Certification and approval of products in contact with drinking water

4MSI Draft Common Approach

France, Germany, the Netherlands, United Kingdom and Denmark work together in the framework of the 4MSI Common Approach as laid down in the Declaration of Intent (January 2011). This common approach aims for convergence of the respective national approval schemes for materials and products in contact with drinking water.

The 4MSI presents this document as a starting document for a common basis for implementing the concept of certification and approval of products in their national regulations. The document is subject to revisions agreed by the 4MSI.

Further information may be obtained from any of the competent authorities of the 4MSI.

Bundesministerium für Gesundheit (Germany)
Ministère en charge de la Santé (France)
Ministerie van Infrastructuur en Waterstaat (The Netherlands)
Department for Environment, Food and Rural Affairs (United Kingdom)
Miljø- og Fødevareministeriet, and Trafik-, Bygge- og Boligstyrelsen (Denmark)

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Introduction

This document describes the requirements for issuing a certificate or approval for the acceptance of products in contact with drinking water (PDW) in respect to their effect on water quality.
It has been prepared in accordance with the 4MSI agreement on co-operation concerning convergence and mutual recognition as laid down in the Declaration of Intent (January 2011).

The members of 4MSI present this draft document for discussion with stakeholders and for a common basis for implementing the concept of certification and approval of drinking water products in their national regulations. The document provides a starting point for the assessment of products, including specifications for dealing with assembled products and a risk based approach for minor components and products.
A decision on the complete set of requirements has not yet been made, and therefore no fully agreed Common Approach is available. It is intended to complete this following discussion with stakeholders. Specifically, the following items are still under discussion within the 4MSI and may lead to revision of the document:

- Requirements to be set for certification, inspection and testing bodies (section 3.2)
- Impact of the certification and approval system on the market
- The division of products into risk groups as given in Annex C

The publication of this draft document is aimed to invite stakeholders to review the content of the document and provide feedback to the 4MSI on its clarity, applicability and impact.

Furthermore, this draft document and its final version will be made available to:

- the European Commission as information relevant to the work ongoing under the Drinking Water Directive and Construction Products Directive to harmonize notified national regulation for the approval of products in contact with drinking water;

- other Member States to inform them of the actions of the 4MSI to regulate materials and products with respect to the certification and approval of products in contact with drinking water under Article 10 of the Council Directive 98/83/EC on the Quality of Water Intended for Human Consumption (DWD).

The 4MSI would be happy to share their experience and practical knowledge in the hope that it will help to promote a wider, harmonized approach to the certification and approval of products in contact with drinking water.

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1. Background

To be added

2. Definitions

The relevant definitions, many taken from other documents, that are used in this document are given below for reference.

2.1 Definitions taken from 4MSI Common Approach Positive List for Organic Materials

2.1.1 Component

A part manufactured out of a specific composition, brought to the market as a product, part of an assembled product, or as a spare part. For drinking water applications, components may be considered as products and be individually approved (e.g. o-ring, gasket) or they are tested in the finished product (e.g. in a valve).

2.1.2 Composition

The constituents found within a material or product.

2.1.3 Product

Clearly identified manufactured item, in its finished form, that comes into contact with water intended for human consumption, or a component part of a manufactured item. A product can be homogeneous, non-homogeneous or may also consist of multiple components made out of one single or different compositions (e.g. a valve). A homogeneous product is a product where the water contact surface is made from the same material as the remainder of the product (e.g. a solid wall pipe), whereas a non-homogeneous product is a product where the water contact surface is made from a material that differs from those comprising the remainder of the product (e.g. multilayered pipes).

2.1.4 Assembled products

These products comprise two or more components, possibly of different materials.

2.2 Definitions taken from the CPR (Regulation (EU) No 305/2011)

2.2.1 factory production control

means the documented, permanent and internal control of production in a factory, in accordance with the relevant harmonised technical specifications;

2.2.2 'economic operator'

means the manufacturer, importer, distributor or authorised representative;

2.2.3 'manufacturer'

means any natural or legal person who manufactures a construction product[1] or who has such a product designed or manufactured, and markets that product under his name or trademark;

2.2.4 'distributor'

means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a construction product[1] available on the market;

2.2.5 'importer'

means any natural or legal person established within the Union, who places a construction product[1] from a third country on the Union market;

[1] This document applies to a broader scope than the CPR: it applies to all 'material based products' that come into contact with water intended for human consumption but not to (treatment) chemicals.

