the corresponding formulation constituents displaying highest contents are further considered for the assessment.

For solvents the cut-off criteria can be applied for the residual content.

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

An aluminium layer, not intentionally perforated, is for example a total barrier. For food contact materials functional barriers are defined besides a total barrier. These functional barriers are not considered as total barriers, as they only delay but do not prevent the diffusion of migrating substances.

For multilayer products the details of the formulation need to be provided for each layer individually. However, for the calculation of the percentage (e.g. for the application of the cut-off value) the mass is related to total mass of all layers made of organic materials between the total barrier and the surface in contact with drinking water.

6.1.2.2.2 Relevant Substances (Chapter 2.2.2 of Annex I of CID (EU) 2024/368)

The formulation shall be evaluated and compared with the accepted starting substances of the European positive list of starting substances for organic materials set out in Annex I of Commission

Implementing Decision (EU) 2024/367. One of the objectives of the evaluation is to define the relevant substances, which shall be analysed in the migration water.

The relevant substances are:

(a) Starting substances used in the formulation, listed in the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367 and for which an MTC_{tap} applies;
(b) Substances like impurities, degradation or reaction products specified in the condition of use of the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367 used in the formulation;
(c) All substances set out in Table 4 of Annex I of Commission Implementing Decision (EU) 2024/367 of starting substances for organic materials if stabilizers with alkylphenol structural moieties are used;

The listed substances are commonly identified degradation products of stabilizers with alkylphenol structural moieties. The European positive list of starting substances for organic materials indicates these stabilizers for which the listed substances are relevant substances. If one of these stabilizers is used all substances set out in Table 4 of Annex I of Commission Implementing Decision (EU) 2024/367 of starting substances for organic materials are relevant substances and have to be analysed in the migration waters.

The degradation product 3,5-di-tert-butyl-4-hydroxy styrene (CAS 19263-36-6) is a relevant substance in Table 4 of Annex I of CID 2024/367. However, due to technical difficulties in analysing this substance (false positive results), the MTC_{tap} of 3,5-di-tert-butyl-4-hydroxy styrene shall not be checked.

(d) Starting substances used in the formulation, their impurities, degradation and reaction products not listed in the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) 2024/367, but accepted under section 2.2.3 (b) of this Annex;

If starting substances according to of CID (EU) 2024/368 Annex I 2.2.3 (b) (see below) are used the conformity assessment body has to take special notice of impurities and possible reaction and degradation products. It might be that the starting substance is not released into the drinking water but the reaction or degradation products. The identification of possible reaction or degradation products might not always be obvious (e.g. for stabilizers). For stabilizers at least all substances set out in Table 4 of Annex I of Commission Implementing Decision (EU) 2024/367 of starting substances for organic materials have to be considered as relevant substances.

(e) Aluminium, ammonium, barium, cobalt, copper, europium, gadolinium, iron, lanthanum, lithium, manganese, terbium and/or zinc, if the respective salts of authorised acids, phenols or alcohols, authorised in accordance with note 2. 'Scope of an authorisation', point ii. of the Annex I of Commission Implementing Decision (EU) 2024/367 are used;
(f) Starting substances of polymeric substances authorised in accordance with note 2. 'Scope of an authorisation', point iii. of the Annex I of Commission Implementing Decision (EU) 2024/367 for which an MTC_{tap} applies;
(g) Starting substances of pre-polymers and natural or synthetic polymers authorised in accordance with note 2. 'Scope of an authorisation', point v. of the Annex I of Commission Implementing Decision (EU) 2024/367 for which an MTCtap applies;

(h) Antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium if pigments or colorants are used in the formulation not complying with the purity requirements in accordance with section 4.6 of this Annex [I of CID (EU) 2024/368] or if the purity testing was not performed;
(i) Primary aromatic amines (PAA) if organic pigments or colorants are used in the formulation not complying with the purity requirements in accordance with section 4.6 of this Annex or if the purity testing was not performed;

For colorants that may contain primary aromatic amines as impurity or liberate these as reaction or degradation products during polymer processing, the colorant manufacturer shall provide the identity of the relevant primary aromatic amines to the conformity assessment body.

(j) Antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium if fillers are used in the formulation not complying with the purity requirements according to section 4.6 of this Annex or if the purity testing was not performed;
(k) In case additional material-specific criteria apply (see section 2.2.4): all substances or group of substances for which an MTC_{tap} has been set;
(l) In case of migration test with chlorinated test water: haloacetic acids (HAAs) and trihalomethanes total, as defined in part B of Annex I – to Directive (EU) 2020/2184.

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

Modification of the formulation due to the use of different pigments/colorants or the use of different suppliers (e.g. for aids to polymerisations, polymer production aids, glass fibres including sizing agents) might result in the identification of different relevant substances. In this case a complete retesting is not required. The retesting can be limited to the additional relevant substances, odour, flavour, colour, turbidity and TOC.

If during sampling it is not obvious that the test pieces is made of starting substances of a specific supplier, the migration waters have to be analysed for all relevant substances identified for all modifications of the formulation. The conformity assessment body should try to ensure that the test pieces withdrawn during inspection cover the modifications. If in one inspection not all modifications are available, the conformity assessment body should aim to sample the other modification in the course of the inspection in the next year.

6.1.2.2.3 Acceptance of starting substances (Chapter 2.2.3 of Annex I of CID (EU) 2024/368)

Organic materials shall only be made of :

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

(SVHC) under Regulation (EC) No 1907/2006 (REACH) for the ED, PBT or vPvB properties;

2. substances intentionally added in nanoform;
3. monomers of the main polymers in the material.

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

All substances in the formulation that are not falling under the definition of 'non-intentionally added species' are considered as starting substances.

When the conformity assessment body has the complete formulation and checked its plausibility, the conformity assessment body has to check whether the used starting substances are accepted.

The use of a starting substance is possible, if the substance is listed in the European positive list of starting substances for organic materials. In this case the conformity assessment body has to check whether the use of the starting substance corresponds with the technical function, the listed drinking water materials and the condition of use as provided in the EU positive list for the listed starting substance.

Starting substances not listed in EU positive list might still be accepted, if the substance its impurities and/or reaction and degradation products are not released into the drinking water at levels exceeding 0,1 µg/l. The use of such starting substance is further limited (see the legal text above):

Monomers of the main polymer always need to be listed in the EU positive list.

It is very important that the conformity assessment body identifies the relevant impurities, reaction and degradation products. This might not always be obvious (e.g. for stabilizers). Stabilizers are intended to react and a variety of reaction products might be formed. For this reason, it is recommended that the conformity assessment bodies only accept stabilizers listed in the European positive list of starting substances for organic materials.

If the information available seems not be plausible or complete the conformity assessment body shall reject the formulation and insist that the respective starting substance needs to be assessed for the acceptance in the EU positive list of starting substances for organic materials.

For the assessment of starting substances, the scope of an authorisation as defined in Note 2 of the EU Positive list of starting substances for organic materials (Annex I of CID (EU) 2024/367) shall be considered:

i. Where a starting substance appearing on the list as an individual entry is also covered by a group entry, the conditions of use and specifications and expiry dates applying to this starting substance shall be those indicated in the individual entry exclusively.
ii. Unless stated otherwise in [EU Positive list of starting substances for organic materials], the following salts of authorised acids, phenols and alcohols shall be considered covered by that authorisation: aluminium, ammonium, barium, calcium, cobalt, copper, europium, gadolinium, iron, lanthanum, lithium, magnesium, manganese, potassium, sodium, terbium, and zinc. This is subject to compliance with the corresponding $MTC_{tap,\ organics}$ value for the element or ion shown in Annex V [of the CID (EU) 2024/367] for organic materials. In certain

cases, where the safety assessment indicates concerns on the use of the free acids, only the salts should be authorised by indicating in the list the name as '… acid(s), salts'.

For calcium, magnesium, potassium, sodium accepted as salt constituents Annex V of CID (EU) 2024/367 states "Not applicable". This means that these elements do not have to be considered as relevant substances and do not have to be analysed in the migration waters. All other accepted salt constituents are relevant substances when used as starting substance or present as impurity. These elements have to be analysed in the migration waters.

iii. Mixtures obtained by mixing authorised starting substances without a chemical reaction of the components shall be considered covered by that authorisation.

iv. Where a starting substance appears on the list as its anhydrous form, its approval shall be considered to covers its hydrated form.

v. In the case of any natural or synthetic polymeric substance of an authorised monomer or other reactant and that polymeric substance is not used as an additive, that polymeric substance shall be considered covered by the authorisation of that monomer or other reactant. After the first European positive list, only entries for the monomer and other reactant shall be included.

vi. In the case of any natural or synthetic polymeric substance of an authorised monomer or other reactant and that polymeric substance has a molecular weight of at least 1 000 Da, that polymeric substance shall be considered covered by the authorisation of that monomer or other reactant when used as additives. After the first European positive list, only entries for the monomer and other reactant shall be included.
As an exception, this provision shall not apply to polymers obtained from microbial fermentation.

Polymers used as additives have a distribution of the molecular weights. The minimum molecular weight of 1000 Da applies not only to the mean molecular weight but also to the distribution. Information about the distribution (test report is recommended) has to be provided to the conformity assessment body. The fraction of the oligomers below 1000 Da can only be accepted if the dosage of this fraction is less than 1% expressed as mass percentage in the formulation of the final material. For polymers listed in the EU Positive List of starting substances for organic materials different restriction concerning the molecular fraction < 1000 Da might apply.

vii. Pre-polymers and natural or synthetic polymers, as well as their mixtures, used as monomer or other reactant incorporated in the polymer shall be considered covered by the authorisation of the monomers or other reactant required to synthesise them. After the first European positive list, only entries for the monomer or other reactant shall be included.
As an exception, this provision shall not apply to polymers obtained from microbial fermentation, pre-polymers for organopolysiloxanes used in the manufacture of silicones, rubbers, lubricants and surface treatment for fillers, and pre-polymers for coatings.

viii. After the first European positive list, only entries for a polymer shall be included in cases for which points v to vii are not applicable.

ix. Organic cementitious constituents authorised on the European positive list of organic cementitious constituents of Annex III [of CID (EU) 2024/367] may be used in organic materials when used as constituents in cementitious fillers.

x. Ceramic compositions authorised on the European positive list of composition for enamels, ceramic and other inorganic materials of Annex IV [of CID (EU) 2024/367] may be used as fillers in organic materials.

xi. Fibres made of metallic compositions authorised on the European positive list of compositions for metallic materials of Annex II [of CID (EU) 2024/367] may be used in organic materials.

xii. Fibres and microballs made of glass compositions authorised on the European positive list of composition for enamels, ceramics and other inorganic materials of Annex IV [of CID (EU) 2024/367] may be used in organic materials provided that each filament has a diameter above 1 µm and the average diameter of the filaments in the organic material is above 5 µm.

xiii. Water may be used as a starting substance in the manufacture of organic materials that come into contact with water intended for human consumption.

xiv. An entry in [the EU Positive list of starting substances for organic materials] covers a nanoform only when it is explicitly stated in the approval of that entry.

As the result of the formulation review it might be that for several substances MTC_{tap} values are identified, some of them with a very restrictive value, like MTC_{tap} = 0,1 µg/l for starting substances not listed in the European positive list. It has to be clear that the confirmation or even the certification of the formulation does not give any indication about a possible acceptance of the final materials.

6.1.2.2.4 Material specific requirements (Chapter 2.2.4)

For certain materials specific requirements are defined. These are requirements for common reaction or degradation products not covered by the entries of the respective starting substances in the EU positive list of starting substances for organic materials. The material specific requirements yield further relevant substances to be analysed in the migration waters.

For polyamide or polyurethane resin coatings, requirements on the release of primary aromatic amines (PAA) apply:

Parameter	Restriction
Sum of Primary Aromatic Amines (PAA)	MTC tap = N.D. (LOD = 0,1 µg/l) ([1])
([1]) Method should be improved to have a Limit f Detection (LOD) of 0,1 µg/l.	

Currently there is no standardized method available to test for the sum of primary aromatic amines with a sufficient detection limit. In the meantime, EN 17163 (2019-05) 'Pulp, paper and board - Determination of primary aromatic amines (PAA) in a water extract by a LC/MS/MS method' or another method which is at least as sensitive as EN 17163 shall be used to determine individual PAA. The method should at least include, but not be restricted to, the determination of aniline.

Requirements for rubbers are:

Parameter	Restriction
Sum of Primary Aromatic Amines (PAA) (a.o. aniline, o-toluidine)	MTC tap = N.D. (LOD = 0,1 µg/l) ([1])
Sum of secondary amines ([2])	MTC tap = 250 µg/l
Sum of N-nitrosamines ([3])	MTC tap = N.D. (LOD = 0,1 µg/l)
(1) Method should be improved to have a Limit Of Detection (LOD) of 0,1 µg/l. (2) sum of dibutylamine (CAS 111-92-2), diethylamine (CAS 109-89-7), dimethylamine (CAS 124-40-3), dicyclohexylamine (CAS 101-83-7), cyclohexylethylamine (CAS 5459-93-8), diphenylamine (CAS 122-39-4), dibenzylamine (CAS 103-49-1),	

benzyl-N- methylamine (CAS 103-67-3), benzylidenebenzylamine (CAS,780-25-6) N-methylaniline (CAS 100-61-8), N-ethylaniline (CAS 103-69-5), N-butylaniline (CAS 1126-78-9)

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

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

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

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

As substances with aminic, amidic or quaternary ammonium functionalities might react with the chlorine in the water leading to N-nitrosamines the sum of N-nitrosamines are relevant substances. However, in this case these substances need only to be analysed in the migration waters of the chlorinated test water.

6.1.3 Testing Requirements (Chapter 3 of Annex I of CID (EU) 2024/368)

This chapter describes step 2 of the procedure for testing and accepting final organic materials and provides information concerning the migration testing, the testing for Enhancement of Microbial Growth (EMG) and the testing for the residual content of substances.

The required testing is probably not in the scope of accreditation of the conformity assessment body. In this case the conformity assessment body will have to use test laboratories. For further specifications see EN ISO/IEC 17065.

See section 5.3.4 for the specification of the withdrawal of the test pieces.

6.1.3.1 Migration testing (Chapter 3.1 of Annex I of CID (EU) 2024/368)

6.1.3.1.1 Standards (Chapter 3.1.1 of Annex I of CID (EU) 2024/368)

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

(a) For factory-made products: EN 12873-1:2014;

(b) For site-applied materials: EN 12873-2:2021.

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

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

EN 1420:2016 has pipes, fittings, ancillaries and coatings in the scope. A revision of this standard is foreseen to include also tanks and containers. So far, EN 14395-1 gives further information for the testing of tanks and containers.

In CID (EU) 2024/368 the standards are referred with a date. This means that the specific version of the standards has to be used, even when a standard should have been revised. Revised standards will

only become mandatory when CID (EU) 2024/368 is revised and specifically refers to this version of the standard.

6.1.3.1.2 Test piece (Chapter 3.1.2 of Annex I of CID (EU) 2024/368)

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

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

The migration testing standards and EN 16421 specify the test pieces to be used. As a general principle real products or components should be used. If this is not possible for testing reason (e.g. due to the size of the product) specifically produced test pieces have to be used. This might include the use of test plates.

If specifically produced test pieces are used for the testing of products or components of RG1 or RG2 the production of the test pieces has to be audited by the conformity assessment body. This applies also if certificates for pre-products or intermediate products are issued.

The specifically produced test pieces have to correspond with the final materials as used in products or components. This is only possible if the production process of the final materials is clearly specified and documented in the test report. As the geometry of the test pieces – especially the thickness of the materials – might also have an impact on the release of substances, the conformity assessment body has to check the representativeness of the test pieces. Films are no suitable test pieces. Correspondence of materials both in test pieces and actual finished pieces should be verified by applying identity testing methods.

In the case of coatings, the backing layers have to correspond with the materials as applied to. The substrate treatment set out in the application instruction (e.g. primer, undercoats) have also to be applied to produce the test pieces.

The manufacturer has to provide the size of the surfaces of the test pieces. The test laboratory has to check the plausibility of the provided information.

6.1.3.1.3 Temperature of testing (Chapter 3.1.3 of Annex I of CID (EU) 2024/368)

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

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

A test performed at 85 °C ± 2 °C covers both hot and the warm water use.

Multilayer products shall always be tested at 60 °C ± 2 °C or 85 °C ± 2 °C additionally, even when not used at these temperatures.

The migration of substances originating from layers not in direct contact with the water lagged as these substances first have to diffuse through the other layers. The testing at higher temperatures enhances the diffusion. This is the reason that multilayer products always have to be tested at elevated temperatures. This test can either be performed at 60 °C ± 2 °C (for cold and warm water multilayer products) or 85 °C ± 2 °C (for hot water products). Additionally, these products have to be stored at room temperature for at least 30 days before testing and the testing has to last for 30 days (see 6.1.3.1.5). However, the testing of cold-water products at elevated temperatures is not suitable if a more or less complete extraction occurs during testing.

Alternatively to the prolonged testing at elevated temperatures, the different layers can be tested separately. For pipes and hoses with a peelable protective layer (considered as multilayer products) a pre-product certificate of the protective layer can be accepted.

Pipe or fittings with colour coding, for example stripes, are formally also multilayer products. If these products are only intended for cold-water use it is sufficient when a pre-product certificate can be provided for the material used for the colour coding. In this case a testing at elevated temperatures is not required.

For protective coatings applied on gaskets classified in RG 3 an intermediate product certificate for the protective layer and a certificate for the gasket is an acceptable alternative to the multilayer testing of the combined product at elevated temperatures.

6.1.3.1.4 Type of test water (Chapter 3.1.4 of Annex I of CID (EU) 2024/368)

Cold water test (23 °C ± 2 °C) shall be performed with chlorinated and non-chlorinated test water.

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

The testing standards clearly specify the composition of the test waters. The required composition of the test water is different for the testing according to EN 12873-1/-2 and EN 1420. In all migration testing standards an option for testing with chlorinated test water exists. However, CID (EU) 2024/368 specifies that for cold water test both test waters (chlorinated and non-chlorinated) have to be used.

The testing standards require duplicate testing and the performance of one blind test. For the cold water test the testing with chlorinated and non-chlorinated test water is sufficient as duplicate testing. The respective migration waters have to be analysed individually. For the test at elevated temperatures duplicate testing means that at least two pipe segments are tested or two tanks containing the test pieces. In this case the migration waters of these parallel tests do not need to be analysed individually, but might be combined for analysis.

6.1.3.1.5 Migration periods (Chapter 3.1.5 of Annex I of CID (EU) 2024/368)

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

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

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

The details for the migration periods to be analysed in CID (EU) 2024/368 are required as the migration standards leave options. For warm/hot water testing the defined migration periods to be analysed even deviate from the standards[2]. This specification was made to ensure a total testing period of at least for 10 days for the cold and warm/hot water testing. The migration scheme and the respective migration periods which needs to be analysed are presented in Annex 6 of this document.

If for certain parameters the pass/fail criteria are not met at the 10th day of testing, the migration testing can be extended to the 31st day of testing. When performing the test test results might not be available at the 10th day of testing. For this reason, the test laboratory might perform an extended test with an option for the analysis of the migration waters of the extended test or to start with a new migration test when the regular test failed and an extended test seems to be reasonable. If a new test is performed the migration periods of the regular test also have to be analysed. It is not possible to relay on the results of the initial test. The laboratories shall reserve sufficient time to the complete test including extended migration tests.

The migration waters of the extended test have to be analysed for these relevant substances and parameters that failed in the regular test. Additionally, relevant substances in relation to these substances (e.g. known reaction products) have also to be analysed.

6.1.3.2 Analysis of migration waters (Chapter3.2 of Annex I of CID (EU) 2024/368)

6.1.3.2.1 Relevant substances (Chapter 3.2.1 of Annex I of CID (EU) 2024/368)

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

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

6.1.3.2.2 Unexpected substances (Chapter 3.2.2 of Annex I of CID (EU) 2024/368)

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

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

The migration waters obtained from the chlorinated and non-chlorinated test waters have to be analysed for unexpected substances. As no trend analysis is required for unexpected substance, it is sufficient to perform the analysis for unexpected substances of the migration waters (chlorinated and unchlorinated) of the first and last (the last being the 3rd or 9th) migration period.

The performance characteristics required in EN 15768:2015 may lead to common problems including low recovery of internal standards (specifically the volatile ones), asymmetric internal standards peak shape etc. However, in some cases the concentration, number and type of compounds present in the sample may have an adverse effect on the analysis which cannot be avoided. In these cases, laboratories will sometimes have to rerun the samples using selected ion monitoring to elucidate individual compounds identified more clearly.

Another issue that may be encountered is compounds associated with the blank and also found in the samples, for example solvents, or phthalates. The standard has a calculation to identify compounds that could be derived from the product under test that are also found in the blank. However, this calculation is not always appropriate for all compounds falling into this category and

[2] EN 12873-1:2014 requires the analysis of the 1st, 2nd and 3rd migration period of the warm/hot water test. According to the CID (EU) 2024/368 the 1st, 6th and 7th migration periods have to be analysed.

each compound should be assessed individually, as a large peak in the blank may mask a smaller peak actually leaching from the product. It should be noted that the blanks should be as clean as possible and blank containing many substances should be questioned.