2.3 Definitions taken from Regulation (EC) No 765/2008

2.3.1 'accreditation'

shall mean 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;

2.3.2 'conformity assessment'

shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

2.4 Other definitions

2.4.1 Product family

To be added

3. Common approach certification / approval

3.1 General

This common approach gives the procedures and requirements for the assessment of products in contact with drinking water in respect to their effect on water quality. It should be used as the starting point of the assessment, certification or approval of a product. For material specific requirements, it refers to the separate Common Approaches on the materials.

As in the material specific Common Approaches, products with a reduced potential effect on the water quality, are assessed to a reduced set of requirements. The list of products with the respective grouping (RG1 – RG5), is given in this document (see Annex C) and is also used by the material specific common approaches. The same is true for the list of conversion factors (see Annex A)

3.2 Involved parties

3.2.1 General

In the assessment, approval and certification of products in contact with drinking water, several parties are involved. These are

- The economic operators
- Certification bodies
- Inspection bodies
- Test laboratories

The certification bodies, inspection bodies and test laboratories are independent third parties and must comply with specific requirements to be allowed to perform the tasks as set out in this Common Approach. In the following sections these requirements are given.

3.2.2 Requirements for Certification bodies

To be added

Items under consideration:

- Accreditation according to ISO 17065 in the relevant area
- Notification
- Confidentiality
-

3.2.3 Requirements for Inspection bodies

To be added

Items under consideration:

- Accreditation according to ISO 17020 in the relevant area
- Notification
-

3.2.4 Requirements for Test laboratories

To be added

Items under consideration:

- Accreditation according to ISO 17025 in the relevant area
- Notification
- Accreditation scope covers relevant methods required (e.g. EN 12873, EN 15768…)
- Participation in relevant inter-laboratory trials
- Participation in relevant proficiency testing scheme (e.g. Aquacheck 22 for GCMS)
- Confidentiality
-

3.3 Tasks for certification / approval

3.3.1 General

Certification / approval of products in contact with drinking water is based on the following tasks:

- Operate Factory Production Control (FPC) system
- Initial and verification sampling
- Initial and verification auditing
- Initial and verification testing
- Hygienic production testing
- Certification / approval

Depending on the risk group, these tasks need to be performed by a third party, by the economic operator or not at all. These details are given in section 3.4. In the paragraphs below, the different tasks are described in more detail. As many of the tasks are governed by other documents, such as the ISO standards 17020, 17025 and 17065, not all relevant details are given.

3.3.2 Operate FPC

FPC stands for Factory Production Control and is the tool for ensuring that products are manufactured with a constant quality and compliance with requirements.

3.3.3 Initial and verification sampling

Sampling means the selection of one or more (parts of) products which are to be subjected to (laboratory) tests. Aim of sampling is to obtain a sample that is representative of the product as it enters the market. Factors such as product homogeneity and tampering potential need to be taken into account. If a (laboratory) test is necessary, these sampling requirements apply.

3.3.4 Initial and verification auditing

Auditing means checking at a production location whether continuous product quality and compliance are ensured. This contains many aspects, from control of incoming goods, to production control and management systems. It can be required initially, before product approval or certification is issued, or regularly during the lifetime of the approval or certification.

3.3.5 Initial and verification testing

Testing refers to any test performed on a product (or any part or formulation) to determine a certain characteristic. It is often performed by a laboratory. It can be required initially, before product approval or certification is issued, or regularly during the lifetime of the approval or certification. Whether testing is necessary and which test should be performed, depends both on the composition of the product and the group the product falls in. These details are given in the material specific Common Approaches.

3.3.6 Hygienic production testing

Hygienic production testing means performing a test as part of the production control by the manufacturer of the product. It is not used to show compliance with the test requirements but as a routine check of the manufacturing process.

3.3.7 Certification / approval

Certification / approval refers to the conclusion that a product complies with a certain set of requirements. Approval means a conclusion that a product complies.
With certification, this conclusion is made by an independent body – a Certification Body – and is maintained and controlled by this body. As long as the certificate is valid, the product is considered approved.