6.1.3.2.3 Relevant other parameters (Chapter 3.2.3 of Annex I of CID (EU) 2024/368)

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

(a) Total Organic Carbon (TOC) shall be determined according to EN 1484:1997 as non-purgeable organic carbon;

(b) Odour shall be determined as Threshold Odour Number (TON) according to EN 1420:2016 and EN 1622:2006;

(c) Flavour shall be determined as Threshold Flavour Number (TFN) according to EN 1420:2016 and EN 1622:2006;

(d) Colour shall be determined according to EN ISO 7887:2011 – method C;

(e) Turbidity shall be determined according to EN ISO 7027-1:2016 - nephelometry.

6.1.3.3 Mathematical modelling (Chapter 3.3 of Annex I of CID (EU) 2024/368)

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

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

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

The following mathematical modelling approaches may be used:

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

Estimation of total migration or modelling according to CEN/TR 16364:2012 or other equivalent standards accepted at international level, simulating a migration test according to the EN 12873-1:2014 and EN 12873-2:2021 may be used as an alternative to analytical determination of relevant substances in migration waters. This approach might be considered to reduce the testing requirements or due to difficulties to analyse certain relevant substances in the migration waters.

It is an important prerequisite for the modelling or calculation, that the content of the relevant substances in the final materials (c_0) is known. The content can be calculated from the initial dosage given for the formulation. For this, solvents are not considered for the calculation of the mass of the final material as these substances are removed during the processing of the final materials to a large degree. However, solvents still have to be considered as relevant substances, as a complete removal during processing can't be assumed as general rule.

As a consequence of dedicated processing steps (like e.g. washing- and drying processes), the actual content of certain starting substances might be different to the content obtained from the dosage. If an increase or significant reduction (e.g. solvent) of the content of relevant substances is suspected, analytical determination of the content in the final material is required. For initiators, kinetic calculations might be used to assess the residual content of the initiators in the final product.

The use of the modelling is not limited to relevant starting substances, but can also be used for reaction or degradation products identified as relevant substances. In this case the content of the substances in the final material needs to be determined analytically.

Alternately, a complete transfer of the corresponding staring substance into the reaction or degradation product can be assumed.

Full **transfer calculation** overestimates considerably the release of the relevant substances into the drinking water. Due to this full transfer calculation might only be considered for a limited number of relevant substances, as for many relevant substances the overestimation will result in an exceedance of the corresponding MTC_{tap} values.

For the full transfer calculation, it is assumed that the total quantity of the relevant substance is released in the same amount into migration waters of 9 migration periods. This number of migration periods corresponds to the extended cold water test:

$$C_{max} = Q*(S/V)*Lp*D/9$$

where:

- C_{max} (in mg/l) is the maximum possible concentration of the relevant substance in the migration water,
- Q (in mg/kg of product) is the content of substance in the final material, or alternatively the quantity of substance used to manufacture 1 kg of product,
- S/V (in dm^{-1}) is the ratio of surface area of the product or component to the water volume as defined in the testing standards (EN 12873-1 or EN 12873-2),
- Lp (in dm) is the thickness of the product,
- D (in g/cm^3) is the density of the product

6.1.3.4 Enhancement of Microbial Growth (EMG) testing (Chapter 3.4 of Annex I of CID (EU) 2024/368)

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

Both test methods might be used alternatively. The conformity assessment body should leave the choice of the method to the manufacturer of the final material. In case a non-compliance for the test results for one of the methods is reported, it is not possible to accept any test results obtained by applying the other method.

The use of the two test methods have certain limitations. These are:

Method 1 (BPP procedure) is not suitable for the testing of multi-layer products (e.g. pipes or hoses), since surfaces which normally have no contact with drinking water will thereby also come into contact with the migration water during the test. Multi-layer products (e.g. pipes or hoses) shall be tested according to method 2.

Both methods are not suitable for testing of lubricants, sealants based on hemp with pasty sizing and anaerobic glues. Currently, for these products no EMG testing procedure is available.

EMG is often tested independently of the migration testing. The use of specially produced test pieces (plates) is more common for testing EMG than for the migration testing. For these reasons, the conformity assessment shall ensure that the processing of the test pieces corresponds with the processing of real products. For products of RG1 and RG2 the conformity assessment body has to audit the production of the test pieces.

6.1.3.5 Testing residual content of substances (QM/QMA) (Chapter 3.5)

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

For some starting substances, both an MTC_{tap} value as well as a requirement in terms of residual content (QM or QMA value) are indicated in the European positive list. In these cases, only one restriction has to be checked. Preference should be given to the MTC_{tap} restriction.

For substances for which the initial content (dosage according to the formulation) is lower than the QM/QMA and which are not formed during production of the final material, no analysis of its residual content is needed.

If a substance with a QMA restriction can be determined analytically in the migration water, the restriction can be converted in an MTC_{tap} and might be checked alternatively via migration testing. The MTC_{tap} can be derived based on the assumption for the definition of QMA in the food legislation that 1 kg of food is packed in a cube with a surface area of 6 dm^2:

MTC_{tap} = 1/20 kg/l × QMA × 6 dm^2/1 kg

6.1.4 Acceptance Requirements: Pass/Fail Criteria (Chapter 4 of Annex I of CID (EU) 2024/368)

6.1.4.1 Formulation (Chapter 4.1 of Annex I of CID (EU) 2024/368)

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

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

The conformity assessment body has to review the formulation for completeness, plausibility (6.1.2.2.1), identification of relevant substances (6.1.2.2.2), the acceptance of starting substances (6.1.2.2.3) and the correct use of the starting substances.

If a starting substance is listed in the European positive list, but is not used for the accepted material or according to the technical function specified in the European positive list or not in compliance with the condition of use established under the European positive list, the starting substances is considered as a non-listed starting substance. Non-listed starting substances might still be accepted, if the substance its impurities and/or reaction and degradation products are not released into the drinking water at levels exceeding 0,1 µg/l. The use of such starting substance is further limited (see section 6.1.2.2.3).

The failure of the formulation review will be caused in most cases due to missing information. On the other hand, the pass of the formulation review will not give any indication about a possible compliance of the final material, as some strict MTC_{tap} values (0,1 µg/l) might be derived and the final material will not comply with these or other requirements.

6.1.4.2 Relevant substances, unexpected substances, TOC (chapter 4.2 of Annex I of CID (EU) 2024/368)

6.1.4.2.1 Conversion of test results (Chapter 4.2.1 of Annex I of CID (EU) 2024/368)

In accordance with the migration standards EN 12873-1:2014 and EN 12873-2:2021, the test results are expressed as migration rates (M) in µg/(dm².d). These results shall be converted to estimate the concentrations at the tap (C_{tap}), defined as $C_{tap} = M * CF$, where CF is the corresponding conversion factor in d/dm.

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

6.1.4.2.2 Pass/Fail Criteria for relevant substances (Chapter 4.2.2 of Annex I of CID (EU) 2024/368)

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

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

If for a parameter no sufficiently sensitive analytical method exists, it is possible to apply a higher surface/volume-ratio in migration testing. provided the respective substance displays sufficiently high aqueous solubility (as e.g. for primary aromatic amines).

If the $MTC_{tap,TOC}$ of the relevant substance expressed as TOC:

$$MTC_{tap,TOC} = MTC_{tap} \frac{M_{carbon}}{M_{total}}$$

where:

M_{total} = molecular mass of the substance,

M_{carbon} = molecular mass of only the carbon atoms in the substance

exceeds 0,5 mg/l, the compliance can also be demonstrated via the pass/fail criteria for TOC. In this case the compliance with the TOC requirement is at the same time a demonstration of the compliance with the MTC_{tap} of the substance and a targeted analysis of the relevant substance is not required.

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

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

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

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

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

There is an increasing trend of the measured concentrations for the relevant substances, if for example the following criteria are fulfilled simultaneously:

- c_{tap} of the relevant migration period is higher than 1/10 of the relevant MTC_{tap}, and
- the measured concentration of the relevant migration period has doubled (i.e. more than can be accounted for by measurement uncertainty) compared to the lowest measured concentration, and
- the measured concentration of the relevant migration period is the highest measured value of the migration series.

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

For haloacetic acids (HAAs) total and trihalomethanes total the MTC_{tap} is the parametric values of part B of Annex I to Directive (EU) 2020/2184 divided by 10. This is the usual allocation factor applied to parameters of this Directive for the determination of MTC_{tap} values.

6.1.4.2.3 Pass/fail criteria for unexpected substances (Chapter 4.2.3 of Annex I of CID (EU) 2024/368)

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

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

The MTC_{tap} for the unexpected substances are set out in Table 6.

Parameter	**MTC_{tap}**
Identified substances with a known MTC_{tap}	MTC_{tap} of the substance
Identified substance without a known MTC_{tap}	1,0 µg/l
Unidentified substances	1,0 µg/l per unidentified substance[1] 5,0 µg/l for the sum of the unidentified substances

[1] Based on the response of the closest internal standard

Identification:

The applied GC-MS screening according to EN 15768 will result in three levels of identification:

- Positive
- Tentative
- Unknown

A positive identification is indicated when 'the mass spectrum and GC retention time are the same as those obtained from a pure standard of the substance run under the identical GC-MS conditions on the GC-MS system used to analyse the concentrated solvent extract' (EN 15768 10.2 a)).

The following interpretations for ranges of percentages of library match are commonly applied (for example when using NIST-library, direct or reverse match):

95% - 100% - unambiguous identification

90% - 95% - satisfactory identification

80% - 90% - tentative identification

60% - 80% - identification of chemical class may be possible

< 60% - no identification

Substances with a library match ≥ 90% are usually considered as positively identified. Substances with a reverse match with NIST library ≥70% and for which the deviation of the Kováts-retention index is < 10% (https://en.wikipedia.org/wiki/Kovats_retention_index) are also considered as positively identified.

A 'tentatively identified substance' might however be similar to one of the expected substances, that is identified as such in the context of the formulation review (e.g. starting substances, its impurities and reaction products). Therefore, checking the list of expected substances can help to identify the determined substances. A substance that has a library match ≥ 80% with an 'expected substance' is considered as positively identified.

All substances not considered as positively identified have to be considered as 'unidentified'.

Substance determined semi-quantitively in concentrations c_{tap} < 1 µg/l do not need to be identified, but have to be considered for the application of the pass/fail criteria for unidentified substances.

From experience substances often identified by applying the GC-MS screening are for instance for rubber: acetophenone and benzothiazoles, and for PVC: diethylphthalate.

Applying the pass/fail criteria:

If the identified substance is listed in the EUPL for organic materials without an MTC_{tap}, no restriction applies.

The concentration determined semi-quantitatively according to EN 15768 are compared with the pass/fail criteria as given in the table above. However, a quantitative analysis will overrule the results obtained by the semi-quantitative analysis. This means, if there is a non-compliance of the semi-quantitative analysis an additional quantitative analysis can be performed to overrule the test results of the semi-quantitative analysis. Accordingly, if by applying the screening method a relevant substance is identified that has been analysed in the migration waters, only the test results obtained by the targeted analysis will be taken into account for verification of the MTC_{tap}.

In case the product fails due to unidentified substances, there are a few options for further assessment.

- For substances that were not clearly identified, standards of assumed substances added to the solvent (blank) might be analysed performing the GC-MS analysis.
- Taking into account the confidentiality agreement (NDA), the supplier of the starting substance that most likely is the source of the compound under investigation might be approached to clarify the identity of the substance.
- The manufacturer of the product might adapt the product by choosing another supplier, or higher purity grade of substances in the formulation; or by changing the percentage of use, or replacing substances with other substances that have the same technical function, and/or by modifying the process conditions.

6.1.4.2.4 Pass/fail criteria for TOC (Chapter 4.2.4 of Annex I of CID (EU) 2024/368)

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

(a) C_{tap} ≤ 0,5 mg/l for the 3rd migration period (10th day of testing) or, C_{tap} ≤ 0.5 mg/l for the 9th migration period (31st day of testing) and C_{tap} ≤ 2,0 mg/l for the 3rd migration period (10th day of testing);

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

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

(a) C_{tap} ≤ 0,5 mg/l for the 7th migration period (10th day of testing) or, C_{tap} ≤ 0,5 mg/l for the 22nd migration period (31st day of testing) and C_{tap} ≤ 2,0 mg/l for the 7th migration period (10th day of testing);

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

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

There is a increasing trend in the measured TOC values if for example the following criteria are fulfilled simultaneously:

- $c_{tap,TOC}$ of the relevant migration period is higher than 0,2 mg/l, and
- the measured TOC concentration in the migration water of the relevant migration period has doubled (i.e. more than can be accounted for by measurement uncertainty) compared to the lowest measured concentration, and
- the measured concentration of the relevant migration period is the highest measurement value of the migration series.

6.1.4.3 Odour, flavour, colour and turbidity (Chapter 4.3 of Annex I of CID (EU) 2024/368)

6.1.4.3.1 Pass/fail criteria for TON/TFN (Chapter 4.3.1 of Annex I of CID (EU) 2024/368)

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

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

(a) TON, TFN ≤ 8,0 for the 3rd migration period (10th day of testing); or

(b) TON, TFN ≤ 8,0 for the 9th migration period (31st day of testing) and TON, TFN ≤ 16 for the 3rd migration period (10th day of testing).

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

(a) TON, TFN ≤ 8,0 for the 7th migration period (10th day of testing); or

(b) TON, TFN ≤ 8,0 for the 22nd migration period (31st day of testing) and TON, TFN ≤ 16 for the 7th migration period (10th day of testing).

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

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

(a) TON, TFN ≤ 2,0 for the 3rd migration period (10th day of testing); or

(b) TON, TFN ≤ 2,0 for the 9th migration period (31st day of testing) and TON, TFN ≤ 4,0 for the 3rd migration period (10th day of testing).

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

(a) TON, TFN ≤ 2,0 for the 7th migration period (10th day of testing); or

(b) TON, TFN ≤ 2,0 for the 22nd migration period (31st day of testing) and TON, TFN ≤ 4,0 for the 7th migration period (10th day of testing).

6.1.4.3.2 Pass/fail criteria for colour (Chapter 4.3.2 of Annex I of CID (EU) 2024/368)

The acceptance criterion for colour is ≤ 5 mg/l Pt/Co.

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

6.1.4.3.3 Pass/fail criteria for turbidity (Chapter 4.3.3 of Annex I of CID (EU) 2024/368)

The acceptance criterion for turbidity is ≤ 0,5 NFU.

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

6.1.4.4 Enhancement of microbial growth (Chapter 4.4 of Annex I of CID (EU) 2024/368)

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

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

Standard			Non-elastomers	Elastomers (CF > 1 d/dm)	Elastomers (1 d/dm ≥ CF > 0,1 d/dm)	Elastomers (CF ≤ 0.1 d/dm)
EN 16421	Method 1	Biomass production potential (BPP)	≤ 1000	≤ 1000	≤ 1000	≤ 1000
EN 16421	Method 2	$V_{biofilm}$ in ml/800 cm^2	≤ 0,05 ± 0,02	≤ 0,05 ± 0,02	≤ 0,12 ± 0,03	≤ 0,20 ± 0,03

6.1.4.5 Pass/fail criteria for residual content of substances (QM/QMA) (Chapter 4.5 of Annex I of CID (EU) 2024/368)

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

The QM and QMA limits apply independently of the product group of final organic materials and the test results are not converted as for c_{tap}.

For substances for which the EU positive list of starting substances specifies that verification of compliance shall be done for QMA but no QMA is provided, QMA shall be calculated as follow:

- in case MTC_{tap} is specified for the substance: QMA = MTC_{tap} * 20 l/kg / (6 dm^2/kg)

- in case QM is specified for the substance, the geometry of the product (test piece) has to be considered.

As an example for pipes: QMA = QM * ($OD^2/4 - ID^2/4$)/ID * 6 dm^2 * ρ

where:

OD = outer diameter of the pipe in dm

ID = inner diameter of the pipe in dm

ρ = density of the organic material, the pipe is made of in kg/dm^3

6.1.4.6 Purity pass/fail criteria for pigments, colourants and fillers (Chapter 4.6 of Annex I of CID (EU) 2024/368)

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

<table>
<tr><td colspan="2">Pigments and colorants</td></tr>
<tr><td colspan="2">Colorants and pigments shall comply with the following purity requirements:</td></tr>
<tr><td>a) When extracted with 0.1 N hydrochloric acid, the following elements may dissolve from the colorant or pigment up to the maximum amount, based on the colorant or pigment:
- antimony 0,05 %
- arsenic 0,01 %
- barium 0,01 %
- cadmium 0,01 %
- chromium 0,1 %
- lead 0,01 %
- mercury 0,005 %
- selenium 0,01 %</td><td>b) The content of primary aromatic amines soluble in 1 M hydrochloric acid shall not exceed 0,05 % (calculated as aniline). This limit does not apply to primary aromatic amines containing carboxyl- or sulfo-groups,
or
When extracted with 2 N ethanolic hydrochloric acid, a maximum of 0,05% aromatic amines (based on the colorant or pigment) may dissolve from the colorant or pigment.</td></tr>
<tr><td colspan="2">Fillers</td></tr>
<tr><td colspan="2">Fillers can be contaminated with impurities. For mineral fillers, the following specification applies:</td></tr>
</table>

After solution in 0.1 N hydrochloric acid, the concentration of the following elements shall not exceed the maximum amount, based on the filler:

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

The manufacturers of pigments, colorants or fillers can submit a respective analysis reports of the extraction to the conformity assessment body to prove the compliance. If these analytical reports are not provided, paragraphs 2.2.2 (h), (i) and/or (j) of CID 2024/368 apply. If no MTC_{tap} is specified in Annex V of EU 2024/367 then the MTC_{tap} is the parametric value of part B of Annex I to Directive (EU) 2020/2184 divided by 10. This is the usual allocation factor applied to parameters of this Directive for the determination of MTC_{tap} values. For primary aromatic amines the restriction given in Annex I, section 2.2.4, Table 2 applies.

6.2 Metallic Materials

6.2.1 General procedure for testing and accepting final metallic materials as used in a product (Chapter 1 of Annex II of CID (EU) 2024/368)

The corrosion process of metallic materials causing the release of constituents of the material into the drinking water is a very complex process. For this reason, the assessment approach for metallic materials is different from the testing and assessment of the other materials. The European Positive List for metallic materials lists compositions. These compositions can be regarded as final materials as used in products. For the assessment of these compositions or metallic materials according to CID (EU) 2024/365 the metal release has to be tested with different water compositions for at least 6 months. The extensive testing on the material level allows to reduce the testing on the product level. Products made of metallic compositions listed in the European Positive List do not need to be tested for the release of substances except for certain plated or soldered products.

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

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

1. Metallic compositions of the final materials

2. Composition of applied platings

Based on the specified composition of the metallic product or the metallic component of an assembled product and the applied plating the relevant substances to be analysed in the migration water and the other relevant parameters have to be determined. In general, only for applied platings and solders relevant substances might be determined. However, applied organic impregnations or organic coatings might result in further relevant substances according to the approach for organic materials (see 6.1). If in the plating process organic substances are used these substances have also

to be considered. For applied inorganic impregnations an individual approach is necessary as these materials are none of the materials covered by CID 2024/368.

Step 2 – Performance of tests:

1. Testing of the composition

The second step comprise analyses of the elemental composition of the final material of the metallic product or of the metallic components of the assembled product.

2. Testing of the release of relevant substances

Testing of the release of relevant substances are to be performed on plated final products and for soldering in some cases.

Migration testing is necessary in cases where organic coatings or impregnations are applied. The relevant substances and unexpected substances have to be tested based on the methodology for organic materials (see 6.1).

Step 3. Compliance with pass/fail criteria

The chemical composition of the final materials has to comply with the compositions in the European positive list for all materials intended to come in contact with drinking water.

In the case of the testing of the release of relevant substances of plated products, soldered products and metallic products with an organic coating the test results need to be converted to calculate the concentration expected at the tap before the results are checked for compliance with the pass/ fail criteria.

For plated products including a nickel layer a specific pass/fail criterion demonstrating the absence of a free nickel layer can be applied. In this case the test results are not converted to a concentration at the tap.

6.2.2 Identification of relevant substances and relevant other parameters (Chapter 2 of Annex II of CID (EU) 2024/368)

6.2.2.1 . Composition review (Chapter 2.1 of Annex II of CID (EU) 2024/368)

6.2.2.1.1 Required information (Chapter 2.1.1 of Annex II of CID (EU) 2024/368)

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

(a) list of all metallic components including the composition of the bulk material as range for all constituents exceeding 0,02% (m/m), details about the processing to obtain the final metallic materials and the wetted surface fraction of the components in relation to the wetted surface of the assembled product;

The manufacturer has to specify the compositions of the metallic product or of all metallic components intended to come in contact with drinking water (wetted surface) of the assembled product as part of the documentation of the product (see 5.3.2 & 5.3.3). The composition of metallic materials plated or coated has also to be specified.

The manufacturer has to provide details about the processing to obtain the final metallic materials. Especially an eventual heat treatment for corrosion resistance is an information to be included in the documentation.

If any processing details are specified in the European positive list as a condition of use, all such process details shall be provided. This might also include a description of the microstructure or phase distribution in the final material as used in products.

(b) list of solders applied including details about the soldering process;

Both hard brazing and soft soldering alloys are to be considered as “solders”.

No specific soldering compositions are specified in the European positive list of composition for metallic materials, the only restriction is the maximum concentration of the impurities Pb, Sb and Cd. Certain combination of soldering alloys and metals may result in a significant release of certain metals into the drinking water. Based on that the entire system soldering and the material to be joined must be evaluated in terms of corrosion risk with regard of migration of substances to the water.

Details about the soldering process to include are: soldering temperature, chemical compositions of soldering parent material, the material to be joined and the joint.

(c) detailed description of applied plating processes;

The detailed description of the plating process includes information about the process type (for example electroplating, galvanizing and electroless plating), the process steps (pre-treatments, platings and posttreatments), the plating bath composition (including organic compounds) and the type of anodes or other metal source (including information about its impurities) used to produce the plating.

This description should be given for platings even when applied to surfaces not intended to be in contact with drinking. Only for components of assembled product plated separately and definitely not in contact with drinking water this description has not to be provided. These platings must be manufactured by a production process that guarantees uniform platings (eg. balls in valves).

Any measures to protect the wetted surfaces against unintended depositions on the wetted surfaces and plating residues on the surfaces in contact with the water should be described.

The following measures can be considered as suitable for this process:

- capping or plugging of these areas during the plating process
- subsequent complete removal of any layers or depositions from the wetted surfaces (e.g. by chemical stripping or machining)
- masking (e.g. with an organic coating) during the plating process

The durability and the completeness of the plating as well as the thickness of the layer should be described for applied platings intended to be in contact with drinking water if the bulk material is not a composition listed in the European positive list for the relevant product group.

(d) detailed description of applied impregnations or organic coatings;

The manufacturer has to provide a detailed description of all impregnations (organic and inorganic) and organic coatings applied on metallic components including its purpose of use. An example for the purpose of use of impregnations is the sealing of microscopic cavities of casted components. An example for the purpose of use of organic coatings is the corrosion protection of the component.

For organic coatings the detailed description includes information of the durability and the completeness of the coatings as well as the thickness of the layers.

The manufacturer has to provide information about the percentage of coverage of the impregnation and the organic coating of the total wetted surface area. This information is needed for the determination of the testing and assessment requirements. If the wetted surface fraction of the impregnation or coating is > 1% a formulation review is required according to section 6.1.2.2.

(e) any other information considered relevant for the assessment of the composition of the final metallic material.

The manufacturer has to provide details about the processing to obtain the final metallic materials. Especially an applied heat treatment to increase the corrosion resistance is an information to be included in the documentation.

6.2.2.1.2 Accepted compositions (chapter 2.1.2 of Annex II of CID (EU) 2024/368)

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

The conformity assessment body has to check whether the provided composition of final metallic materials as used in a product or component/components of an assembled product are in compliance with the accepted compositions as listed in the European positive list of compositions for metallic materials. The conditions of use in the positive list indicates if the composition of the listed alloy is further restricted compared to standardized composition. The entry in the positive list might be further restricted regarding processing details and other characteristics as the microstructure of the final material.

The European positiv list of compositions for metallic materials includes an entry for stainless steels (EUPL Number 1679) refering to stainless steels according to EN 10088 and EN 10283. The entry does not specify certain compositions. Stainless steels grades according to other standards can be accepted if the chemical compositions of the grades are comparable with the grades included in EN 10088 and EN 10283.

Pipes and fittings with specific metallic layers (e.g. tinned copper/fittings, galvanised steel) are included in the European positive list. The conformity assessment body has to check if the composition of the layers correspond with the composition requirements in the European positive list. In this case no testing of the metal release of the products or components is required.

Metallic materials completely coated with an organic coating might not have to comply with the requirements of the European positive list of compositions for metallic materials if the manufacturer can demonstrate that the coating is completely covering the bulk material and that the coating lasts for the intended period of use of the product (e.g. for supply pipes at least for 50 years).

Categorisation of products in product groups for metallic materials is set out in Table 2 of Annex II to Commission Implementing Decision (EU) 2024/365.

Each composition of the European positive list of compositions for metallic materials has been assigned one or more product groups, Product Group A-D (see 5.2.2.1). In the composition review the conformity assessment body has to check whether the use of the compositions is according to the accepted product group(s). This includes that the sum of the fraction of the wetted surfaces for all components made of materials accepted for product group C has to be less than 10% of the total wetted surface of the assembled product intended to be used in domestic installation systems. The

same rule also applies for compositions accepted for product group D and used for assembled products intended to be used in water mains and for water treatment works.

Applied organic impregnations and coatings shall comply with the requirements of Annex I.

Organic coatings and impregnations on metallic components or products are considered as final organic materials and should evaluated according to the approach for organic materials (see 6.1).

6.2.2.1.3 Relevant substances (2.1.3 of Annex II of CID (EU) 2024/368)

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

For the platings listed in the first version of the European positive list of compositions for metallic materials the relevant substances are:

- Nickel for electrolytic nickel/chromium platings (EUPL Number 1682)

If organic substances are present in the plating baths of any plating listed in the European positive list, the manufacturer has to demonstrate that these substances not are not present in the final products or that these substances do not migrate into the drinking water.

Soldered products have to be considered as plated products.

For soldered products, relevant substances are:

- all constituents and impurities of the solder with a content greater than 0,02% (related to the applied solder)
- In case of stainless steel as bulk material: Ni, Cr, Fe, Mo, and all elements with a content exceeding 2% in the bulk materials
- In case of copper alloys as bulk material: all elements with a content exceeding 0,02% in the bulk material except P, S, Si and Sn.

However, for the following products no relevant substances have to be considered and testing of the metal release is not required:

1. Products made of copper, tinned copper or compositions of copper included in the European positive list of compositions for metallic materials joined with solders according to EN 806-4 table A1 or table A2, either on-site or factory-made.
2. Products made of stainless steel included in the European positive list of compositions for metallic materials joined with soft solders exclusively, whereby the constituents of the solder exceeding 0.02% (related to the solder) are only Sn, Cu or Ag and the soldered area is < 1% of the wetted surface of the product.

6.2.3 Testing requirements (Chapter 3 of Annex II of CID (EU) 2024/368)

6.2.3.1 Composition testing (Chapter 3.1 of Annex II of CID (EU) 2024/368)

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

The conformity assessment body has to arrange the analysis of the composition of the test pieces withdrawn in the cause of the initial inspection and annual inspection (for products/components classified in RG1/RG2) or of the test pieces sent to the conformity assessment body / laboratory (for products classified in RG3/RG4). These tests have to performed additionally to the test performed by the manufacturer in the scope of the quality assurance (see 5.3.5).

The analysis of the composition of the final metallic material of the product shall be performed with a standardised (when possible) suitable test method (see Table 6.

Table 6: Examples of test methods for the analyses of metallic compositions.

	X-Ray Fluorescence (XRF)	**Atomic Absorption Spectroscopy (AAS)**	**Spark/optical Atomic Emission Spectrometry (OES)**	**Inductively Coupled Plasma Mass Spectrometry (ICP-MS)**	**Inductively Coupled Plasma Optical Atomic Emission Spectrometry (ICP-OES)**
Cu alloys	EN-15063-1 EN 15063-2	X	EN 15079	X	EN 15605
Stainless steel	ASTM E572		ASTM E1086		
Cast iron			ASTM E1999		
Ti alloys	ASTM E539				
Al alloys			ASTM E1251		

For the choice of a suitable test methods it has to be considered that the precision of the analytical methods used is comparable with the number of significant decimals for the composition as specified for the respective entry of the European positive list of compositions for metallic materials. Additionally, the matrix, and the geometry of samples has to be considered.

Regarding the number of measurements of each sample the procedures described in the respective standard shall be followed. If the reported value is based on several individual measurements only a mean value should be reported. The result has to be reported for the decimals as specified for each element in the respective entry of the European positive list of compositions for metallic materials.

If the applied method has a higher accuracy than required for the specific element the results have to be rounded according to the following:

1. if the figure after the last figure to be retained is less than 5, the last figure to be retained shall be kept unchanged;
2. if the figure after the last figure to be retained is equal to or greater than 5, the last figure to be retained shall be increased by one.

Rounding of results from calculated mean values has to performed in the same way.

If the condition of use of the positive list entry for the specific metallic composition specifies a certain production process or a certain type of microstructure additional analyses of the final metallic material is required. This might include the preparation of metallographic samples for the evaluation of the microstructure and the phase distribution. Such an analysis might include etching of the surface of the final materials and subsequent investigations in light optical microscope and image

analyses or advanced techniques such as (EBSD Electron Backscatter Diffraction) in SEM (Scanning electron microscope).

6.2.3.2 Testing of release of relevant substances from plated products (Chapter 3.2 of Annex II of CID (EU) 2024/368)

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

The testing of release of nickel are not needed for components with a metallic platings on the inner surface in contact with water that are manufactured by a production process that guarantees uniform platings over the entire surface.

Kitchen and sanitary taps as well as other components of domestic distribution systems, such as angle valves, are plated with nickel-containing layers (e.g. chromium-nickel plating) in an electroplating process for aesthetic reasons and to protect against corrosion. Depending on the manufacturing process, the deposition of nickel on the inner surfaces of the components that come into contact with drinking water during this process cannot always be completely avoided or can only be avoided at great expense, as this process is influenced by a large number of parameters. Therefore, plated products shall be tested for the nickel release or the nickel residue on the surface.

Not for all products the nickel release is considered as relevant. The following table specifies the products to be tested.

Table 7 Products to be tested for nickel release

		Type of product	
		Intended for drinking, cooking or food preparation*	**Intended for other domestic purposes****
Constructive design	Component(s) in contact with drinking water are plated with nickel containing layers	EN 16058	No testing
	Component(s) in contact with drinking water are plated with nickel containing layers but measures are taken to significantly reduce or remove nickel depositions on the surfaces in contact with drinking water	Surface residue testing	No testing
	No plated components in contact with drinking water	No testing	No testing

* such as kitchen taps, wash basin taps, angle valves
** such as shower or bath taps

The test method described in EN 16058 is, in principle, a suitable instrument for assessing products including components with surface coatings containing nickel layers. However, as it provides for a test with a test duration of 26 weeks on 5 products in parallel, it is many cases not applicable for the assessment of product conformity and for production control measures for purely practical reasons. Despite several efforts, it has not yet been possible to establish a test procedure that can reliably predict the long-term behaviour of products with regard to the nickel release of coated components using a short-term test.

However, if measures are taken to significantly reduce or remove the deposition of nickel on the surfaces in contact with drinking water (e.g. plugging of the components before the plating is applied), a short-term test can be carried out to verify that there is no significant nickel residue on the surface.

This test method has to be based on a mixture chemiclas that rapidly dissolves nickel from the surface in the production process. The mixture has to be selected as the basis for a test method to determine the amount of nickel present on the surface of products. The principle of the test method has to be that the product is rapidly and selectively stripped of nickel with the solution and following that the nickel content of the solution is analysed.

For the testing of soldered products EN 16058 should be applied. The test water shall be suitable for this purpose. Test water 1 according to EN 15664-2 is found to be suitable. If another test water is used, evidence of its suitability must be provided, e.g. by a comparative test using test water 1. The test of soldered heat exchangers shall be carried out using the test set-up for outlet devices according to Figure A.2 of EN 16058.

When soldered products are intended for use in cold water, just cold water tests need to be carried out. Products in contact with warm water should be subjected to a cold and a warm water test. For the warm water test of heat exchangers the test pieces should be filled with cold water and heated to 60°C by the heating circuit during stagnation.

If the volume of stagnated water in the product to be tested, including the connected pipe line for sampling, exceeds 500 ml, a sample volume has to be selected in deviation from EN 16058, by which the entire water in the test sample is sampled.

The testing of the release of organic substances used in the plating process shall be performed in accordance with the requirements set out in Annex I [of CID (EU) 2024/368].

The conformity assessement body has to arrange for the testing of organic substances as identified as relevant substances in the description of the plating process. The testing procedure should follow the procedure for oragnic material (see 6.1).

6.2.4 Acceptance requirements: Pass/Fail criteria (Chapter 4 of Annex II of CID (EU) 2024/368)

6.2.4.1 Compliance with the European positive list of metallic compositions (Chapter 4.1 of Annex II of CID (EU) 2024/368)

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

The compliance of the composition with the respective requirements as listed in the European positive list of compositions for metallic materials has to be based on the reported test results. If

there is a failure to comply with the composition as specified in the European positive list an additional test can be performed for two different test pieces from the same batch of the final material/products. The retesting is only possible if the reported deviations can be attributed to the precision of the applied test method. If the results of the additional tests are in compliance with the specification of the European positive list, the final material can be considered as in compliance. If the additional analyses still fail to comply with the composition requirements the final product is not in compliance.

Test laboratory accredited according to EN ISO/IEC 17025 have provide information about the uncertainty and precision of the applied analytical methods.

6.2.4.2 Pass/fail criteria for relevant substances (Chapter 4.2 of Annex II of CID (EU) 2024/368)

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

Evaluation against the pass/fail criteria for the release of relevant substances is only relevant for certain platings and certain soldered products.

The pass/fail criteria for Ni in the stripping solution after the test described in 6.2.3.2 is under evaluation

The pass/fail criteria for Ni when tested according to EN 16058 are the following:

For assessing taps the reference volume of 1 l of standardized nickel concentration according to EN 16058 is used. For assessing other components, a surface fraction of 10 % (assumed contact surface 'a'; Annex II table 2 of CID (EU) 2024/365) is applied:

$$c_n^*(T) = 0{,}1\, c_{EP,n}^*(T)$$

Angle valves are to be assessed as „other components". The assessment as „drain valve" is not possible because angle valves are not the only source of nickel in a sample volume of 1 liter, when the product is in real use.

A sliding mean of 5 consecutive values of T (e.g. T = 12, 13, 14, 15, 16 weeks) is formed for each tap or each test line

$$\bar{c}_n^*(T) = \frac{1}{5}\sum_{m=0}^{4} c_n^*(T+m)$$

with T = time (week) of the first value.

<u>The tap or the other component is considered to fulfil the requirements if</u>

$c_n^*(T) < 40\ \mu g/l$ for all n and T < 12 weeks

and

$\bar{c}^*(T) + 2\sigma(T) < 10\ \mu g/l$ for T ≥ 12 weeks

with $\bar{c}^*(T) = \frac{1}{5}\sum_{n=1}^{5} \bar{c}_n^*(T)$ *and* $\sigma(T)^2 = \frac{1}{4}\sum_{n=1}^{5}\left(\bar{c}_n^*(T) - \bar{c}^*(T)\right)^2$

or

$c_n^*(T) < 10$ µg/l for T ≥ 12 weeks and all n

The measured test results according to EN 16058 of soldered products shall be converted as described in 5.2.2.2 in C_{tap}- values. For soldered heat exchangers, the conversion factor of 2 d/dm (according to Table 5 to Annex Iof CID (EU) 2024/368) shall be used.

The requirement $C_{tap} \leq MTC_{tap,metallics}$ has to meet from the 16th week onwards. In addition, the relevant results shall not show an increasing trend. If necessary, an extension of the test until the 52nd week is possible.

6.3 Cementitious Materials

6.3.1 General Procedure for testing and accepting final cementitious materials as used in a product (Chapter 1 of Annex III of CID (EU) 2024/368)

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

The procedure for testing and accepting final cementitious materials as used in a product includes three main steps.

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

For the identification of the required testing the risk group of the product or component has to be determined.

Based on the identified risk groups a formulation review is required (RG1 -RG3). In most cases the formulation review is a quite complex task as the conformity assessment body will have to contact suppliers and upstream suppliers. As a result of the positive formulation review the relevant substances to be analysed in the migration waters will be identified.

Step 2 – Performance of tests

Two different types of migration testing are required. For the relevant substances and unexpected substance, a migration testing according to EN 14944-3 or EN 14944-4 has to be performed. For the parameters TOC, odour, flavour, colour and turbidity the migration test has to be performed according to EN 14944-1 or EN 14944-2. For relevant substances modelling of the migration can be used instead of the testing.

Testing for the Enhancement of the Microbial Growth (EMG) according to EN 16421 is carried out independently of the migration testing. It might even be performed by a different testing laboratory.

If the formulation review reveals that for certain starting substances QM or QMA restrictions apply the residual content of these substances in the final materials has to be determined.

Step 3 – Compliance with pass/fail criteria

Finally, the conformity assessment body has to check the test results for compliance with the pass/fail criteria. In case of the migration testing for TOC, relevant substances and unexpected substances a conversion of the test results to calculate the concentration expected at the tap (c_{tap}) has to be made (see 5.2.2.2).

Final cementitious materials can be divided into 3 types of products:

- Type 1: Factory-made products: These are products mass-produced in factories, such as pipes and fittings made of concrete or lined internally with mortar, and prefabricated concrete components.

- Type 2: Ready-to-use products (coatings and packaged products for site application). These are products manufactured and packaged in factories according to a defined formulation, to which water or a water-based mixing resin, which is an integral part of the formulation, must be added at the time of use *in situ*. Examples include pre-packaged concretes or dry mortars, such as coating or waterproofing mortars, or repair products.
- Type 3: *in-situ* made products made from constituent products. This refers to a final material mixed from constituent products and manufactured on the construction site. Alternatively, the material is ready-mixed off-site in a ready-to-use concrete (RTC) plant and transported to the point of use, where the final (hardened) material is made. The point of use can either be a construction site (e.g. for the production of a tank) or a factory for notably precast concrete products (not mass-produced). Due to the larger size of these products, the surface-to-water volume (S/V) ratio is less than or equal to 1.33 dm^2/dm^3.

The final products can be a bulk product or a lining.

Only for final materials a certificate according to CDR (EU) 2024/370 can be issued. For type 1 the final material is the factory-made product and for these products certificates according to CDR (EU) 2024/370 can be issued.

For type 2 the final material is the material produced on site during the construction work and is not the packaged mortar. The final material is a singular product and a certificate according to CDR (EU) 2024/370 would cover only this singular product (construction work). For components or repair work classified in RG3 and RG4 the issuing of these specific certificates for the individual construction works are not suitable. Member States might rely to certificates issued for intermediate products for the conformity assessment of these products. Additionally, a certificate issued for the ready-to-use product (intermediate product) simplifies the conformity assessment of the singular product made of the final material. If an intermediate product certificate (see 5.4.6) is issued for the ready-to-use product the certificate according to CDR (EU) 2024/370 for the final material can be based on the intermediate product. In this case the conformity assessment body has only to check, whether the ready-to-use product as specified is actually used for the production of the final material. Alternatively, the conformity assessment body has to assess the final material as produced on the construction site and has to withdraw test pieces produced on the construction site in parallel to the production of the materials intended to come in contact with the water intended for human consumption.

For type 3 the final material is also produced on the construction site. However, if similar products made of the same formulation are made in a factory and are delivered to different construction sites, these products are considered as a series of products made of final materials and the approach for type 1 products apply. In case the final material is produced on the construction site and the final material is, similar to type 2, a singular product and a certificate according to CDR (EU) 2024/370 would cover only this singular product (construction work). As in this case the final material is not made only from one intermediate product mixed with water the conformity assessment of the final material can be based on the use of certified constituent products (see 5.4.7). In this case the conformity assessment body (when required) has only to check, whether the certified constituent products as specified are actually used for the production of the final material. Alternatively, the conformity assessment of the single construction work can be based on the assessment of the individual assessment of the formulation of all constituent products and the testing of test pieces produced on the construction site in parallel to the production of the materials intended to come in contact with the water intended for human consumption.

For the conformity assessment of products made of final materials produced on the construction site only certificates for the individual construction product can be issued. It is only valid for this construction work and has therefore no expiry date. For products or components classified in RG3 & RG4 an individual certification is not be feasible. In this case Member States might accept the use of constituent product certificates without a certification of the singular construction work.

Certificates issued for constituent products can also be used as a pre-assessment for the conformity assessment of type 1 cementitious materials according to CDR (EU) 2024/370 and for type 2 cementitious materials for an intermediate certificate.

Certificates issued for intermediate products can also be used as a pre-assessment for the conformity assessment of type 1 cementitious materials according to CDR (EU) 2024/370.

*Table 8; **Application of intermediate and constituent product certificates for the assessment of final materials***

	Type 1	Type 2	Type 3
Intermediate product certificate	Yes	Yes	-
Constituent product certificate	Yes	Yes	Yes

6.3.2 Identification of relevant substances and relevant other parameters (Chapter 2 of Annex III of CID (EU) 2024/368)

6.3.2.1 Categorisation of products into risk groups and corresponding testing requirements (Chapter 2.1 of Annex III of CID (EU) 2024/368)

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

In accordance with Table 5 of Annex I (of CID (EU) 2024/368), a product group and a corresponding conversion factor (CF) shall be determined for the product or the component. Based on the determined CF, the product or component is categorised in a risk group (RG).

The determination of the risk group is based on the conversion factor to be applied (see 5.2.2 and 5.2.3).

Table 1 (of Annex III of CID (EU) 2024/368): Risk-based testing requirements for products or components of assembled products

Risk Group	CF in d/dm	Formulation review	Relevant substances	Screening for unexpected substances	TOC	TON[1], TFN[2], colour, turbidity	EMG
RG1	≥ 4	Yes	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used	Yes, on product or test piece	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used
RG2	≥ 0.4 and < 4						
RG3	≥ 0.04 and < 0.4						

RG4	< 0.04	No	No	No	Yes, on product or test piece	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used

[1] Threshold odour number

[2] Threshold flavour number

In accordance with Table 1 of this Annex (III of CID (EU) 2024/368), the categorisation in a RG determines the corresponding testing requirements and relevant other parameters.

For cementitious materials there is no differentiation in the testing requirements for RG1 – RG3. In these cases, the product or the representative test piece made by the specific manufacturer has to be tested. For products classified in RG1 and RG2 the conformity assessment body has to audit the production of the specific test pieces.