3.4 Requirements for approval / certification of products

3.4.1 General

Below and in Annex B a table is given that summarises the requirements for approval / certification of products in contact with drinking water. The table is comprised of rows with risk groups RG1 – RG5 and columns with the certification / approval tasks. For each risk group, each certification / approval task is detailed. In the sections below, this is elaborated into more detail.

Risk based testing program for (assembled) products - Certification requirements											
Risk group*	**Conversion factor***	**Operate FPC**	**Hygienic production testing**	**Certification**	**Sampling**	**Initial testing****	**Verification testing (material specific)**			**Initial audit**	**Verification audit**
							Organic	**Metal**	**Cementitious**		
RG1	≥ 4	yes	TON	Certification	Yes initial and regular by third party	Yes by third party	TOC and organoleptics yearly; specifics, EMG, unknowns and formulation review every 5 years	*To be added*	*To be added*	Yes by third party	Yearly by third party
RG2	≥ 0.4 and < 4	yes	None	Certification	Yes initial and regular by third party	Yes by third party	TOC, organoleptics yearly; specifics, EMG, unknowns, formulation review every 5 years	*To be added*	*To be added*	Yes by third party	Yearly by third party
RG3	≥ 0.4 and < 4	yes	None	Certification	Yes initial and regular by third party	Yes by third party	TOC, organoleptics, specifics, EMG, formulation review every 5 years	*To be added*	*To be added*	Yes by third party	Every 5 years by third party
RG4	≥ 0.004 and < 0.04	yes	None	Certification	Not by third party	Yes by third party	TOC, organoleptics, EMG every 5 years	*To be added*	*To be added*	no	no
RG5	< 0.004	yes	None	declaration producer	No	no	none	*To be added*	*To be added*	no	no
* see product listing for applicable risk group and conversion factor											
** see material specific Common Approaches for testing requirements											

3.4.2 Column 'Operate FPC'

For products in all risk groups the manufacturer shall operate a Factory Production Control system.

3.4.3 Column 'Hygienic production testing'

For products in the RG1 risk group the manufacturer shall perform applicable hygienic production testing, to show continued compliance with the TON parameter. This may be covered by alternative testing. Details are given in the material specific Common Approaches.

3.4.4 Column 'Certification'

For risk groups RG1 – RG4 compliance with the requirements set out in the material specific Common Approaches shall be shown via certification. For products in group RG5, a declaration by the economic operator shall be sufficient. A certificate or declaration shall clearly state to which risk group compliance is shown.

3.4.5 Column 'Sampling'

For risk groups RG1 – RG3 sampling shall be performed by a third party, if testing is required. For products in risk groups RG4 and RG5, the economic operator can choose the samples to be tested, if testing is required.

3.4.6 Column 'Testing'

For products in risk group RG5, no testing is required. For other products, testing shall be performed by a third party.

3.4.7 Columns 'Initial audit' and 'Verification audit'

Auditing is not required for RG5 products. For RG1 and RG2 products, initial and yearly auditing shall be performed by a third party. For RG3 products auditing shall be performed initially and every 5 years. For RG4 products auditing shall be performed only initially.

The audits shall cover the following aspects

- Correct working of the FPC system

- Control of incoming goods used for the production
- Unchanged composition of the (wetted parts of the) product
- Production testing, including prescribed Hygienic production testing (if required)
- Traceability

3.5 Approval / certification of components

3.5.1 General

For components of assembled products, the same table with requirements applies as for the products. For a component, a different risk group may apply than for the assembled product. This depends on the relative contact area of all components made from the same material with the water, compared to the total contact area of the assembled product with the water. For each factor ten, the next lower risk group applies. A component with relative contact area less than or equal to 10% in a RG2 product would therefore fall in the RG3 category.

All requirements, except for the 'certification', apply.

This means that components of assembled products do not need to be certified separately, even when the component falls in risk groups RG1 – RG4. Other requirements, most notably initial and verification audits do apply. A component manufacturer therefore needs to be audited separately, in addition to any audits performed at the assembled product manufacturer. An exception to this rule applies to certain RG3 components, as described below.