For an assembled product, the components shall be determined. For each component in an assembled product, a product group shall be determined. If an assembled product consists of components made of the same final materials, then the surface fraction of these components shall be cumulatively added for the determination of the product group in accordance with Table 5 of Annex I (of CID (EU) 2024/368).

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

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

6.3.2.2 Formulation review (Chapter 2.2 of Annex III of CID (EU) 2024/368)

A formulation review shall be performed in accordance with the requirements in Table1 (of Annex III of CID (EU) 2024/368).

For further information see 6.1.2.2.

6.3.2.2.1 Required information (Chapter 2.2.1 of Annex III of CID (EU) 2024/368)

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

(a) list of all constituents (including information on their impurities) used to produce the final cementitious material;

(b) the respective percentage by mass (m/m %) of constituents with respect to cement content used to produce the final cementitious material;

(c) any other information considered relevant for the assessment of the formulation of the final cementitious material.

In particular for mineral constituents this information has to include at least:

- documents attesting compliance with the applicable standard;
- the composition of the constituent
- the metal content in mass percentage (% m/m) for cement and inorganic additions and the impurity levels for aggregates

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

For the formulation review of type 1 and type 2 cementitious products the mass percentage of the respective constituent related to the cement content can be directly used to apply the cut off value. In case of constituent product certificates, it is necessary to additionally consider the highest dosage as defined in the technical specification.

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

6.3.2.2.2 Relevant substances (Chapter 2.2.2 of Annex III of CID (EU) 2024/368)

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

(1) Organic cementitious constituents used in the formulation of the final cementitious material, listed in the European positive list of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 or listed in the European positive list of starting substances for organic materials, of Annex I to Commission Implementing Decision (EU) 2024/367 and for which an MTC_{tap} applies;

(2) Impurities, degradation or reaction products specified in the condition of use of the European positive list of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 or specified in the condition of the use of the European positive list of starting substances for organic materials, of Annex I to Commission Implementing Decision (EU) 2024/367 used in the formulation;

(3) Organic cementitious constituents used in the formulation, their impurities, degradation and reaction products not listed in the European positive list of organic constituents for cementitious materials in Annex III of Commission Implementing Decision (EU) 2024/367 or in the European positive list of starting substances for organic materials, of Annex I to Commission Implementing Decision (EU) 2024/367, but accepted under section 2.2.3 of this Annex;

(4) Metals for which $MTC_{tap,cementitious}$ exist according to Table 1 in Annex V to Commission Implementing Decision (EU) 2024/367;

(5) Primary aromatic amines (PAA) if organic pigments or colorants are used in the formulation not complying with the purity requirements according to section 4.6 of Annex I or when purity testing was not performed.

6.3.2.2.3 Accepted constituents (Chapter 2.2.3 of Annex III of CID (EU) 2024/368)

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

The use of the following additional constituents is allowed:

(a) Inorganic constituents;

(b) Organic cementitious constituents for which there is no possibility that they, including their reaction products, migrate at levels exceeding 0,1 µg/l in water intended for human consumption. This only applies to substances that do not belong to either one of the following categories:

(i) Substances classified as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B, endocrine disrupters (ED) for human health category 1, persistent, bioaccumulative and toxic substances (PBT) or very persistent and very bioaccumulative substances (vPvB) in accordance with Regulation No. 1272/2008 (CLP); or being included in the candidate list as substances of very high concern (SVHC) under Regulation (EC) No 1907/2006; and (REACH) for their ED, PBT or vPvB properties;

(ii) Substances intentionally added in nanoform.

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

For essential mineral constituents (cements, inorganic additions and aggregates) of cementitious materials in CID (EU) 2024/367 no European positive list exists. The consequence is that cementitious materials always have to be tested for the migration of all elements specified in Table 1 in Annex V to CID (EU) 2024/367 (see 6.3.2.2.2).

Table 8 gives further guidance on constituents of cementitious materials. It sets out:

(1) the different categories of generic constituents of cementitious materials that may be used in the preparation of cementitious products,
(2) an informative and non-exhaustive list of existing standards for generic constituents,
(3) possible requirements of the European positive list and
(4) establishes conditions of use for each category of generic constituents.

Table 9: List of generic constituents of cementitious materials

Generic constituent category	Types of constituents per category	Informative and non-exhaustive list of standards)	Organic constituents	Relevant European Positive List	Conditions of use
Cement	Cement	• EN 197-1 (Common cements) • EN 197-5 (Portland-composite cement CEM II/C-M and Composite cement CEM VI) • EN 197-6 (cement with recycled concrete fines) • EN 413-1 (Masonry cement) • EN 14216 (Very low heat special cements) • EN 15743 (Supersulfated cement) • EAD 150008-00-0301 (Rapid setting cement) and NF P15-314 (Hydraulic binders- prompt naturel cement) • EN 14647 (Calcium alumina cement; for raw water applications only)	Organic grinding aids or other organic substances used for the preparation of cement	European positive list of organic constituents of cementitious materials	
Inorganic additions	• Fly ash for concrete • Silica fume • Blast furnace slag • Limestone • Siliceous additions • Trass • Tempered rock flour • Natural pozzolanic additives	• EN 450-1 (Fly ash for concrete) • EN 13263-1 (Silica fume) • EN 15167-1 or BS 6699 (Ground granulated blast furnace slag) • BS 7979, NF P 18-508 or LNEC E 466 (Limestone additions) • NF P 18-509 (Siliceous additions) • DIN 51043 (Trass) • NF P18-513 (Metakaolin)	Organic grinding aids or other organic substances used for the preparation of inorganic additions	European positive list of organic constituents of cementitious materials	
Aggregates	• Aggregates for concrete • Aggregates for mortar • Aggregates for grout	• EN 12620 (Aggregates for concrete) • EN 13139 (Aggregates for mortar) • EN 13055-1 (Lightweight aggregates for concrete, mortar and grout)	Not relevant	Not relevant	Recycled concrete aggregates (RCA) derived from concrete that has not been used (e.g. surplus pre-cast units or returned ready mixed concrete), has previously been approved for contact with DW, and has

Generic constituent category	Types of constituents per category	Informative and non-exhaustive list of standards)	Organic constituents	Relevant European Positive List	Conditions of use
					not been contaminated in storage, will not require further testing. Other sources of RCA and recycled aggregates will need testing for metals, admixtures and other organic substances
Mixing water	• Mixing water for concrete, including drinking water	• EN 1008 (Mixing water for concrete) - Drinking water	Not relevant	Not relevant	
Organic additions	• Polymer dispersions and powers • Auxiliaries for polymer additions		Main constituent and all additional organic constituents	European positive list of starting substances for organic materials European positive list of organic constituents of cementitious materials	Starting substances that are authorised in the European positive list for organic materials which are authorised for use in the manufacture of coatings may be used to manufacture organic additions for use in cementitious materials
Admixtures	• Organic constituents of admixtures • Inorganic constituents of admixtures • Auxiliaries for constituents of admixtures (e.g. biocides, defoamers)	• EN 934-1, 2, 3, 4 or 5 (Admixtures for concrete, mortar and grout)	Main constituent and all additional organic constituents	European positive list of organic constituents of cementitious materials	Only biocidal active substances of Product Type 6 (Preservatives for products during storage) in accordance with Regulation (EU) No 528/2012) are permitted to be used as auxiliaries to cementitious admixtures.
Fibres	• Organic fibres for concrete • Inorganic fibres for concrete	• EN 14889-1 (Steel Fibres for concrete) • EN 14889-2 (Polymer fibres for concrete)	All organic constituents	European positive list of starting substances for organic materials	Starting substances that are authorised in the European positive list for organic materials may be used to manufacture organic fibres (polymer fibres and their bunding aids) for use in cementitious materials

Generic constituent category	Types of constituents per category	Informative and non-exhaustive list of standards)	Organic constituents	Relevant European Positive List	Conditions of use
Formwork release agents	• Formwork release agents • Auxiliaries for formwork release agents		All organic constituents	European positive list of organic constituents of cementitious materials	
Curing compounds (including inorganic surface treatment compounds)	• Organic curing compounds		Main constituent and all additional organic constituents	European positive list of organic constituents of cementitious materials European positive list of stating substances for organic materials	

Biocides can only be used as in-can preservatives (BPR Product Type 6) (see possible acceptance in CID (EU) 2024/367). The maximum concentration of a biocide in an admixture has to be < 0,5%, with the final concentration in the cementitious product being < 0,001%.

6.3.2.2.4 Material-specific requirements (Chapter 2.2.4 of Annex III of CID (EU) 2024/368)

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

6.3.3 Testing requirements (Chapter 3 of Annex III of CID (EU) 2024/368)

Cementitious products are considered 'organic free' when they are made only of cement, inorganic additions, aggregates and mixing water provided that the cement and the inorganic additions do not contain more than 0,2% of organic substances (typically grinding aids).

Otherwise cementitious products are considered 'organic containing'.

Testing for unsuspected substances and EMG is required only for organic containing materials/products.

Testing requirements depend on the generic constituents as used to produce the final cementitious materials (see Table 10).

Table 10: Testing requirements depending on the generic constituents

Constituent category	Testing parameters					
	TON, TFN, colour, turbidity	Relevant substances (e.g. metals)	TOC	Screening for release of unexpected substances	Relevant substances / Specific organic determinants	EMG
Cement	X	X(3)	X	X(1)	X(1)	X(1)
Inorganic additions	X	X(3)	X	X(1)	X(1)	X(1)
Aggregates (2)	X	X(3)	X			
Mixing water						
Admixtures	X	X(4)	X	X	X	X
Fibres	X	X(4)	X	X	X	X
Organic additions	X	X(4)	X	X	X	X
Formwork release agents	X	X(4)	X	X	X	X
Curing compounds	X	X(4)	X	X	X	X

(1) Not required if only grinding aids at less than 0.2% by mass of the constituent are used as organic substances
(2) Recycled concrete aggregates (RCA) derived from concrete that has not been used (e.g. surplus pre-cast units or returned ready mixed concrete), has previously been approved for contact with DW, and has not been contaminated in storage, will not require further testing. Other sources of RCA and recycled aggregates will need full testing.

(*3) All elements (metals) which are specified with an. $MTC_{tap,cementitious}$ in Table 1 in Annex V to CID (EU) 2024/367 are relevant substances.*

(4) Elements (metals) which are specified with an. $MTC_{tap,cementitious}$ in Table 1 in Annex V to CID (EU) 2024/367 are only relevant substances if declared in the formulation.

6.3.3.1 Migration testing (Chapter 3.1 of Annex III of CID (EU) 2024/368)

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

6.3.3.1.1 Specifications for testing final cementitious materials for migration of organoleptic parameters (odour, flavour, colour and turbidity), TOC, relevant and unexpected substances (Chapter 3.1.1 of Annex III of CID (EU) 2024/368)

(a) Test pieces

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

Products made of cementitious materials cannot be tested directly due to the size of the products. In most cases specially produced test pieces are used for testing.

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

Test pieces shall be representative for the product. This might be a real challenge as the same surface characteristics have to be obtained.

The representative test piece for type 1 cementitious materials shall be made under the same conditions, as factory made products. EN 14944-1 and -3 shall be considered.

The representative test pieces for type 2 of cementitious materials (for an intermediate certificate) shall be made under the conditions given in the application advises. Representative test pieces for type 3 of cementitious materials (for a constituent product certificate) shall be made with the highest dosage as defined in the technical specification of the constituent product. For both types EN 14944-2 and -4: shall be considered.

For type 2 and 3 cementitious materials, test pieces can be produced either in a laboratory or on the construction site during the construction work.

To ensure the conformity of the product as it will be used, the migration test should begin within the period between 28 (minimum age for mortars and concretes reach maturity) and 90 days after the production of the sample (for practical reason and avoid the impact of excessive ageing). This means that the preconditioning shall start in the period 21 days to 82 days after production of the test pieces.

(b) Preconditioning of test pieces

Test pieces shall be preconditioned by immersion in demineralised water containing anhydrous calcium chloride ((222 ± 2) mg $CaCl_2$ L^{-1}) and sodium hydrogen carbonate ((336 ± 2) $NaHCO_3$ mg L^{-1}) adjusted to a pH of (7.4 ± 0,1) by air or CO_2 bubbling.

Test pieces shall be preconditioned at (23 ± 2) °C in three successive periods of (24 ± 1) h followed by one period of (72 ± 1) h and one period of (24 ± 1) h. After each period the water is discarded and the

test piece is not rinsed. If the pH of the last preconditioning water exceeds 9,5 then the preconditioning shall be repeated with new test pieces.

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

This description corresponds with the preconditioning for site-applied products according to EN 14944-2 and -4

The date of the beginning of the preconditioning and the migration test shall be mentioned in the test report.

(c) Migration test

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

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

Non-chlorinated migration test water shall be natural water without gas or demineralised water containing anhydrous calcium chloride ((222 ± 2) mg $CaCl_2$ L^{-1}), sodium hydrogen carbonate ((482 ± 2) $NaHCO_3$ mg L^{-1}) and sodium silicate ((71 ± 1) $Na_2SiO_3 \cdot 9 \cdot H_2O$ mg L^{-1}). It shall have a pH of (7.4 ± 0,1) by air or CO_2 bubbling, a conductivity of (500 ± 50) µS cm^{-1}, an alkalinity of (350 ± 50) mg HCO_3- L^{-1}, a concentration of calcium of (80 ± 10) mg $^{-1}$ L and a concentration of silica of (15 ± 5) mg SiO_2 L^{-1}. Non-chlorinated migration test water shall have no odour (< 2 TON), flavour (< 2 TFN), colour (< 0,1 m^{-1}), turbidity (< 0,1 FNU) and TOC (<0,2 mg C L^{-1}).

Chlorinated migration test water shall consist of non-chlorinated test water containing (1.0 ± 0.2) mg L^{-1} of free chlorine.

This corresponds to EN 14944-1 and -2.

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

Non-chlorinated migration test water shall be demineralised water containing anhydrous calcium chloride ((110 ± 1) mg $CaCl_2$ L^{-1}), sodium hydrogen carbonate ((140 ± 1) $NaHCO_3$ mg L^{-1}) and sodium silicate ((48 ± 1) $Na_2SiO_3 \cdot 9 \cdot H_2O$ mg L^{-1}). It shall have a pH of (7,0 ± 0,1) by air or CO_2 bubbling.

Chlorinated migration test water shall consist of non-chlorinated test water containing (1,0 ± 0,2) mg L^{-1} of free chlorine.

This corresponds to EN 14944-3 and -4.

(iii) Migration test water temperature

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

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

(iv) Duration of migration test periods

The test piece for cold water application shall be in contact with test water for 72 h ± 1 h. The test piece for elevated temperature applications shall be in contact with water for 24h. The

test shall be repeated at least two more times using fresh test water each time. For cold water tests, the migration samples of the 1st, 2nd and 3rd migration period shall be analysed. The compliance with the pass/fail criteria shall be assessed at the 3rd migration period. If the pass/fail criteria (see sections 4.2 and 4.3) are not met at the 3rd migration period the testing can be extended and the 5th, 7th and 9th period shall be analysed additionally. In this case the pass/fail criteria shall be assessed at the 9th migration period.

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

The migration scheme and the respective migration periods which needs to be analysed are presented in Annex 6 of this document.

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

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

(vi) Additional specifications

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

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

For the cold water test the testing with chlorinated and non-chlorinated test water is sufficient as duplicate testing. The respective migration waters have to be analysed individually. For the test at elevated temperatures duplicate testing means that at least two pipe segments are tested or two tanks containing the test pieces. In this case the migration waters of these parallel tests do not need to be analysed individually, but might be combined for analysis.

6.3.3.2 Analysis of migration waters (chapter 3.2 of Annex III of CID (EU) 2024/368)

6.3.3.2.1 Relevant substances (chapter 3.2.1)

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

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

Concentrations of elements (metals) shall be analysed according to EN ISO 17294-2:2023[3].

[3] EN ISO 17294-2 specifies a testing method for the following 64 elements: aluminium, antimony, arsenic, barium, beryllium, bismuth, boron, cadmium, caesium, calcium, cerium, chromium, cobalt, copper, dysprosium, erbium, europium, gadolinium, gallium, germanium, gold, hafnium, holmium, indium, iridium, iron, lanthanum, lead, lithium, lutetium, magnesium, manganese, mercury, molybdenum, neodymium, nickel, palladium, phosphorus, platinum, potassium, praseodymium, rubidium, rhenium, rhodium, ruthenium, samarium, scandium, selenium, silver, sodium, strontium,

6.3.3.2.2 Unexpected substances (chapter 3.2.2 of Annex III of CID (EU) 2024/368)

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

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

Tests for migration of unexpected substances according to EN 15768:2015 shall be performed if organic constituents are used according to the formulation ≥ 0.2% related to the cement content.

See also 6.1.3.2.2.

6.3.3.2.3 Relevant other parameters (chapter 3.2.3 of Annex III of CID (EU) 2024/368)

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

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

- Total Organic Carbon (TOC) shall be determined according to EN 1484:1997 as non-purgeable organic carbon;
- Odour shall be determined as Threshold Odour Number (TON) according to EN 1420: 2016 and EN 1622:2006;
- Flavour shall be determined as Threshold flavour number (TFN) according to EN 1420:2016 and EN 1622:2006;
- Colour shall be determined according to EN ISO 7887:2011; method C
- Turbidity shall be determined according to EN ISO 7027-1:2016 - nephelometry.

6.3.3.3 Mathematical modelling (chapter 3.3 of Annex III of CID (EU) 2024/368)

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

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

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

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

The following mathematical modelling approaches may be used:

(a) Migration modelling according to standards accepted at international level, simulating a migration test according to the EN 14944 -3 and -4;

(b) Full transfer calculation, simulating full transfer of substances from the product into the migration water.

terbium, tellurium, thorium, thallium, thulium, tin, titanium, tungsten, uranium and its isotopes, vanadium, yttrium, ytterbium, zinc and zirconium.

For further details see 6.1.3.3.

6.3.3.4 Enhancement of microbial growth (EMG) testing (Chapter 3.4 of Annex III of CID (EU) 2024/368)

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

Tests for enhancement of microbial growth shall only be performed if organic constituents are used according to the formulation (organic content ≥ 0.2% related to the cement content).

6.3.4 Acceptance requirements: Pass/Fail criteria (Chapter 4 of Annex III of CID (EU) 2024/368)

6.3.4.1 Formulation (Chapter 4.1 of Annex III of CID (EU) 2024/368)

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

(a) in accordance with the technical function specified in the relevant European positive lists;

(b) in compliance with conditions of use established under the relevant European positive lists.

Only generic constituents listed in Table 8 may be used in the preparation of cementitious mixtures.

6.3.4.2 Relevant substances, unexpected substances (Chapter 4.2 of Annex III of CID (EU) 2024/368)

6.3.4.2.1 Conversion of migration test results (Chapter 4.2.1 of Annex III of CID (EU) 2024/368)

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

The conversion factors for the different product groups are listed in Table 5 to Annex I of CID (EU) 2024/368.

6.3.4.2.2 Pass/fail criteria for relevant substances (Chapter 4.2.2)

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

(a) $C_{tap} \leq MTC_{tap}$ for the 3rd migration period or, in case extended testing is needed, at the 9th migration period;

If the $MTC_{tap,TOC}$ of the relevant substance expressed as TOC:

$$MTC_{tap,TOC} = MTC_{tap} \frac{M_{carbon}}{M_{total}}$$

where:

M_{total} = molecular mass of the substance,

M_{carbon} = molecular mass of only the carbon atoms in the substance

exceeds 0,5 mg/l, the compliance can also be demonstrated via the pass/fail criteria for TOC. In this case the compliance with the TOC requirement is at the same time a demonstration of the compliance with the MTC_{tap} of the substance and a targeted analysis of the relevant substance is not required.

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

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

(a) $C_{tap} \leq MTC_{tap}$ for the 7th migration period or, in case extended testing is needed, at the 22nd migration period.

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

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

There is an increasing trend of the measured concentrations for the relevant substances, if for example the following criteria are fulfilled simultaneously:

- c_{tap} of the relevant migration period is higher than 1/10 of the relevant MTC_{tap}, and
- the measured concentration of the relevant migration period has doubled (i.e. more than can be accounted for by measurement uncertainty) compared to the lowest measured concentration, and
- the measured concentration of the relevant migration period is the highest measured value of the migration series.

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

6.3.4.2.3 Pass/fail criteria for unexpected substances (Chapter 4.2.3 of Annex III of CID (EU) 2024/368)

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

The MTC_{tap} for the unexpected substances are set out in Table 6 of Annex I of CID (EU) 2024/368.

For further details see 6.1.4.2.3.

For certain cementitious products the S/V ratio does not allow to meet the limit of MTC_{tap} = 1 µg/L as established for organic materials.

In this case MTC_{tap} < Limit of Quantification for the highest S/V ratio shall apply.

The S/V recommended in the standards for cementitious materials (EN 14944-3/4) are lower than those for organic materials. This leads to lower corresponding concentrations in migration water and the requirement for the MTC_{tap}= 1 µg/l might correspond to a concentration below the threshold value (limit of quantification) as given in the EN 15768 with 2,0 µg/l.