3.5.2 Outsourced RG3 components

In certain circumstances, initial and verification auditing of the manufacturer of RG3 components is not required. The following conditions apply:

- The component manufacturer produces the component according to exact specification of the assembled product manufacturer, including the exact formulation
- There is a written agreement between component and assembled product manufacturer laying down these specifications
- The assembled product manufacturer has checks in place that ensure that the agreed specifications are followed
- The Certification Body verifies these conditions at the assembled product manufacturer

NOTE: a standard situation where these conditions may apply is outsourcing of injection moulding of assembled product parts.

3.6 Requirements and assessment procedure for materials

This document does not contain requirements for or assessment procedures of the materials that make up a product. These requirements are laid down in separate, material specific Common Approaches. The same principle of reduced requirements for products and components with a reduced potential effect on the water quality is used. The listing in Annex C is used as starting point for both the material assessments and the certification / approval.

3.7 Step by step instructions

3.7.1 General

In the next sections, step-by-step instructions are given that may be followed to

- Determine the set of requirements that applies to a product
- Test a product according to this set of requirements
- Certify a product

These instructions are also graphically presented in flow schemes, given in Annex D.

3.7.2 Determining set of requirements for a product

Below a short step-by-step procedure is given to determine the set of requirements that applies to a product in contact with drinking water. Both certification / approval requirements (as described in this document) and material specific requirements (as laid down in respective material specific Common Approaches) are determined via this procedure.

1- Look up the risk group, conversion factor and product group that apply to the specific product (see Annex C)
2- Go to the table 'Risk based testing program - Certification requirements' (see Annex B)
3- Look up the correct line in the table, based on the risk group (e.g. RG1)
4- The requirements apply to the product
5- For each material type
    a. Sum the relative contact area of all components made from the same material
    b. Go to the applicable material specific Common Approach
    c. If the summed relative contact is greater than 10 %, lookup the line based on the risk group (e.g. RG1). These requirements apply to the material.
    d. If the summed relative contact is equal to or less than 10 %, lookup the line based on the next lower risk group apply (e.g. RG2 for a product in risk group RG1), if available. These requirements apply to the material.
    e. If the summed relative contact is equal to or less than 1 %, lookup the line based on the risk group two rows lower apply (e.g. RG3 for a product in risk group RG1) , if available. These requirements apply to the material.
    f. For each extra factor 10 lower relative contact are (e.g. 0.1% or 0.01%), the next lower risk group applies (e.g. RG4 or RG5 for a RG1 product)

3.7.3 Testing a product according to the requirements

Below a short step-by-step procedure is given to determine whether a product complies with the applicable set of test requirements (see 3.7.2). Evaluation of certification requirements is described in the next section.

1- Collect available test reports
2- For each requirement
    a. If product testing is allowed and a product test report is available
        i. Evaluate the usability of the report
        ii. Compare the results to the requirements
    b. If formulation or component testing is allowed and test report is available
        i. Evaluate the usability of the report
        ii. Compare the results to the requirements
3- Summarise whether all requirements have been tested and passed
4- For any remaining requirement
    a. Consider additional product, component or formulation testing
    b. Order additional testing to be carried out
    c. Repeat the procedure from step 1

Annex A Conversion Factors

Conversion factors for organic, cementitious and assembled products in contact with water intended for human consumption