Table 11: GC-MS screening – concentrations (C_n^T) measured in migration water corresponding to an MTC_{tap} = 1 µg/l based on the S/V ratios recommended in the EN 14944-3 / -4

Product group		MTC_{tap} (µg/l)	CF	M^T_n (µg/dm²/ day)	S/V (dm^{-1})	C^T_n (µg/l)	EN 15768 LQ (µg/l)
A: Pipes and pipe linings	Domestic installations, buildings (ID < 80 mm)	1	20	0,05	Actual "worst case" S/V ratio of the pipe diameter		2
	Service piping (80 mm ≤ ID < 300 mm)	1	10	0,1	5.0*	1.5	2
	Mains piping (ID ≥ 300 mm)	1	5	0,2	1.3*	0,78	2
B: Fittings, ancillaries	Domestic installations, buildings (ID < 80 mm)	1	20	0,05	Actual "worst case" S/V ratio of the pipe diameter		2
	Service piping (80 mm ≤ ID < 300 mm)	1	1	1	5.0	15	2
	Mains piping (ID≥ 300 mm)	1	0,5	2	1.3	7,8	2
E Storage system (reservoirs)	In water supply	1	1	1	1.3	3,9	2

* S/V ratio values where the MTC_{tap} of 1 µg/l cannot be verified due to analytical constraints

6.3.4.2.4 Pass/fail criteria for Total organic carbon (TOC) (chapter 4.2.4 of Annex III of CID (EU) 2024/368)

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

(a) C_{tap} ≤ 0,5 mg/l for the 3rd migration period or C_{tap} ≤ 0,5 mg/l for the 9th migration period and C_{tap} ≤ 2,0 mg/l for the 3rd migration period;

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

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

(a) C_{tap} ≤ 0,5 mg/l for the 7th migration period or C_{tap} ≤ 0,5 mg/l for the 22nd migration period and C_{tap} ≤ 2,0 mg/l for the 7th migration period.

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

The measured TOC in the migration water from the successive migration periods shall be used to assess the trend. However, if the TOC in the relevant migration period is below 0.2 mg/l no trend analysis is required.

There is an increasing trend in the measured TOC values if for example the following criteria are fulfilled simultaneously:

- $c_{tap,TOC}$ of the relevant migration period is higher than 0,2 mg/l, and

- the measured TOC concentration in the migration water of the relevant migration period has doubled (i.e. more than can be accounted for by measurement uncertainty) compared to the lowest measured concentration, and
- the measured concentration of the relevant migration period is the highest measurement value of the migration series.

6.3.4.3 Odour, flavour , colour and turbidity (Chapter 4.3 of Annex III of CID (EU) 2024/368)

6.3.4.3.1 Pass/fail criteria for TON, TFN (Chapter 4.3.1 of Annex III of CID (EU) 2024/368)

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

(a) TON, TFN ≤ 2,0 for the 3rd migration period; or

(b) TON, TFN ≤ 2,0 for the 9th migration period and TON ≤ 4,0 for the 3rd migration period.

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

(a) TON, TFN ≤ 2,0 for the 7th migration period; or

(b) TON, TFN ≤ 2,0 for the 22nd migration period and TON, TFN ≤ 4,0 for the 7th migration period.

6.3.4.3.2 Pass/fail criteria for colour (Chapter 4.3.2 of Annex III of CID (EU) 2024/368)

The acceptance criterion for colour is ≤ 5 mg/l Pt/Co

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

6.3.4.3.3 Pass/fail criteria for turbidity (Chapter 4.3.3 of Annex III of CID (EU) 2024/368)

The acceptance criterion for turbidity is ≤ 0,5 NFU

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

6.3.4.4 Enhancement of Microbial Growth (EMG) (Chapter 4.4 of Annex III of CID (EU) 2024/368)

The pass/fail criteria for Enhancement of Microbial Growth (EMG) for method 1 (EN 16421:2015) is < 1000 pg ATP/ cm^2 and for method 2 (EN 16421:2015) is ≤ (0,05 ± 0,02) ml/800 cm^2.

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

Table 12: Summary of parameters and pass/fail criteria for cementitious materials

Parameters	Migration Testing	Analytical Methods	Pass/Fail Criteria
Odour and flavour (TON/TFN)	EN 14944-1/2	EN 1420 and 1622	TON/TFN ≤ 2,0 at 10th day, or TON/TFN ≤ 4,0 at 10th day AND TON/TFN ≤ 2,0 at 31st day in case of extended testing
Colour	EN 14944-1/2	EN ISO 7887- method C	≤ 5 at 10th day, or at 31st day in case of extended testing
Turbidity	EN 14944-1/2	EN ISO 7027-1	≤ 0.5 NFU at 10 days, or at 31 days in case of extended testing
TOC	EN 14944-1/2	EN 1484	TOC ≤ 0.5 mg/l at 10th day and no increasing trend testing or TOC ≤ 2.0 mg/l at 10th day AND TOC ≤ 0.5 mg/l at 31st day in case of extended testing, and no increasing trend (however if TOC < 0.2, no trend analysis is required)
GC-MS screening **Only in cold water and only if organic constituents are used (≥ 0.2%)**	EN 14944-3/4	EN 15768	At 10th day or at 31st day in case of extended testing: $C_{tap} \leq MTC_{tap}$; for substances without MTC_{tap}, and/or for peaks unidentified: $C_{tap} \leq 1$ µg/l (or LQ of the standard) per peak and $C_{tap} \leq 5$ µg/l for sum of unidentified peaks.
EMG only chlorine-free water and only if organic constituents are used (≥ 0.2%)	EN 16421	EN 16421	Method 1 | BPP | 1000 pg ATP/cm^2 Method 2 | $V_{biofilm}$ | ≤ 0.05 ± 0.02 ml/800 cm^2
Substances with MTC_{tap}	EN 14944-3/4	Analysis or calculation or modelling	$C_{tap} \leq MTC_{tap}$ at 10th day, or at 31st days in case of extended testing and no increasing trend (however if the $C_{tap} < 1/10 * MTC_{tap}$, no trend analysis is required)
Metallic and mineral elements with $MTC_{tap,\ cementitious}$	EN 14944-3/4	EN ISO 17294-2 (ICP-MS)	$C_{tap} \leq MTC_{tap,\ cementitious}$ at 10th day, or at 31st day in case of extended testing and no increasing trend (however if the $C_{tap} < 1/10 * MTC_{tap,,\ cementitious}$ no trend analysis is required)

6.4 Enamels, ceramic materials and other inorganic materials (including glass)

6.4.1 General Procedure for testing and accepting final enamels, ceramic materials and other inorganic materials (including glass) (Chapter 1 of Annex IV of CID (EU) 2024/368)

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

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

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

2. Composition review

Step 2 – Performance of tests

1. Testing of composition

2. Migration test for relevant substances

Step 3 – Compliance with pass/fail criteria

6.4.2 Identification of relevant substances and relevant other parameters (Chapter 2 of Annex IV of CID (EU) 2024/368)

6.4.2.1 Categorisation of products or components into risk groups and corresponding testing requirements (Chapter 2.1 of Annex IV of CID (EU) 2024/368)

For each product or component of an assembled product, a product group and a corresponding conversion factor (CF) shall be determined in accordance with Table 5 of Annex I [of CID (EU) 2024/368]. Based on the determined CF, the product or component is categorised in a risk group (RG) in accordance with Table 1.

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

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

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

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

Risk group	Conversion factor CF in d/dm	Composition review & testing	Specific migration testing
RG1	≥ 4	Yes	Yes, on product or component.
RG2	≥ 0,4 and < 4		

			Enamels: test piece(s) produced by enameller
RG3	≥ 0,04 and < 0,4	Yes	Yes, on product or component. Enamels: test piece(s) produced by enamel manufacturer
RG4	< 0,04	Yes	No

The following table contains exemplary products or components for the respective product groups. For the assignment of the components into the product groups, the actual wetted surface parts of the individual components must be taken into account. The surface portions of components made of the same materials must be summed up.

Table 13: Exemplary overview of the different products in the respective product group

Product group (risk group)	Products (examples)
Pipes (RG1)	Flange pipes (usually < 1 m length)
Ancillaries (RG2)	Valves, fittings
Components of ancillaries with a wetted surface fraction < 10% of the assembled product (RG3)	Valve housings and lids
Small components of ancillaries with a wetted surface fraction < 1% of the assembled product (RG4)	Ceramic bearings and ceramic shafts in drinking water pumps
Storage systems (RG1 / RG2)	Enamelled storage drinking water heaters
Components of storage systems with a wetted surface fraction < 10% of the assembled product (RG2 / RG3)	
Small components of storage systems with a wetted surface fraction < 1% (RG3 / RG4)	Glass tubes for level indication in drinking water storage tanks

There are no large differences in the testing requirements depending on the risk groups. Only for components classified in RG4 no specific migration testing is required. The difference for enamels classified in RG1/RG2 and RG3 is that for RG1/RG2 products the test pieces have to be produced by the specific enameller and that the certificates are limited to the specific enameller. In case of RG3 components the test pieces can be produced by any company and a certificate for the enamel frits (pre-product) can be issued for the enamel manufacturers. These-pre-product certificates are valid for any RG3 component produced by any enameller using this specific enamel composition if no further substances are added (e.g. mill additives).

6.4.2.2 Composition review (Chapter 2.2 of Annex IV of CID (EU) 2024/368)

6.4.2.2.1 Required information (Chapter 2.2.1 of Annex IV of CID (EU) 2024/368)

For the final materials the complete composition with the range for all constituents exceeding 0.02 % (m/m) is required. The content of lead and cadmium shall be declared.

The manufacturer has to provide the intended composition including the tolerances of the final material to the conformity assessment body. If the manufacturer is not responsible for the composition (e.g. enameller) the composition has to be provided by the respective supplier.

6.4.2.2.2 Accepted compositions (Chapter 2.2.2 of Annex IV of CID (EU) 2024/368)

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

The content of lead and cadmium shall be less than 0.02% (m/m).

The conformity assessment body has to check whether the provided compositions complies with the European positive list of compositions of enamels, ceramic and other inorganic materials. The conformity assessment body can only accept composition complying with the positive list. This applies also to the condition of use as specified in the positive list.

6.4.2.2.3 Relevant substances (Chapter 2.2.3 of Annex IV of CID (EU) 2024/368)

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

The relevant elements to be analysed in the migration waters are specified for each entry of the European positive list. For example, for enamels (Status 23 January 2024) the relevant substances are: Al, B, Ba, Cd, Ce, Co, Cr, Cu, Li, Mn, Mo, Ni, Pb, Sb, Sr, Ti, Zr.

Table 14, based on CID (EU) 2024/367 Annex IV and Annex V, indicates the accepted composition constituents for enamels and the maximum tolerable concentration at the tap of relevant chemical species. For substances indicated as not relevant no requirement applies. For chemical species, for which no MTC_{tap} is available MTC_{tap} = 0,1 µg/l applies.

Table 14: Accepted composition constituents and $MTC_{tap,\ inorganic}$ for enamels (Status 23 January 2024)

Constituent identity	Formulation / Minimum concentration (% w/w)	Formulation / Maximum concentration (% w/w)	Element	Allocation factor of the element	Maximum Tolerable Concentration at the tap for relevant substances / element (MTC_{tap}, inorganic) in µg/l
SiO_2	25	80	Si	Not relevant	Not relevant
B_2O_3	0	20	B	0,1	150
Na_2O	0	30	Na	Not relevant	Not relevant
K_2O	0	10	K	Not relevant	Not relevant
Li_2O	0	10	Li	0,1	30
CaO	0	10	Ca	Not relevant	Not relevant
BaO	0	15	Ba	0,1	50
SrO	0	5	Sr	Not available	Not available
Sb_2O_3	0	1	Sb	0,1	1
MgO	0	5	Mg	Not relevant	Not relevant

CeO_2	0	15	Ce	Not available	Not available
ZnO	0	10	Zn	Not relevant	Not relevant
Al_2O_3	0	5	Al	0,5	100
CoO	0	5	Co	0,5	13
NiO	0	3	Ni	0,1	2
CuO	0	3	Cu	0,1	200
MnO_2	0	5	Mn	0,5	25
Fe_2O_3	0	5	Fe	Not relevant	Not relevant
MoO_3	0	5	Mo	Not available	Not available
P_2O_5	0	5	P	Not relevant	Not relevant
SnO_2	0	5	Sn	Not relevant	Not relevant
TiO_2	0	16	Ti	Not available	Not available
ZrO_2	0	30	Zr	Not available	Not available
F	0	10	F	Not relevant	Not relevant
Cr_2O_3	0	3	Cr	0,1	5
--	--	--	Cd	0,05	0,25
--	--	--	Pb	0,05	0,25

For ceramic materials and other inorganic materials, the accepted composition constituents, the relevant chemical species to be analysed in the migration waters and the maximum tolerable concentrations at the tab ($MTC_{tap,\ inorganic}$) apply as defined in Commission Implementing Decision (EU) 2024/367 Annex IV and Annex V.

6.4.3 Testing requirements (Chapter 3 of Annex IV of CID (EU) 2024/368)

6.4.3.1 Testing of the composition (Chapter 3.1 of Annex IV of CID (EU) 2024/368)

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

The conformity assessment body has to arrange the analysis of the composition of the test species withdrawn in the cause of the initial inspection and annual inspection (for products/components classified in RG1/RG2) or of the test pieces sent to the conformity assessment body / laboratory (for products classified in RG3/RG4). The analysis of the composition of the final material shall be performed with a standardised (when possible) suitable test method. Example on suitable test methods are: Inductively Coupled Plasma Mass Spectrometry (ICP-MS), X-Ray Fluorescence (XRF) e.g. EN 15063-1 and EN 15063-2), Atomic Absorption Spectroscopy (AAS) and Optical Emission Spectroscopy (OES) e.g. S-OES EN 15079, ICP-OES EN 15605. Examples of factors to consider in the choice of a suitable test methods are elements to be analysed, the concentration of element, the matrix, and the geometry of samples. The assigned laboratory should be accredited for the respective test method.

For enamels, the composition might be determined alternatively for the traded enamel before firing instead for the enamelled plates. In this case the conformity assessment body has to sample the enamel before firing additionally in the course of the initial and annual inspections.

6.4.3.2 Migration testing (Chapter 3.2 of Annex IV of CID (EU) 2024/368)

6.4.3.2.1 Standards (Chapter 3.2.1 of Annex IV of CID (EU) 2024/368)

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

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

The migration test is carried out in accordance with EN 12873-1. Each sample is subjected to a pre-treatment, consisting of a rinsing phase, a stagnation phase and a further rinsing phase. The sample pre-treatment is followed by migration periods (stagnation phases in the closed test batch) at a defined ratio of test specimen surface area to water volume. At the end of each migration period, the migration water shall be replaced by fresh test water. The migration waters of the defined migration periods are used for further investigations.

For the testing of enamelled products/components or products/components made of carbon free ceramic materials, no glass containers or glass vessels shall be used. The migration test of ceramic materials containing carbon have to be carried out exclusively in glass containers or glass vessels.

When testing components, a ratio of test pieces' surface area to water volume (O/V) of at least 5 dm^{-1} shall be set. When testing specifically manufactured test pieces, the test setup shall be dimensioned so that a ratio of test pieces' surface area to water volume (O/V) of 5 dm^{-1} ± 10 % is achieved.

Figure 1 shows a suitable apparatus for carrying out the migration test for enamelled test plates. In the three test chambers of the apparatus, the test water has contact with two enamelled test plates in each of two chambers, while the blank test is carried out in the centre chamber.

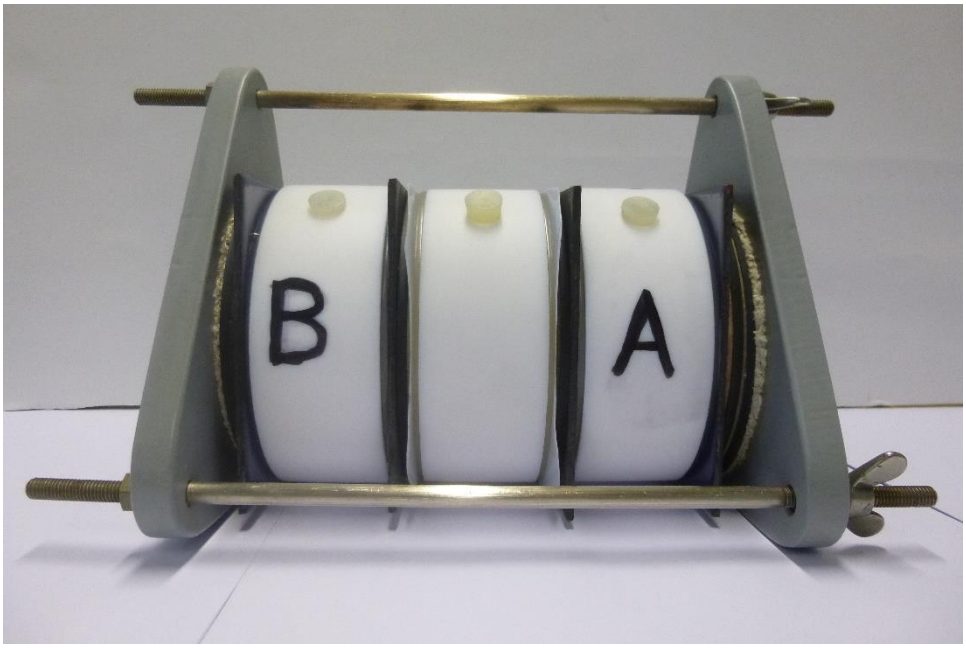

Figure 1: Exemplary setup for migration testing of enamelled test plates (photo: TÜV SÜD Industrie Service GmbH)

However, other test set-ups are also possible. *Figure* 2 shows a test setup in which funnels are pressed onto the enamelled test plates containing the migration water.

Figure 2: Alternative test setup (photo: German Environment Agency)

6.4.3.2.2 Test piece (Chapter 3.2.2 of Annex IV of CID (EU) 2024/368)

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

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

For enamels the use of specifically produced test pieces for testing is common. For the certification of products or components classified in RG1/RG2 the conformity assessment body has to audit the production of the production of the test pieces. The test pieces shall be made of the same material as the component to be enamelled. Plates measuring 105 x 105 mm are to be used. The specimens are drilled with a hole of approx. 5 mm diameter, the centre of the hole is 4 mm from the edge. Pre-treatment and enamelling shall correspond to regular production. The back of the sample is protected against corrosion with a thin layer of enamel. After drying, the enamel layer on the test pieces is burned together with the regular products under the usual conditions. If specially manufactured test pieces are used instead of the component, the conformity assessment body has to prepare a record of the manufacture of the test pieces and this has to be attached to the test report.

6.4.3.2.3 Temperature of testing (Chapter 3.2.3 of Annex IV of CID (EU) 2024/368)

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

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

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

The test pieces are tested by repeated, consecutive stagnation contact with demineralised water at 23 °C ± 2 °C,60 °C ± 2 °C or 85 °C ± 2 ° for the migration of the constituents. Table 3 lists the test conditions for the various products according to their intended use.

Table 15: Examples of Products and their testing conditions

Examples of Products/components	Test conditions
Products/components that are intended exclusively for cold water use	Cold water test at 23 °C ± 2 °C
Products/components that are properly in contact with hot and cold water (e.g. mixing cartridges of a tap)	Cold water test at 23 °C ± 2 °C and warm water test at 60 °C ± 2 °C
Drinking water heaters	Cold water test at 23 °C ± 2 °C and warm water test at 60 °C ± 2 °C
Drinking water heaters that are intended to deliver boiling hot water	Cold water test at 23 °C ± 2 °C and hot water test at 85 °C ± 2 °C

For the warm or hot water test, the test water shall reach the required test temperature after a maximum of one hour. This can be ensured, for example, by using preheated test water

6.4.3.2.4 Type of test water (Chapter 3.2.4 of Annex IV of CID (EU) 2024/368)

Cold water test (23 °C ± 2 °C) shall be performed with non-chlorinated test water. In the case PAH analysis is required the test shall be performed with chlorinated test water additionally.

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

EN 12873-1 requires duplicate testing and the performance of one blind test. If the cold water test is performed with chlorinated and non-chlorinated test water this can be regarded as duplicate testing. In all other cases duplicate testing means that at least two tanks containing the test pieces are used. The migration waters of these parallel tests do not need to be analysed individually, but might be combined for analysis.

6.4.3.2.5 Migration periods (Chapter 3.2.5 of Annex IV of CID (EU) 2024/368)

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

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

The migration scheme and the migration waters of the respective migration periods, which are to be taken for analyses for the cold water test and warm/hot water test, respectively are presented in Annex 6 of this document.

6.4.3.3 Analysis of migration waters (Chapter 3.3 of Annex IV of CID (EU) 2024/368)

6.4.3.3.1 Relevant substances

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

The migration waters for the determination of the elements (not for the PAK determination) should be acidified immediately with concentrated HNO_3 to 2 % (v/v) acidity. The analysis should be undertaken by an adequate measurement method, e. g. ICP-MS as described in EN ISO 17294-1.

6.4.4 Acceptance requirements: Pass/fail criteria (Chapter 4 of Annex IV of CID (EU) 2024/368)

6.4.4.1 Composition (Chapter 4.1 of Annex IV of CID (EU) 2024/368)

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

6.4.4.2 Relevant substances (Chapter 4.2 of Annex IV of CID (EU) 2024/368)

6.4.4.2.1 Conversion of test results (Chapter 4.2.1 of Annex IV of CID (EU) 2024/368)

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

The conversion factors for the different product groups are listed in [CID (EU) 2024/368] Table 5 of Annex I.