#	Product group	Examples	CF in day/dm
A	**Pipes and their linings**		
1	ID < 80 mm (domestic installations, buildings) [2]		20
2	80 mm ≤ ID < 300 mm (service piping)		10
3	ID ≥ 300 mm (mains piping)		5
B	**Fittings, ancillaries** [3]		
1	ID < 80 mm (domestic installations, buildings)		2
2	80 mm ≤ ID < 300 mm (service piping)		1
3	ID ≥ 300 mm (mains piping)		0.5
4	Housing of treatment steps and their coatings	Housing for filters or ion exchange	0.05
5	Water abstraction devices	Pump	0.005
C	**Components of fittings, ancillaries** [4]		
1	ID < 80 mm (domestic installations, buildings)		0.2
2	80 mm ≤ ID < 300 mm (service piping)		0.1
3	ID ≥ 300 mm (mains piping)		0.05
4	Components of housing of treatment steps and their coatings		0.005
5	Components of water abstraction devices		0.0005
D	**Small Components of fittings, ancillaries** [5]		
1	ID < 80 mm (domestic installations, buildings)		0.02
2	80 mm ≤ ID < 300 mm (service piping)		0.01
3	ID ≥ 300 mm (mains piping)		0.005
4	Small components of housing of treatment steps and their coatings	(e.g. sealing agents for dilatations, (controlling) valves, check valves (back flow protection), sensors for controlling devices)	0.0005
5	Small components of water abstraction devices		0.00005
E	**Storage systems (reservoirs)**		
1	In domestic installations, buildings		4
2	In water supply		1
F	**Products for storage systems**		
1	In domestic installations, buildings:		
1.1	Parts of storage systems (> 10 % of the total surface)		4
1.2	Parts of storage systems (1 – 10 % of the total surface)		0.4
1.3	Parts of storage systems (≤ 1% of the total surface)		0.04
2	In water supply:		
2.1	Products covering the total surface or a substantial part of that (e.g. coatings)		1

[2] *If from a series of different diameter pipes made from the same raw and ancillary materials 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.*

[3] *Components (sum of components made of similar materials) of assembled products with a wetted surface fraction > 10% of the assembled products*

[4] *Components (sum of components made of similar materials) of assembled products with a wetted surface fraction ≤ 10% of the assembled products.*

[5] *Components (sum of components made of similar materials) of assembled products with a wetted surface fraction ≤ 1% of the assembled products.*

2.2	Products covering < 1% of the total surface		0.01
2.3	Elements of raw water basins, covering < 1‰ of the total surface	bubble aerator for raw water basins, bubble screen for raw water basins, preventing facility for fishes, preventing grate for rubbish	0.001

Annex B Risk based testing program - Certification requirements

Risk based testing program for (assembled) products - Certification requirements											
Risk group*	Conversion factor*	Operate FPC	Hygienic production testing	Certification	Sampling	Initial testing**	Verification testing (material specific)			Initial audit	Verification audit
							Organic	Metal	Cementitious		
RG1	≥ 4	yes	TON	Certification	Yes initial and regular by third party	Yes by third party	TOC and organoleptics yearly; specifics, EMG, unknowns and formulation review every 5 years	*To be added*	*To be added*	Yes by third party	Yearly by third party
RG2	≥ 0.4 and < 4	yes	None	Certification	Yes initial and regular by third party	Yes by third party	TOC, organoleptics yearly; specifics, EMG, unknowns, formulation review every 5 years	*To be added*	*To be added*	Yes by third party	Yearly by third party
RG3	≥ 0.4 and < 4	yes	None	Certification	Yes initial and regular by third party	Yes by third party	TOC, organoleptics, specifics, EMG, formulation review every 5 years	*To be added*	*To be added*	Yes by third party	Every 5 years by third party
RG4	≥ 0.004 and < 0.04	yes	None	Certification	Not by third party	Yes by third party	TOC, organoleptics, EMG every 5 years	*To be added*	*To be added*	no	no
RG5	< 0.004	yes	None	declaration producer	No	no	none	*To be added*	*To be added*	no	no
*	see product listing for applicable risk group and conversion factor										
**	see material specific Common Approaches for testing requirements										

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Annex C Product Listing

Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials '[7]	Risk group
Connection units (for watermeters)	Distribution	C1: 0.2		RG3
Sealants (for metal screw connections; see also 'Glues, for epoxy and other materials')	Abstraction Treatment Storage Distribution Installations	D5: 0.00005 D4: 0.0005 F2.2: 0.01 D2, D3: 0.01, 0.005 D1: 0.02		RG5 RG5 RG4 RG4, RG5 RG4
Sealing rings (with several shapes, e.g. O-rings and gaskets of rubber (SBR, EPDM and NBR))	Abstraction Treatment Storage Distribution Installations	D5: 0.00005 D4: 0.0005 F2.2: 0.01 D2, D3: 0.01, 0.005 D1: 0.02		RG5 RG5 RG4 RG4, RG5 RG4
Valves	Abstraction Treatment Storage Distribution Installations	C5: 0.0005 D4: 0.0005 To be added B2, B3: 1, 0.5 B1: 2		RG5 RG5 To be added RG2 RG2
Housings for treatment steps, concrete (that means direct contact with drinking water; for the case of no direct contact, see 'Coatings, for mineral materials')	Treatment	B4: 0.05		RG3
Housings for treatment steps, metal (that means direct contact with drinking water; for the case of no direct contact, see 'Coatings, for metal materials')	Treatment	B4: 0.05		RG3