6.4.4.2.2 Pass/fail criteria for relevant substances

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

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

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

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

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

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

There is an increasing trend in the measured concentrations, if the following criteria are fulfilled simultaneously:

- c_{tap} of the relevant migration period is higher than 1/10 of the relevant MTC_{tap}, and
- the measured concentration of the relevant migration period has doubled (i.e. more than can be accounted for by measurement uncertainty) compared to the lowest measured concentration, and
- the measured concentration of the relevant migration period is the highest measured value of the migration series.

7 EU Declaration of Conformity and Marking of Products

7.1 EU Declaration of Conformity

CDR (EU) 2024/370 Article 2 paragraph 5:

Where compliance of a product with the applicable minimum hygiene requirements has been demonstrated by the conformity assessment procedure referred to in paragraph 1 or 2 [of Article 2 of CDR (EU) 2024/370], **manufacturers**, or their authorised representatives, **shall draw up an EU declaration of conformity**.

By drawing up the EU declaration of conformity, or by having it drawn up by its authorised representative, the manufacturer, assumes responsibility for the compliance of the product with the minimum hygiene requirements.

The EU declaration of conformity shall have the model structure set out in the Annex [of CDR (EU) 2024/370] and shall be continuously updated. It shall be translated by the manufacturer, or its authorised representative, into the language or languages required by the Member State in which the product is placed on the market.

For products of RG1 and RG2 (product group A & B for metallic materials) the EU declaration of conformity is based on the certificate issued by the conformity assessment body.

For products of RG3 and RG4 (product group C & D for metallic materials) the EU declaration of conformity is based on the certificate for the type examination issued by the conformity assessment body and the declaration of the manufacturer for the internal production control.

The EU declaration of conformity should be part of the documentation of the product.

Decision No 768/2008/EC Annex II Module C paragraph 3.2. and Module D paragraph 5.2.:

The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. …

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

7.2 Marking

7.2.1 Meaning of the marking

As a result of the EU declaration of conformity the manufacturer has to mark the respective product as described below. The intention of the marking is that water suppliers, plumbers, authorities, wholesalers, retailers but also the consumers can easily identify products complying with the requirements according to CDR (EU) 2024/370. This compliance indicates a compliance with CID (EU) 2024/368 and with Article 11 of the DWD as well.

Differently from other EU Directives and Regulations, a dedicated symbol different from CE marking has been adopted, more likely visually suggesting the products use. It represents a tap and a glass of water, surrounded by stars. Similar to the solution that has been adopted for materials and articles intended to come into contact with food (regulation (EC) 1935/2004), where the symbol consists in a fork and a glass.

Figure 3: Symbol

The marking does not indicate that a product was made in the European Union. The marking does not serve commercial purposes i.e. it is not a marketing tool.

The symbol on the products does not replace and is not to be confused with any other similar symbol intended to identify installation systems (e.g.: potable water symbol in EN 806 to be used to distinguish plumbing systems for water intended for human consumption from plumbing system for other waters).

7.2.2 Products affected by marking

In principle all products intended to be used in contact with water intended for human consumption have to comply with the requirements according to article 11 DWD and have to be marked with the symbol.

CDR (EU) 2024/371 Article 1 no 1.:

… The symbol shall be at least 5 mm high.

Where the symbol of the minimum size cannot be affixed on the product, it shall be affixed to the packaging and to the documentation.

The symbol shall be indelible and visibly affixed to one or more surfaces of the product, on any technical and administrative documents accompanying the product (the ‘documentation’) and on the packaging of the product.

In the following cases the symbol does not need to be affixed on the product:

- The product is too small to affix the symbol in the required size
- Products sold as spare parts for assembled products
- Products made of a material that does not provide adhesion, e.g. liquid sealants.
- Products of a shape that does not allow to affix the symbol correctly
- Products with a function that is hampered by affixing the symbol

However, in these cases the marking has to be affixed on the packaging and has to be printed in the documentation.

In case of products where the aesthetic is hampered by affixing the symbol, the symbol can be affixed in a position, which is not visible after installation. When also this option is not practicable, then the symbol can be affixed by using a sticker directly applied on the product.

If components are produced by the manufacturer of the assembled product or produced specifically for the manufacturer of the assembled product and are certified these components do not have to

be marked. In this case the symbol does also not need to be affixed on the packaging. If these components are provided as spare parts, the marking in the documentation is sufficient.

7.2.3 Who must affix the marking?

The marking is affixed by the manufacturer (established inside or outside the EU), or by his authorised representative established within the EU.

By affixing the marking the manufacturer declares on his sole responsibility that the product conforms to article 11 of DWD, and that the appropriate conformity assessment procedures according to CDR (EU) 2024/370 have been successfully completed.

The manufacturer, whether established inside or outside the Union, is the entity ultimately responsible for the conformity of the product with the provisions of the Union legislation and for the affixing of the marking. The manufacturer may mandate an authorised representative to affix the marking on his behalf.

If the importer or distributor or another operator places products on the market under his own name or trademark or modifies them, he then takes over the manufacturer's responsibilities. This includes the responsibility for the conformity of the product and the marking. In this case he must have sufficient information on the design and production of the product, as he will be assuming the legal responsibility when affixing the marking.

7.2.4 Packaging and documentation

The symbol shall be affixed to the packaging of the product, if exists, and to the documentation. Any technical and administrative documents accompanying the product are considered as documentation. Technical documents are for example the user manual or user instruction (but not the technical documentation referred in 5.3.2 and 5.3.3).

The use of a sticker which is affixed to the packaging serves as example for the purpose required.

Additionally, the marking on the packaging and on the documentation of the product shall include the following informative text:

'SUITABLE FOR DRINKING WATER'

CDR (EU) 2024/370 Article 1 no 3.:

The information text ['SUITABLE FOR DRINKING WATER'] shall be clearly visible and shall be placed below the symbol, in upper case and in Helvetica Bold with a minimum font size of 5 mm.

The information text affixed on the documentation shall be written in the official languages of the Member State where the product is placed on the market unless that Member State provides otherwise.

The information text affixed on the packaging shall be written in at least one of the official languages of the Member State where the product is placed on the market.

Additional languages may be used for the information text than those required in this paragraph provided that the same information appears in all languages used.

Where the information text is translated into another language than the required languages referred to in this paragraph, the translated text shall be placed below the information text in those required languages.

The affixing of the information text shall not negatively impact on resources and environment when placed on labels and documentation. Packaging material and label sizes shall not be increased only for the reason of adapting to the information text requirements.

On the packaging or at least in the documentation the identification of the involved notified conformity assessment body and a reference to the respective certificate number have to be specified.

Annex 1: Risk-based approach for organic materials

Product groups	Conversion factors (CF)	Risk Groups (RG)	Testing requirements						Applicable conformity assessment procedure
			Formulation review	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG	
A1: Pipes and pipe linings with an inner diameter < 80 mm	20	RG1	Yes	Yes, on product	Yes, on product	Yes, on product	Yes, on product	Yes, on product	**Module B (EU type examination)** **With the following specifications:** • examination of a test piece (production type) • all relevant tests • withdrawal of test pieces by notified body **Module D (Conformity to type based on quality assurance of the production process)** **With the following specifications:** • quality system shall be assessed • initial inspection of the production • annual inspection of the production site • annual reduced testing
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	10							Yes, on product or test piece of the formulation	
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	5								
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	4								
B1: Fittings and ancillaries of product group A1	2	RG2	Yes	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product or component	Yes, on (assembled) product or component	Yes, on component or test piece of the formulation	
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	2								
B2: Fittings and ancillaries of product group A2	1								
E3: Storage systems (reservoirs) In water supply	1								
B3: Fittings and ancillaries of product group A3	0.5								
F1: Components of product group E1	0.4								
C1: Components of fittings and ancillaries of product group B1	0.2	RG3	Yes	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on component or test piece of the formulation	**Module B (EU type examination) carried out by a notified body** **With the following specifications:** • examination of a test piece (production type) • all relevant tests • test pieces shall be supplied by the manufacturer **Module C (Conformity to type based on internal production control)**
F2: Components of product group E2	0.2								
C2: Components of fittings and ancillaries of product group B2	0.1								
F3: Components of of product group E3	0.1								
C3: Components of fittings and ancillaries of product group B3	0.05								
G1: Small Components of product group E1	0.04								
D1: Small of fittings and ancillaries of product group B1	0.02	RG4	No	No	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on (assembled) product, component or test piece of the formulation	Yes, on component or test piece of the formulation	
G2: Small Components of product group E2	0.02								
D2: Small Components of fittings and ancillaries of product group B2	0.01								
G3: Small Components of product group E3	0.01								
D3: Small Components of fittings and ancillaries of product group B3	0.005								

Annex 2: Risk-based approach for metallic materials

<table>
<tr><th rowspan="2">Product groups</th><th rowspan="2">Assumed contact surface ‘a’ (only for information)</th><th colspan="2">Testing requirements</th><th rowspan="2">Applicable conformity assessment procedure</th></tr>
<tr><th>Composition review and testing</th><th>Release of relevant substances

Only for plated or soldered products</th></tr>
<tr><td>A: Pipes</td><td>100 %</td><td rowspan="2">Composition review and testing of the composition of the final metallic material.

Applied organic impregnations and coatings shall comply with the requirements for final organic materials.

For plated and soldered products, relevant substances shall be identified.</td><td rowspan="2">Testing of residues on the surface.

Testing of release of organic substances used in the plating process in accordance with requirements for final organic materials.</td><td rowspan="2"><u>Module B (EU type examination)</u>
With the following specifications:
• examination of a test piece (production type)
• all relevant tests
• withdrawal of test pieces by notified body

<u>Module D (Conformity to type based on quality assurance of the production process)</u>
With the following specifications:
• quality system shall be assessed
• initial inspection of the production
• annual inspection of the production site
• annual reduced testing</td></tr>
<tr><td>B: Fittings and ancillaries in buildings installations.</td><td>10%</td></tr>
<tr><td>C1: Components of products of Product Group B</td><td rowspan="2">1%</td><td rowspan="3">Composition review and testing of the composition of the final metallic material.

Applied organic impregnations and coatings shall comply with the requirements for final organic materials.

For plated and soldered products, relevant substances shall be identified.</td><td rowspan="3">Testing of residues on the surface.

Testing of release of organic substances used in the plating process in accordance with for final organic materials.</td><td rowspan="3"><u>Module B (EU type examination) carried out by a notified body</u>
With the following specifications:
• examination of a test piece (production type)
• all relevant tests
• test pieces shall be supplied by the manufacturer

<u>Module C (Conformity to type based on internal production control)</u></td></tr>
<tr><td>C2: Fittings and ancillaries in water mains and water treatment works with permanent flow</td></tr>
<tr><td>D: Components of products of product group C2</td><td>0,1%</td></tr>
</table>

Annex 3: Risk-based approach for cementitious materials

Product groups	Conversion factors (CF)	Risk Groups (RG)	Testing requirements						Applicable conformity assessment procedure
			Formulation review	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG	
A1: Pipes and pipe linings with an inner diameter < 80 mm	20	RG1	Yes	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used	Yes, on product or test piece	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used	**Module B (EU type examination)** **With the following specifications:** • examination of a test piece (production type) • all relevant tests • withdrawal of test pieces by notified body **Module D (Conformity to type based on quality assurance of the production process)** **With the following specifications:** • quality system shall be assessed • initial inspection of the production • annual inspection of the production site • annual reduced testing
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	10								
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	5								
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	4								
B1: Fittings and ancillaries of product group A1	2	RG2	Yes	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used	Yes, on product or test piece	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used	
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	2								
B2: Fittings and ancillaries of product group A2	1								
E3: Storage systems (reservoirs) In water supply	1								
B3: Fittings and ancillaries of product group A3	0.5								
F1: Components of product group E1	0.4								
C1: Components of fittings and ancillaries of product group B1	0.2	RG3	Yes	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used	Yes, on product or test piece	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used	**Module B (EU type examination) carried out by a notified body** **With the following specifications:** • examination of a test piece (production type) • all relevant tests • test pieces shall be supplied by the manufacturer **Module C (Conformity to type based on internal production control)**
F2: Components of product group E2	0.2								
C2: Components of fittings and ancillaries of product group B2	0.1								
F3: Components of of product group E3	0.1								
C3: Components of fittings and ancillaries of product group B3	0.05								
G1: Small Components of product group E1	0.04								
D1: Small of fittings and ancillaries of product group B1	0.02	RG4	No	No	No	Yes, on product or test piece	Yes, on product or test piece	Yes, on product or test piece if organic constituents are used	
G2: Small Components of product group E2	0.02								
D2: Small Components of fittings and ancillaries of product group B2	0.01								
G3: Small Components of product group E3	0.01								
D3: Small Components of fittings and ancillaries of product group B3	0.005								

Annex 4: Risk-based approach for enamels, ceramic materials and other inorganic materials

Product groups	Conversion factors (CF)	Risk Groups (RG)	Testing requirements			Applicable conformity assessment procedure
			Composition review & testing	Specific migration testing		
				Ceramic and other inorganic materials (including glass)	Enamels	
A1: Pipes and pipe linings with an inner diameter < 80 mm	20	RG1	Yes	Yes, on product or component	Yes, on test piece(s) produced by enameller	**Module B (EU type examination)** **With the following specifications:** • examination of a test piece (production type) • all relevant tests • withdrawal of test pieces by notified body **Module D (Conformity to type based on quality assurance of the production process)** **With the following specifications:** • quality system shall be assessed • initial inspection of the production • annual inspection of the production site • annual reduced testing
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	10					
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	5					
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	4					
B1: Fittings and ancillaries of product group A1	2	RG2	Yes	Yes, on product or component	Yes, on test piece(s) produced by enameller	
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	2					
B2: Fittings and ancillaries of product group A2	1					
E3: Storage systems (reservoirs) In water supply	1					
B3: Fittings and ancillaries of product group A3	0.5					
F1: Components of product group E1	0.4					
C1: Components of fittings and ancillaries of product group B1	0.2	RG3	Yes	Yes, on product or component	Yes, on test pieces(s) produced by enamel manufacturer	**Module B (EU type examination) carried out by a notified body** **With the following specifications:** • examination of a test piece (production type) • all relevant tests • test pieces shall be supplied by the manufacturer **Module C (Conformity to type based on internal production control)**
F2: Components of product group E2	0.2					
C2: Components of fittings and ancillaries of product group B2	0.1					
F3: Components of of product group E3	0.1					
C3: Components of fittings and ancillaries of product group B3	0.05					
G1: Small Components of product group E1	0.04					
D1: Small Components of fittings and ancillaries of product group B1	0.02	RG4	Yes	No	No	
G2: Small Components of product group E2	0.02					
D2: Small Components of fittings and ancillaries of product group B2	0.01					
G3: Small Components of product group E3	0.01					
D3: Small Components of fittings and ancillaries of product group B3	0.005					

Annex 5: Inspection of the production sites

1 Scope

This Annex is intended to facilitate and support the practical implementation of the requirements regarding the initial and annual inspections for the conformity assessment according Module D as set out in Annex II to Decision No 768/2008/EC and specified in Article 2 paragraph 1 (b) of CDR (EU) 2024/370.

These inspections are required for products and components classified in RG 1 or RG 2 and are intended to survey the quality assurance of the production process.

2 Initial Inspection

2.1 Scope

The initial inspection has the following purpose:

- to assess the manufacturer's quality system;
- to verify that the products are in accordance with the technical documents sent along with the application;
- to ensure that the general information provided by the manufacturer is complete and adequate (headquarters, personnel, manufacturing sites, test laboratories, service equipment, etc.);
- to withdraw, identify and seal test pieces for type examination of the products, in accordance with the Sample Taking Plan.

Sample Taking Plan is defined by the conformity assessment body and is based on the documentation received from the manufacturer. Sample Taking Plan shall take into consideration at least the following:

- applicable risk group of the assembled products and components;
- type of the test piece(s) to be used for testing ((assembled) product, component or test piece(s) of the formulation according to Table 1 of Annex I of CID (EU) 2024/368 for organic materials, Table 1 of Annex III of CID (EU) 2024/368 for cementitious materials and Table 1 of Annex IV of CID (EU) 2024/368 for enamels, ceramics and other inorganic materials including glass);
- the necessity to use specifically produced test piece(s) (e.g. prisms for cementitious materials or enamelled plates made of steel for enamelled materials);
- availability of the valid certificates for single components, pre-products, intermediate products, constituent products or formulation and if the provided certificates cover the risk group and testing requirements identified for the (assembled) product or component;
- presence of different production sites of the manufacturer;
- use by the manufacturer of the alternative suppliers of pre-products, starting substances, constituents or compositions (e.g. the use of granulated polymers obtained from different suppliers to manufacture pipes or other products, a testing of the products manufactured by using the alternatives is required);
- product type series (see chapters 5.4.3. and 5.4.4.).

2.2 Method to be applied

The initial inspection involves at least the verification:

- of the design (project status and modifications), where applicable;
- of the manufacturing process (from the verification of incoming materials acceptance procedures (e.g. components, granulates in case of piping, metallic bars) to the end of production cycle including the storage conditions of the (assembled) products and components), also by analysing the possible pollutants that remain on the product during all the processing phases;
- of the identification (material and suppliers) and check of used starting substances / pre-products/ intermediate-products for organic materials / metallic compositions / constituent products for cementitious materials / composition for enamels and ceramic materials / components made of final materials;
- of the availability, adequacy and maintenance status of the production equipment
- of traceability during production phases;
- of non-conformity and complaints management;
- of the quality records;
- of measuring instruments and testing equipment management (if applicable);
- of the company laboratory and internal test procedures (if applicable);
- of subcontracting of production and/or controls;
- of the training and authorisation records of the staff;
- of the marking on the product, its packaging and documents;

The initial inspection shall be made in presence.

The duration for the inspection visit includes on-site time at a manufacturer's premises and time spent off-site carrying out planning, document review, interacting with manufacturer's personnel and report writing.

If the manufacturer uses multiple production sites for the manufacturing of products subject to certification, the initial inspection is carried out at each of these sites.

If the manufacturer makes use of components classified in RG 1 or RG 2 and produced by a different manufacturer (supplier), during the inspection the methods of control of these suppliers by the manufacturer shall be assessed. The inspection can be limited to the manufacturer of the (assembled) product in case the documentation for the component, to ensure that the quality assessment of the production process is fulfilled by the manufacturer of the component, is provided to the conformity assessment body. This documentation shall include declarations of conformity and/or conformity certificates provided by supplier, proof of the compliance with supply specifications, documentation on carrying out second-party audits, process parameters (e.g. pressure and temperature) applied for the individual lots delivered by the supplier etc.

During the inspection visit the Check List for Audit Report specifying recommendations or non-conformities and indicating the adequacy or inadequacy of each applicable item shall be filled by the conformity assessment body. The Check List for Audit Report is provided in section 6 of this Annex.

The availability of a certified quality system (e.g. according to EN ISO 9001) does not exempt the conformity assessment body from assessing all aspects of the manufacturer's quality system that have an impact on the product with respect to the requirements of the CID (EU) 2024/368.

2.3 Withdrawal of test pieces for type examination

In the course of initial inspection the test pieces for type examination shall be withdrawn by the conformity assessment body according to the Sample Taking Plan.

The selection of the test pieces is of importance and shall be based on the following:

- The actual product or component has to be sampled. Only in case the size of the product or component does not allow the practical application of testing, a representative test piece for testing shall be provided (e.g. prisms for cementitious materials, enamelled plated made of steel for enamels). The specifically produced test pieces have to correspond with the final materials as used in products or components. The conformity assessment body has to audit the production of the representative test pieces. This applies also if certificates for pre-products or intermediate products are issued, which will be used for the assessment of products or components of RG1 or RG2. As the geometry of the test pieces – especially the thickness of the materials – might also have an impact on the release of substances, the conformity assessment body has to check the representativeness of the test pieces.
- In case of assembled products, the components are tested. It might be necessary to withdraw the components directly as a larger number of the components might be required for testing.
- In case of the certification of a product type series or component type series the conformity assessment body has to select a representative test piece or representative test pieces. For pipes made of organic materials this shall be the pipe with the smallest ID. For metallic, cementitious materials, enamels, ceramics and other inorganic materials the largest S/V representative of the product type series or component type series shall be sampled (see chapters 5.4.3 and 5.4.4)
- Test pieces shall be withdrawn at the warehouse or at the place of internal release of the manufacturer applying for certification, any exceptions shall be assessed on a case-by-case basis.
- The conformity assessment body has to ensure that the test pieces were not subjected to a special treatment to improve the quality of the test pieces. To ensure that the test pieces are suitable to represent the on-going production, the sampling procedure shall provide sufficient documentation regarding the origin of the test pieces and regarding any basic property and any stage of production process with a potential to influence the performance of the product.

For material specific test pieces requirements, see the sections:

6.1.3.1.2. for organic materials;

6.3.3.1.1. for cementitious materials;

6.4.3.2.2. for enamels, ceramics and other inorganic materials.

In case valid certificates are available for all components, no further testing is required. In this case no sample withdrawal will be performed by the conformity assessment body and the inspection at the production site will be limited to the check that the correct components are used.

All test pieces to be used for testing purposes need to be suitably marked to allow a subsequent verification of their identity without altering the quality and hygienic properties. The conformity assessment body has to physically withdraw and to preserve the test pieces to prevent damage and

alterations to the characteristics relevant to testing. If the inspector is not able to transport the test pieces, he/she has to seal the package used for sending.

2.4 Initial Inspection Report

As a result of the initial inspection a specific Audit Report is prepared, specifying, recommendations or non-conformities and indicating the adequacy or inadequacy of each applicable item. The manufacturer is given a copy of the Audit Report as a notification of the operation. The Audit Report is countersigned by the manufacturer as acceptance of all issued findings.

3 Annual Inspection

3.1 Scope

The annual inspection has the following purpose:

- to re-assess the manufacturer's quality system;
- to verify the maintenance of the characteristics of the product against the applicable certification scheme;
- to withdraw, identify and seal test pieces for the re-assessment of the type examination or for the reduced testing of the products, in accordance with the Sample Taking Plan. Sample Taking Plan is defined in the section 3.1. of this Annex. In case yearly testing is required, the Sample Taking Plan shall take into account the yearly withdrawal of different test pieces so as to cover, if applicable, all products making part of product type series over a 5-year period and, in case the manufacturer has several production sites, the withdrawal of the samples at different production sites so as to cover all production sites over a 5-year period.
-

3.2 Method to be applied

The annual inspection is carried out to ensure the maintenance of compliance with the requirements set forth in the normative reference document and follows the same rules as the initial inspection defined in section 3.2., including the verification of the last inspection report.

If the manufacturer uses multiple production sites for the manufacturing of products subject to certification, the annual inspection, if deemed necessary, is carried out at each of these. In any case, each one of the multiple production sites shall be checked at least once during the validity of the certificate.

The Annual Inspection Visit shall be made in presence. In extraordinary situation (e.g. health crisis, natural disasters, war, upheaval, etc.) the inspections can be on remote. In case of remote audit IAF MD 4:2018 should be known and considered by the auditors.

3.3 Withdrawal of test pieces for type examination

In the course of annual inspection, the test pieces for complete type examination (every 5th year) or for the reduced testing (in-between years) shall be withdrawn by the conformity assessment body.

3.4 Annual Inspection Report

As a result of the annual inspection a specific Audit report is prepared, specifying recommendations or non-conformities and indicating the adequacy or inadequacy of each applicable item. The manufacturer is given a copy of the Audit Report as a notification of the operation. The Audit Report is countersigned by the manufacturer as acceptance of all issued findings.

4 Unexpected visit

A conformity assessment body may carry out unexpected visits. When an unexpected visit is required it shall be set up and executed by the conformity assessment body separately from and in addition to the regular inspection cycle. The unexpected visit shall be a traceability inspection based on the criteria reported in the check list for Audit Report.

An Inspection Report with findings should be delivered following the Unplanned Inspection Visit.

5 Check List for Audit Report

5.1 Quality Management System

- Verify if the quality management system is applied or if there are valid certificates (e.g. ISO 9001).
- Verify if the internal organizational chart exists.
- Verify if the personnel involved in the production is sufficiently qualified and trained to operate and maintain the production equipment.
- In case of staff alterations since the initial or the last annual visits, verify if the new staff was sufficiently trained.
- Verify if all processes and procedure instructions of the production are recorded and audited at regular intervals and if the results are recorded.
- In case of changes related to the hygienic aspects (see 5.4) in the production process since the initial or the last annual visits, verify if those changes are recorded.
- Verify if the internal audits are carried out regularly.
- For the products to be certified, verify if the manufacturer has a system to document the production process, from purchasing/delivery of the basic materials through to the storage and the delivery of the finished products.
- Verify if complaint management system is maintained and if the appropriate measures to correct non-conformities are being used, documented and controlled.
- Verify if the maintenance of machinery is carried out properly and regularly and if the related maintenance schedule is available.
- Verify if the testing equipment is correctly maintained and calibrated and if the related maintenance schedule is available.
- Verify if any changes have been made concerning machinery, testing equipment and test methods since the initial or the last annual visits, and if the appropriate comparable measurements and controls has been performed and documented.
- Verify if the quality system for production is implemented, documented and regularly revised (representatives, operation procedures etc.)
- Verify the methods of the quality system for production is in accordance with the hygienic requirements.
- The documents shall be saved for at least 10 years after the product has been placed on the market.

5.2 Production Process

- Provide the description of the production process (methods, conditions of the production areas, identification of the production machine, recording of machine parameters, ensuring constant production etc.).
- Verify the critical process parameters (e.g. temperature, pressure of injection moulding, temperature of post-treatment of the metallic materials);

- Verify if the production process changed since the initial or the last annual visits. In positive case, verify if the documentation has been revised accordingly.
- Verify if a purchasing management procedure (list of qualified suppliers, outsourced processes, availability of the conformity documentation from the suppliers, technical references) is available for components, starting substances, pre-products, intermediate products for organic materials, metallic compositions, constituent products for cementitious materials and composition for enamels, ceramics and other inorganic materials used.
- Verify if a design management process is available.
- Verify if the regulatory references relating to the design and hygienic requirements are available and correctly reported.
- Verify the design and technical specifications of the products/product type series subject to certification.
- Verify if the design and/or technical specifications of the products/product type series subject to certification changed since the initial or the last annual visits. In positive case, verify if the documentation has been revised accordingly.
- Verify if the quality control of the incoming material (components, starting substances, pre-products, intermediate products for organic materials, metallic compositions, constituent products for cementitious materials and composition for enamels, ceramics and other inorganic materials) is carried out and if the records of the incoming materials control are available and stored for an appropriate time (e.g. material certificates).
- Verify the storage conditions of the assembled products, components, starting substances, pre-products, intermediate products for organic materials, metallic compositions, constituent products for cementitious materials and composition for enamels, ceramics and other inorganic materials) and if the provisions for shelf life are respected.
- Verify if the procedure of a constant final quality control of the finished products is implemented and documented.
- Verify if a product traceability procedure is available and the level of detail (e.g. components, production phases, final testing).
- Verify if a procedure for the correct packaging and preservation of the assembled products, components, starting substances, pre-products, intermediate products for organic materials, metallic compositions, constituent products for cementitious materials and composition for enamels, ceramics and other inorganic is available and if the technical documentation is provided in the packaging.
- Verify if the content of the EU Declaration of Conformity is correct.
- Verify the possibility of the cross-contamination during all production phases.
- The manufacturer has to provide the list of all materials in contact with drinking water.
- The documents shall be saved for at least 10 years after the product has been placed on the market.

5.3 Example Forms of Check List for Audit Report

Company: _____

Legal Address

Certification Scheme

Product(s) covered

ACTIVITIES CARRIED OUT BY THE AUDIT GROUP					
TYPE OF THE AUDIT	Production Facilities verified	Date	Inspector Name	Duration	SIGNATURE
☐ Initial / Renewal					
☐ Annual (1)					
☐ Annual (2)					
☐ Annual (3)					
☐ Annual (4)					

1. COMPANY'S DATA			
Company Staff	Quality Manager:	Tecnical Manager:	Production Manager:
	N. of employees		
Available Management System Certifications			
Available Product Certifications			

2. QUALITY MANAGEMENT SYSTEM					
Is the quality management system applied by the company. Does the company have valid certificates (e.g. ISO 9001)? In positive case, list the available management system certificates.					
Initial / Renewal		P ☐	NCM ☐	NCm ☐	RAC ☐
Annual (1)		P ☐	NCM ☐	NCm ☐	RAC ☐
Annual (2)		P ☐	NCM ☐	NCm ☐	RAC ☐
Annual (3)		P ☐	NCM ☐	NCm ☐	RAC ☐
Annual (4)		P ☐	NCM ☐	NCm ☐	RAC ☐

☐ **initial inspection of factory**

☐ **continuous surveillance of factory production**

I. General data

Reference number inspection body:	
Certification holder:	
Ordering customer:	
Manufacturer(s):	
Production facility:	
Auditor:	
Participants:	
Date of inspection:	
Date of last inspection:	

II. Product-specific details

Product designation:		
Product's application:		
Model name:		
Distributor:		
Type	Technical specification	Remark
Used raw materials:		

Legend

a) non complaint b) Minor non-compliance c) Significant non-compliance

Questions		**Assesment/ comments**	**Reviewed documents**	**Ass.** ***a, b, c***
1. QS-System ***QS-System***				
1.1	Does the manufacturer still apply a **quality management system**? Is there a valid certificate (e.g. ISO 9001)? In positive case, list all the available system management certificates.			

Annex 6 Migration Flowcharts

Table A6-1: Migration periods of the extended cold water test

Week	Migration period	Total contact time in days	End of the migration period	Contact duration in days per migration	Analyse For organic, cementitious, enamels and ceramics or other inorganic materials
1	0 (pre-treatment)	1	Thursday	1	No
1	1	4	Friday	3	Yes
2	2	7	Monday	3	Yes
2	3	10	Thursday	3	Yes
3	4	14	Monday	4	No
3	5	17	Thursday	3	Yes
4	6	21	Monday	4	No
4	7	24	Thursday	3	Yes
5	8	28	Monday	4	No
5	9	31	Thursday	3	Yes

Table A6-2: Migration periods of the extended warm or hot water test

Week	Migration period	Total contact time in days	End of the migration period	Contact duration in days per migration	Analyse for organics and cementitious materials	Analyse for enamels and ceramics or other inorganic materials
1	0 (pre-treatment)	1	Tuesday	1	No	No
1	1	2	Wednesday	1	Yes	Yes
1	2	3	Thursday	1	No	Yes
1	3	4	Friday	1	No	Yes
2	4	7	Monday	3	No	No
2	5	8	Tuesday	1	No	No
2	6	9	Wednesday	1	Yes	No
2	7	10	Thursday	1	Yes	Yes
2	8	11	Friday	1	No	No
3	9	14	Monday	3	No	No
3	10	15	Tuesday	1	No	No

3	11	16	Wednesday	1	No	No
3	12	17	Thursday	1	Yes	Yes
3	13	18	Friday	1	No	No
4	14	21	Monday	3	No	No
4	15	22	Tuesday	1	No	No
4	16	23	Wednesday	1	No	No
4	17	24	Thursday	1	Yes	Yes
4	18	25	Friday	1	No	No
5	19	28	Monday	3	No	No
5	20	29	Tuesday	1	No	No
5	21	30	Wednesday	1	No	No
5	22	31	Thursday	1	Yes	Yes

Annex 7 Examples for the summation of the wetted surface fraction

Example 1:

Table A7-1 lists as example the wetted surface fractions of the components of an assembled product.

Table A7-1: Components of an assembled products

Part No.	PART	Qty.	MATERIAL	% Wetted surface
1	Body	1	Metal 1	41,0%
2	Slider	1	Plastics 1	0,7%
3	Seal	1	Elastomer 1	0,1%
4	Screen	1	Metal 2	1,5%
5	Control slider	1	Ceramics 1	0,5%
6	Control disc	1	Ceramics 2	1,8%
7	Gasket	1	Elastomer 1	0,7%
8	Bottom	1	Plastics 2	7,0%
9	Seal	2	Elastomer 1	0,0%
10	Seal	1	Elastomer 1	0,3%
11	Adaptor	1	Plastics 3	25,3%
12	Flow regulator	1	Plastics 1	1,6%
13	Slider	1	Plastics 1	1,9%
14	Seal	2	Elastomer 1	1,1%
15	Seal	2	Elastomer 1	0,5%
16	Mousseur	1	Multicomponent	9,2%
17	Water Guide	1	Plastics 1	5,1%
18	Water Guide	1	Plastics 1	1,8%
				100,0%

Table A7-2: Summation of the components made of the same main polymers and the identified risk groups

Material	% Wetted surface	Risk Group
Plastics 1	11,1%	RG 2
Plastics 2	7,0%	RG 3
Plastics 3	25,3%	RG 2
Elastomer 1	4,3%	RG 3

The different types of plastics materials stand for example for POM (polyoxymethylene), PE (polyethylene including crosslinked polyethylene), PA (polyamide), PS (polysulfone), PPE (polyphenyl ether). The different types of elastomers stand for example for EPDM, NBR.

One type of plastics materials is made of the same main polymer. In most cases the manufacturer of the assembled product defines the type of material the different components are made of including the pre-products (granulates) used for the production. There might be alternative manufacturer of the pre-products, so that the formulation is not exactly the same for the components or even for the same component made of one plastics material.

For the determination of the product group and as consequence the risk group the wetted surface fractions of the components made of the same main polymers have to be summed up (see table A7-2).

In this example all components made of plastics 1 have an individual wetted surface below 10%, but in total a wetted surface fraction of 11,1 % is reached, so that the components made of this plastics material have to be classified in Risk Group (RG) 2. For the assessment of these components a conversion factor (CF) of 2 d/dm has to be applied.

For components falling in RG2 the conformity assessment procedure is different from the procedure for RG3. However, in this case as all individual components have a wetted surface fraction below 10% the conformity assessment procedure for RG2 (modules B & D) applies only for the component with the largest wetted surface fraction (here component no. 17). Probably in many cases the components made of the same plastics material (even when used for different assembled products) will be covered by one component certificate. In this case a component certificate issued for RG2 is required and certificates issued for the corresponding pre-product are not sufficient.

For the other components made of plastics materials, no summation of the wetted surface fractions is necessary, as there is only one part for plastics 2 and one for plastics 3. Component no 8 made of plastics 2) with a wetted surface fraction of below 10 % falls ins RG3 and component no 11 made of plastics 3 with a wetted surface fraction of 25,410% falls in RG2.

Besides plastics materials also components made of elastomers are used in this assembled product. All these components are made of elastomer 1 made of the same main polymer. The total wetted surface fraction of all these components is 4,3%. As this is less than 10% all these components are classified in RG3 and a conversion factor of 0,2 d/dm has to be applied for the assessment.

The summation of the fractions of the wetted surfaces also applies for components made of ceramic materials, if they are made of compositions of the same entry of the European positive list of compositions of enamels, ceramic materials and other inorganic materials (e.g. Al_2O_3 and SiO_2 ceramics, hard ferrite ceramics, ZnO_2 ceramics). In the example this is not the case a summation is not required. Component no 5 (wetted surface fraction: 0,5%) is classified in RG3 and component no 6 (wetted surface fraction: 1,8%) in RG2.

If for an assembled component (in the example component no 16) a valid certificate is available specifying the total wetted surface of the complete assembled component and a maximum wetted surface fraction of the assembled component in the final assembled product, then the individual components of the assembled component do not need to be further specified. The wetted surface fraction of the assembled product only has to be less than the maximum wetted surface fraction in the final assembled product as specified in the certificate.

Example 2

For the assessment of metallic components, a summation of the wetted surface fraction is required to check whether the metallic materials are used as accepted. For products used in domestic distribution system only metallic materials accepted in the EU PL for product groups A, B and C can be used. The total surface fraction of the components made of materials accepted for product group C has to be less than 10% of the wetted surface of the assembled product. For the assembled product A (see table A7-3) this would be the case, whereas for the assembled product B (see table A7-4) this would not be the case. As a consequence, assembled product B does not comply with the requirements and can’t be certified.

Table A7-3: Wetted surface fractions of metallic components of assembled product A

Material	Accepeted Product Group	Wetted surface fraction
Metal 1	B	41%
Metal 2	B	4%
Metal 3	C	3%
Metal 4	C	2%

passed

Table A7-4 Wetted surface fractions of metallic components of assembled product B

Material	Accepeted Product Group	Wetted surface fraction
Metal 1	B	41%
Metal 2	B	4%
Metal 3	C	3%
Metal 4	C	8%

failed

Annex 8 Template of product certificates

Certificate

[Certificate No.]

of conformity with the minimum hygiene requirements for materials in contact with drinking water of a product according to CDR (EU) 2024/370

Conformity assessment procedure	☐ Module B (type examination) and Module D (Conformity to type based on quality assurance of the production process) according to Decision No 768/2008/EC ☐ Module B (type examination) according to Decision No 768/2008/EC

Certificate owner	*[name, address]*
Manufacturing site(s)	
Designation of the product(s)	*[trade name and/or article name, article number and dimension (ID) if applicable;* *if the certificate is issued for a product type series all covered products have to be specified -if necessary as a separate list of the certificate]*
Product type	*[Examples: single-layer/multilayer pipe/hose, fitting, pump, storage tank, storage water heater, shutoff valve, filter cartridge, water meter, lubricant]*
Product group and applied conversion factor	*[according to CID (EU) 2024/368 Annex I Table 5,* *Example: Pipes and pipe linings ID < 80 mm CF: 20 d/dm* *For products made only of metallic materials the conversion factor has not to be specified]*
Regulatory document(s)	CID (EU) 2024/368
Temperature range	☐ cold water 23 °C ☐ warm water 60 °C ☐ hot water 85 °C
Further restrictions	*[if applicable, e.g. outside domestic distribution system only]*

Please observe the legal notes on the following pages.

Period of validity	
Date & signature	

Annex 9 Template of component certificates

Certificate

[Certificate No.]

of conformity with the minimum hygiene requirements for materials in contact with drinking water of a component according to CDR (EU) 2024/370

Conformity assessment procedure	☐ Module B (type examination) and Module D (Conformity to type based on quality assurance of the production process) according to Decision No 768/2008/EC) ☐ Module B (type examination) according to Decision No 768/2008/EC

Certificate owner	*[name, address]*
Manufacturing site(s)	
Designation of the component(s)	*[trade name and/or article name, article number and dimension (ID) if applicable;* *if the certificate is issued for a product type series all covered components have to be specified -if necessary as a separate list of the certificate]*
Type of component(s)	*[Examples: pipe fitting; seal ring; cartridge; valve; penstock; filter module; valve for taps]*
Product group and applied conversion factor	*[according to CID (EU) 2024/368 Annex I Table 5,* *Example: Components of fitting, ancillaries for pipes ID < 80 mm CF: 0,2 d/dm* *For components made only of metallic materials the conversion factor has not to be specified]*
Regulatory document(s)	CID (EU) 2024/368
Wetted surface of the component	XXXX cm^2
Max. wetted surface fraction in final assembled product	XX,X %
Temperature range	☐ cold water 23 °C ☐ warm water 60 °C ☐ hot water 85 °C
Further restrictions	*[if applicable, e.g. outside domestic distribution system only]*

Please observe the legal notes on the following pages.

Period of validity	
Date & signature	

Annex 10 Template of pre-product certificates

Certificate

[Certificate No.]

of a pre-product

as a pre-assessment for issuing certificates of conformity with the minimum hygiene requirements for materials in contact with drinking water of products according to CDR (EU) 2024/370

This certificate confirms that a formulation review was completed, and it is based on the assessment of test samples made of final material prepared from the pre-product. The testing and assessment were performed for all parameters according to CID (EU) 2024/368. This certificate can be used for the conformity assessment of products in contact with drinking water according to CDR (EU) 2024/370 and reduces the testing requirements depending on the risk group of the products. The herewith certified pre-product is not a final material in contact with drinking water and the pre-product must not be marked according to CDR (EU) 2024/371.

Conformity assessment procedure	Module B (type examination) according to Decision No 768/2008/EC incl. supervised withdrawal of test specimen(s)

Certificate owner	*[name, address]*
Manufacturing site(s)	
Designation of the pre-product	*[trade name and/or article name and article number if applicable]*
Type and application of the pre-product	*[e.g. granulate for manufacture of …]*
Processing conditions covered	*[e.g. injection moulding; compression moulding; extrusion and reference to the specifications of the manufacturer of the pre-product – the certificate might not cover all processing conditions as declared by the manufacturer in the specification]*
Product group and conversion factor of final product(s)	*[according to CID (EU) 2024/368 Annex I Table 5,* *Example: Pipes and pipe linings ID < 80 mm CF: 20 d/dm]*
Regulatory document(s)	CID (EU) 2024/368
Temperature range	☐ cold water 23 °C ☐ warm water 60 °C ☐ hot water 85 °C
Further restrictions	

Please observe the legal notes on the following pages.

Period of validity	
Date & signature	

Annex 11 Template of intermediate product certificates

Certificate

[Certificate No.]

of an intermediate product

as a pre-assessment for issuing certificates of conformity with the minimum hygiene requirements for materials in contact with drinking water of products according to CDR (EU) 2024/370

This certificate confirms that a formulation review was completed, and it is based on the assessment of test samples made of final material prepared from the intermediate product. The testing and assessment were performed for all parameters according to CID (EU) 2024/368. This certificate can be used for the conformity assessment of products in contact with drinking water according to CDR (EU) 2024/370 and reduces the testing requirements depending on the risk group of the products. The herewith certified intermediate product is not a final material in contact with drinking water and the intermediate product must not be marked according to CDR (EU) 2024/371.

Conformity assessment procedure	Module B (type examination) according to Decision No 768/2008/EC incl. supervised withdrawal of test specimen(s)

Certificate owner	*[name, address]*
Manufacturing site(s)	
Designation of the intermediate product	*[trade name and/or article name and article number if applicable]*
Type and application of the intermediate product	*[e.g. coating system for factory-made (automated) linings of containers; coating system for on-site (manual) pipe relining and repair purposes; non-crosslinked elastomer compound; adhesive agent; …]*
Processing conditions covered	*[adherence to processing conditions as specified by the manufacturer of the intermediate product is required, see accessory documentation "…"]*
Product group and conversion factor of final product(s)	*[according to CID (EU) 2024/368 Annex I Table 5,* *Example: Coating systems for storage systems (reservoirs),* *water volume ≥ 10 l, CF: 2 d/dm]*
Regulatory document(s)	CID (EU) 2024/368
Temperature range	☐ cold water 23 °C ☐ warm water 60 °C ☐ hot water 85 °C
Further restrictions	*[e.g. not for on-site application; for factory-applied coating processes only; on-site relining of domestic installations must obey to national regulations; max. temperature for chlorinated water … °C]*

Please observe the legal notes on the following pages.

Period of validity	
Date & signature	

Annex 12 Template of constituent product certificates

Certificate

[Certificate No.]

of a constituent product for cementitious materials

as an assessment or a pre-assessment for issuing certificates of conformity with the minimum hygiene requirements for materials in contact with drinking water of products according to CDR (EU) 2024/370

This certificate confirms that a formulation review was completed, and it is based on the assessment of test samples made of final material prepared from the constituent product. The testing and assessment were performed for all parameters according to CID (EU) 2024/368. This certificate can be used for the conformity assessment of in-situ made products or for the pre-assessment of factory-made products or ready-to-use products. The herewith certified constituent product is not a final material in contact with drinking water and the constituent product must not be marked according to CDR (EU) 2024/371.

Conformity assessment procedure	Module B (type examination) according to Decision No 768/2008/EC incl. supervised withdrawal of test specimen(s)

Certificate owner	*[name, address]*
Manufacturing site(s)	
Designation of the constituent product	*[trade name and/or constituent product name and constituent product number if applicable]*
Type of the constituent product	*[e.g. cement, inorganic addition, aggregate, organic addition, admixture (including type as retarder), fibre, formwork release agent, curing compound]*
Processing conditions covered	*[adherence to processing conditions as specified by the manufacturer of the constituent product is required, see accessory documentation "…"]*
For constituent other than cement: Max. dosage related to the cement content	*[X.X]* %
Product group and conversion factor of final product(s)	*[according to CID (EU) 2024/368 Annex I Table 5,* *Example: constituent product used for the production of the final material which is a storage systems (reservoirs), water volume ≥ 10 l, CF: 2 d/dm*
Regulatory document(s)	CID (EU) 2024/368
Temperature range	☐ cold water 23 °C ☐ warm water 60 °C ☐ hot water 85 °C
Further restrictions	

Please observe the legal notes on the following pages.

Period of validity	
Date & signature	

Annex 13 Template of formulation certificates

Certificate

[Certificate No.]

of a formulation of a [product / pre-product /intermediate product] made of organic materials

as a pre-assessment for issuing certificates of conformity with the minimum hygiene requirements for materials in contact with drinking water of products according to CDR (EU) 2024/370

This certificate confirms that a formulation review was completed. The formulation review only serves to identify relevant substances and parameters to be determined in migration waters. This certificate does not give any indication whether the respective product follows the minimum hygiene requirements according to CID (EU) 2024/368.

Certificate owner	*[name, address]*
Manufacturing site(s)	
Designation of the product for which the formulation has been assessed	*[trade name and/or article name and article number if applicable]*
Type of product incl. intended use	*[e.g. additive used as colourant or filler; resin/hardening agent for coatings; glass fibres incl. PPA; peroxidic crosslinking agents, initiator agent; stabiliser mixture; granulate for plastics]*
Formulation was assessment for:	
Product group and conversion factor of final product(s)	*[according to CID (EU) 2024/368 Annex I Table 5, Example: Pipes and pipe linings ID < 80 mm CF: 20 d/dm]*
Max. dosage in final product	*[X.X]* %
Positive list	CID (EU) 2024/367 Annex I *[date]*

The issuing conformity assessment body will provide another conformity assessment body [the number of relevant substances / the identity of the substances] to be determined in migration waters and the extent of exhaustion of the allowed limit of 0.1 % for totalled minor substances on request.

Please observe the legal notes on the following pages.

Period of validity	
Signature field	

Annex 14 Template of an Annex for pre-product certificates indicating the coverage of the certificate

The certificates of pre-products can be used as a pre-assessment for the assessment of products or components made of the final material. The issued certificates for pre products should include the following annex to facilitate the use of the certificate. The first table is the template followed by two tables for examples. The examples demonstrate how the template should be completed for the individual certificates.

Template of an Annex for pre-product certificates indicating the coverage of the certificate

Product group	CF in d/dm	Risk Group	Formu-lation	Max T. in °C	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG
A1: Pipes and pipe linings with an inner diameter < 80 mm	**20**	**RG1**	**(√)**	**(23/ 60/ 85)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	**10**			**(23/ 60/ 85)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**	**(√)**
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	**5**			**(23/ 60/ 85)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**	**(√)**
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	**4**			**(23/ 60/ 85)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**	**(√)**
B1: Fittings and ancillaries of product group A1	**2**	**RG2**	**(√)**	**(23/ 60/ 85)**	**(√)**	**(√)**	**(P* / C*)**	**(P* / C*)**	**(√)**
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	**2**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(P* / C*)**	**(P* / C*)**	**(√)**
B2: Fittings and ancillaries of product group A2	**1**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(P* / C*)**	**(P* / C*)**	**(√)**
E3: Storage systems (reservoirs) in water supply	**1**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(P* / C*)**	**(P* / C*)**	**(√)**
B3: Fittings and ancillaries of product group A3	**0,5**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(P* / C*)**	**(P* / C*)**	**(√)**
F1: Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,4**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(P* / C*)**	**(P* / C*)**	**(√)**
C1: Components of fittings and ancillaries of product group B1	**0,2**	**RG3**	**(√)**	**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
F2: Components of storage systems in domestic installations, buildings (water volume ≥ 10 l)	**0,2**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
C2: Components of fittings and ancillaries of product group B2	**0,1**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
F3: Components of storage systems in water supply	**0,1**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
C3: Components of fittings and ancillaries of product group B3	**0,05**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
G1: Small Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,04**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
D1: Small Components of fittings and ancillaries of product group B1	**0,02**	**RG4**	**n.r.**	**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**
G2: Small Components of storage systems in domestic installations and buildings (water volume ≥ 10 l)	**0,02**			**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**
D2: Small Components of fittings and ancillaries of product group B2	**0,01**			**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**
G3: Small Components storage systems in water supply	**0,01**			**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**
D3: Small Components of fittings and ancillaries of product group B3	**0,005**			**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**

( ) Possible entry depending on the certificate – rows have to be completely filled or remain empty **√** covered n.r. not required

P* test sample complied with requirements, but additional final product test required P*/C* test sample complied with the requirements, but additional final product or component test required

Example of an Annex of a pre-product certificate issued for a pre-product covering product group B1 for cold and warm water application

Product group	CF in d/dm	Risk Group	Formu-lation	Max T. in °C	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG
A1: Pipes and pipe linings with an inner diameter < 80 mm	**20**	**RG1**							
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	**10**								
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	**5**								
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	**4**								
B1: Fittings and ancillaries of product group A1	**2**	**RG2**	**√**	**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	**2**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
B2: Fittings and ancillaries of product group A2	**1**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
E3: Storage systems (reservoirs) in water supply	**1**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
B3: Fittings and ancillaries of product group A3	**0,5**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
F1: Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,4**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
C1: Components of fittings and ancillaries of product group B1	**0,2**	**RG3**	**√**	**60**	**√**	**√**	**√**	**√**	**√**
F2: Components of storage systems in domestic installations, buildings (water volume ≥ 10 l)	**0,2**			**60**	**√**	**√**	**√**	**√**	**√**
C2: Components of fittings and ancillaries of product group B2	**0,1**			**60**	**√**	**√**	**√**	**√**	**√**
F3: Components of storage systems in water supply	**0,1**			**60**	**√**	**√**	**√**	**√**	**√**
C3: Components of fittings and ancillaries of product group B3	**0,05**			**60**	**√**	**√**	**√**	**√**	**√**
G1: Small Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,04**			**60**	**√**	**√**	**√**	**√**	**√**
D1: Small Components of fittings and ancillaries of product group B1	**0,02**	**RG4**	**n.r.**	**60**	**n.r.**	**√**	**√**	**√**	**√**
G2: Small Components of storage systems in domestic installations and buildings (water volume ≥ 10 l)	**0,02**			**60**	**n.r.**	**√**	**√**	**√**	**√**
D2: Small Components of fittings and ancillaries of product group B2	**0,01**			**60**	**n.r.**	**√**	**√**	**√**	**√**
G3: Small Components storage systems in water supply	**0,01**			**60**	**n.r.**	**√**	**√**	**√**	**√**
D3: Small Components of fittings and ancillaries of product group B3	**0,005**			**60**	**n.r.**	**√**	**√**	**√**	**√**

√ covered n.r. not required

P* test sample complied with requirements, but additional final product test required P*/C* test sample complied with the requirements, but additional final product or component test required

Example of an Annex of a pre-product certificate issued for a pre-product covering product group A1 for cold water application

Product group	CF in d/dm	Risk Group	Formu-lation	Max T. in °C	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG
A1: Pipes and pipe linings with an inner diameter < 80 mm	**20**	**RG1**	**√**	**23**	**P***	**P***	**P***	**P***	**P***
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	**10**			**23**	**P***	**P***	**P***	**P***	**√**
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	**5**			**23**	**P***	**P***	**P***	**P***	**√**
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	**4**			**23**	**P***	**P***	**P***	**P***	**√**
B1: Fittings and ancillaries of product group A1	**2**	**RG2**	**√**	**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	**2**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
B2: Fittings and ancillaries of product group A2	**1**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
E3: Storage systems (reservoirs) in water supply	**1**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
B3: Fittings and ancillaries of product group A3	**0,5**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
F1: Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,4**			**60**	**√**	**√**	**P* / C***	**P* / C***	**√**
C1: Components of fittings and ancillaries of product group B1	**0,2**	**RG3**	**√**	**60**	**√**	**√**	**√**	**√**	**√**
F2: Components of storage systems in domestic installations, buildings (water volume ≥ 10 l)	**0,2**			**60**	**√**	**√**	**√**	**√**	**√**
C2: Components of fittings and ancillaries of product group B2	**0,1**			**60**	**√**	**√**	**√**	**√**	**√**
F3: Components of storage systems in water supply	**0,1**			**60**	**√**	**√**	**√**	**√**	**√**
C3: Components of fittings and ancillaries of product group B3	**0,05**			**60**	**√**	**√**	**√**	**√**	**√**
G1: Small Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,04**			**60**	**√**	**√**	**√**	**√**	**√**
D1: Small Components of fittings and ancillaries of product group B1	**0,02**	**RG4**	**n.r.**	**60**	**n.r.**	**√**	**√**	**√**	**√**
G2: Small Components of storage systems in domestic installations and buildings (water volume ≥ 10 l)	**0,02**			**60**	**n.r.**	**√**	**√**	**√**	**√**
D2: Small Components of fittings and ancillaries of product group B2	**0,01**			**60**	**n.r.**	**√**	**√**	**√**	**√**
G3: Small Components storage systems in water supply	**0,01**			**60**	**n.r.**	**√**	**√**	**√**	**√**
D3: Small Components of fittings and ancillaries of product group B3	**0,005**			**60**	**n.r.**	**√**	**√**	**√**	**√**

√ covered n.r. not required

P* test sample complied with requirements, but additional final product test required P*/C* test sample complied with the requirements, but additional final product or component test required

Annex 15 Template of an Annex for intermediate product certificates indicating the coverage of the certificate

The certificates of intermediate products can be used as a pre-assessment for the assessment of products or components made of the final material. The issued certificates for intermediate products should include the following annex to facilitate the use of the certificate. The first table is the template followed by a table for an example. The example demonstrates how the template should be completed for the individual certificates.

Template of an Annex for intermediate product certificates indicating the coverage of the certificate

Product group	CF in d/dm	Risk Group	Formu-lation	Max T. in °C	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG
A1: Pipes and pipe linings with an inner diameter < 80 mm	**20**	**RG1**	**(√)**	**(23/ 60/ 85)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	**10**			**(23/ 60/ 85)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**	**(√)**
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	**5**			**(23/ 60/ 85)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**	**(√)**
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	**4**			**(23/ 60/ 85)**	**(P*)**	**(P*)**	**(P*)**	**(P*)**	**(√)**
B1: Fittings and ancillaries of product group A1	**2**	**RG2**	**(√)**	**(23/ 60/ 85)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(√)**
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	**2**			**(23/ 60/ 85)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(√)**
B2: Fittings and ancillaries of product group A2	**1**			**(23/ 60/ 85)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(√)**
E3: Storage systems (reservoirs) in water supply	**1**			**(23/ 60/ 85)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(√)**
B3: Fittings and ancillaries of product group A3	**0,5**			**(23/ 60/ 85)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(√)**
F1: Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,4**			**(23/ 60/ 85)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(P* / C*)**	**(√)**
C1: Components of fittings and ancillaries of product group B1	**0,2**	**RG3**	**(√)**	**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
F2: Components of storage systems in domestic installations, buildings (water volume ≥ 10 l)	**0,2**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
C2: Components of fittings and ancillaries of product group B2	**0,1**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
F3: Components of storage systems in water supply	**0,1**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
C3: Components of fittings and ancillaries of product group B3	**0,05**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
G1: Small Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,04**			**(23/ 60/ 85)**	**(√)**	**(√)**	**(√)**	**(√)**	**(√)**
D1: Small Components of fittings and ancillaries of product group B1	**0,02**	**RG4**	**n.r.**	**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**
G2: Small Components of storage systems in domestic installations and buildings (water volume ≥ 10 l)	**0,02**			**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**
D2: Small Components of fittings and ancillaries of product group B2	**0,01**			**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**
G3: Small Components storage systems in water supply	**0,01**			**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**
D3: Small Components of fittings and ancillaries of product group B3	**0,005**			**(23/ 60/ 85)**	**n.r.**	**(√)**	**(√)**	**(√)**	**(√)**

( ) Possible entry depending on the certificate – rows have to be completely filled or remain empty **√** covered n.r. not required

P* test sample complied with requirements, but additional final product test required P*/C* test sample complied with the requirements, but additional final product or component test required

Example of an Annex of an intermediate product certificate issued for an intermediate product covering product group F3 for cold and warm water application

Product group	CF in d/dm	Risk Group	Formu-lation	Max T. in °C	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG
A1: Pipes and pipe linings with an inner diameter < 80 mm	**20**	**RG1**							
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	**10**								
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	**5**								
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	**4**								
B1: Fittings and ancillaries of product group A1	**2**	**RG2**							
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	**2**								
B2: Fittings and ancillaries of product group A2	**1**								
E3: Storage systems (reservoirs) in water supply	**1**								
B3: Fittings and ancillaries of product group A3	**0,5**								
F1: Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,4**								
C1: Components of fittings and ancillaries of product group B1	**0,2**	**RG3**	**√**						
F2: Components of storage systems in domestic installations, buildings (water volume ≥ 10 l)	**0,2**								
C2: Components of fittings and ancillaries of product group B2	**0,1**			**23**	**√**	**√**	**√**	**√**	**√**
F3: Components of storage systems in water supply	**0,1**			**23**	**√**	**√**	**√**	**√**	**√**
C3: Components of fittings and ancillaries of product group B3	**0,05**			**23**	**√**	**√**	**√**	**√**	**√**
G1: Small Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,04**			**23**	**√**	**√**	**√**	**√**	**√**
D1: Small Components of fittings and ancillaries of product group B1	**0,02**	**RG4**	**n.r.**	**23**	**n.r.**	**√**	**√**	**√**	**√**
G2: Small Components of storage systems in domestic installations and buildings (water volume ≥ 10 l)	**0,02**			**23**	**n.r.**	**√**	**√**	**√**	**√**
D2: Small Components of fittings and ancillaries of product group B2	**0,01**			**23**	**n.r.**	**√**	**√**	**√**	**√**
G3: Small Components storage systems in water supply	**0,01**			**23**	**n.r.**	**√**	**√**	**√**	**√**
D3: Small Components of fittings and ancillaries of product group B3	**0,005**			**23**	**n.r.**	**√**	**√**	**√**	**√**

√ covered n.r. not required

P* test sample complied with requirements, but additional final product test required P*/C* test sample complied with the requirements, but additional final product or component test required

Annex 16 Template of an Annex for constituent product certificates indicating the coverage of the certificate

The certificates of constituent products can be used as a pre-assessment for the assessment of products or components made of the final material. The issued certificates for constituent products should include the following annex to facilitate the use of the certificate. The first table is the template followed by a table for an example. The example demonstrates how the template should be completed for the individual certificates.

Template of an Annex for constituent product certificates indicating the coverage of the certificate

Product group	CF in d/dm	Risk Group	Formu-lation	Max T. in °C	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG
A1: Pipes and pipe linings with an inner diameter < 80 mm	**20**	**RG1**	**(√)**	**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	**10**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	**5**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	**4**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
B1: Fittings and ancillaries of product group A1	**2**	**RG2**	**(√)**	**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	**2**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
B2: Fittings and ancillaries of product group A2	**1**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
E3: Storage systems (reservoirs) in water supply	**1**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
B3: Fittings and ancillaries of product group A3	**0,5**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
F1: Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,4**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
C1: Components of fittings and ancillaries of product group B1	**0,2**	**RG3**	**(√)**	**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
F2: Components of storage systems in domestic installations, buildings (water volume ≥ 10 l)	**0,2**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
C2: Components of fittings and ancillaries of product group B2	**0,1**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
F3: Components of storage systems in water supply	**0,1**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
C3: Components of fittings and ancillaries of product group B3	**0,05**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
G1: Small Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,04**			**(23/ 60/ 85)**	**(√)**	**(√/ n.r. [1])**	**(√)**	**(√)**	**(√/ n.r. [1])**
D1: Small Components of fittings and ancillaries of product group B1	**0,02**	**RG4**	**n.r.**	**(23/ 60/ 85)**	**n.r.**	**n.r.**	**(√)**	**(√)**	**(√/ n.r. [1])**
G2: Small Components of storage systems in domestic installations and buildings (water volume ≥ 10 l)	**0,02**			**(23/ 60/ 85)**	**n.r.**	**n.r.**	**(√)**	**(√)**	**(√/ n.r. [1])**
D2: Small Components of fittings and ancillaries of product group B2	**0,01**			**(23/ 60/ 85)**	**n.r.**	**n.r.**	**(√)**	**(√)**	**(√/ n.r. [1])**
G3: Small Components storage systems in water supply	**0,01**			**(23/ 60/ 85)**	**n.r.**	**n.r.**	**(√)**	**(√)**	**(√/ n.r. [1])**
D3: Small Components of fittings and ancillaries of product group B3	**0,005**			**(23/ 60/ 85)**	**n.r.**	**n.r.**	**(√)**	**(√)**	**(√/ n.r. [1])**

( ) Possible entry depending on the certificate – rows have to be completely filled or remain empty **√** covered n.r. not required

P* test sample complied with requirements, but additional final product test required P*/C* test sample complied with the requirements, but additional final product or component test required

Example of an Annex of a constituent product certificate issued for a constituent product covering product group E1 for cold water application

Product group	CF in d/dm	Risk Group	Formu-lation	Max T. in °C	Relevant substances	Screening for unexpected substances	TOC	TON, TFN, colour, turbidity	EMG
A1: Pipes and pipe linings with an inner diameter < 80 mm	**20**	**RG1**	**√**	**23**					
A2: Pipes and pipe linings with an inner diameter ≥ 80 mm and < 300 mm	**10**			**23**					
A3: Pipes and pipe linings with an inner diameter ≥ 300 mm	**5**			**23**					
E1: Storage systems (reservoirs) in domestic installations and buildings (water volume < 10 l)	**4**			**23**	**√**	**√**	**√**	**√**	**√**
B1: Fittings and ancillaries of product group A1	**2**	**RG2**	**√**	**60**	**√**	**√**	**√**	**√**	**√**
E2: Storage systems (reservoirs) in domestic installations and buildings (water volume ≥ 10 l)	**2**			**60**	**√**	**√**	**√**	**√**	**√**
B2: Fittings and ancillaries of product group A2	**1**			**60**	**√**	**√**	**√**	**√**	**√**
E3: Storage systems (reservoirs) in water supply	**1**			**60**	**√**	**√**	**√**	**√**	**√**
B3: Fittings and ancillaries of product group A3	**0,5**			**60**	**√**	**√**	**√**	**√**	**√**
F1: Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,4**			**60**	**√**	**√**	**√**	**√**	**√**
C1: Components of fittings and ancillaries of product group B1	**0,2**	**RG3**	**√**	**60**	**√**	**√**	**√**	**√**	**√**
F2: Components of storage systems in domestic installations, buildings (water volume ≥ 10 l)	**0,2**			**60**	**√**	**√**	**√**	**√**	**√**
C2: Components of fittings and ancillaries of product group B2	**0,1**			**60**	**√**	**√**	**√**	**√**	**√**
F3: Components of storage systems in water supply	**0,1**			**60**	**√**	**√**	**√**	**√**	**√**
C3: Components of fittings and ancillaries of product group B3	**0,05**			**60**	**√**	**√**	**√**	**√**	**√**
G1: Small Components of storage systems in domestic installations and buildings (water volume < 10 l)	**0,04**			**60**	**√**	**√**	**√**	**√**	**√**
D1: Small Components of fittings and ancillaries of product group B1	**0,02**	**RG4**	**n.r.**	**60**	**n.r.**	**n.r.**	**√**	**√**	**√**
G2: Small Components of storage systems in domestic installations and buildings (water volume ≥ 10 l)	**0,02**			**60**	**n.r.**	**n.r.**	**√**	**√**	**√**
D2: Small Components of fittings and ancillaries of product group B2	**0,01**			**60**	**n.r.**	**n.r.**	**√**	**√**	**√**
G3: Small Components storage systems in water supply	**0,01**			**60**	**n.r.**	**n.r.**	**√**	**√**	**√**
D3: Small Components of fittings and ancillaries of product group B3	**0,005**			**60**	**n.r.**	**n.r.**	**√**	**√**	**√**

√ covered n.r. not required

P* test sample complied with requirements, but additional final product test required P*/C* test sample complied with the requirements, but additional final product or component test required