[6] The conversion factor group (e.g. A1 for 'Pipes and their linings ID < 80 mm (domestic installations, buildings)', see Annex A) and the actual value for the conversion factor are given in this column

[7] See https://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/12th_revision_4ms_scheme_for_metallic_materials_part_b.pdf, page 6.

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Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials ’[7]	Risk group
Covering (of reservoirs for raw water), several materials	Abstraction	F2.3: 0.001		RG5
Aerators (in reservoirs for raw surface water)	Abstraction	F2.3: 0.001		RG5
Aeration screens (in reservoirs for raw surface water)	Abstraction	F2.3: 0.001		RG5
Concrete repair agents	Storage	F2.2: 0.01		RG4
Bonding agents	Distribution Installations	D2, D3: 0.01, 0.005 D1: 0.02		RG4 RG4
Hydrants	Distribution	B3: 0.5		RG2
Pipe renovation systems (full re-lining)	Distribution Installations	A3: 5 A1: 20		RG1
Pipe renovation systems (small crack re-lining)	Distribution	To be added		To be added
Pipes, cement bounded, concrete	Distribution	A3: 5		RG1
Pipes, cement bounded, internal cement lining of existing steel and cast iron pipes	Distribution	A2, A3: 10, 5		RG1
Pipes, cement bounded, internal cement lining of new steel and cast iron pipes	Distribution	A2, A3: 10, 5		RG1
Pipes, organic materials, epoxy	Abstraction Treatment Distribution	A2, A3: 10, 5 A2, A3: 10, 5 A2, A3: 10, 5		RG1 RG1 RG1
Pipes, organic materials, PB	Abstraction Treatment Distribution Installations	A2, A3: 10, 5 A2, A3: 10, 5 A2, A3: 10, 5 A1: 20		RG1 RG1 RG1 RG1

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Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials ’[7]	Risk group
Pipes, organic materials, PE	Abstraction Treatment Distribution Installations	A2, A3: 10, 5 A2, A3: 10, 5 A2, A3: 10, 5 A1: 20		RG1 RG1 RG1 RG1
Pipes, organic materials, PE/Al	Distribution	A1, A2, A3: 20, 10, 5		RG1
Pipes, organic materials, PE-RT	Distribution Installations	A2, A3: 10, 5 A1: 20		RG1 RG1
Pipes, organic materials, PE-RT/Al	Distribution	A2, A3: 10, 5		RG1
Pipes, organic materials, PE-X (PE-Xa, PE-Xb, PE-Xc)	Distribution Installations	A2, A3: 10, 5 A1: 20		RG1 RG1
Pipes, organic materials, PE-X/Al	Distribution Installations	A2, A3: 10, 5 A1: 20		RG1 RG1
Pipes, organic materials, polyester	Abstraction Treatment Distribution	A2, A3: 10, 5 A2, A3: 10, 5 A2, A3: 10, 5		RG1 RG1 RG1
Pipes, organic materials, PP-R	Distribution Installations	A2, A3: 10, 5 A1: 20		RG1 RG1
Pipes, organic materials, PP-R/Al	Distribution Installations	A2, A3: 10, 5 A1: 20		RG1 RG1
Pipes, organic materials, (biaxial orientated) PVC	Abstraction Treatment Distribution	A2, A3: 10, 5 A2, A3: 10, 5 A1, A2, A3: 20, 10, 5		RG1 RG1 RG1
Pipes, organic materials, PVC-C	Distribution Installations	A1, A2, A3: 20, 10, 5 A1: 20		RG1 RG1
Pipes, metal, copper[8]	Distribution Installations	A1: 20 A1: 20	A	RG1

[8] Conversion factors don’t concern to metalic products. Metalic products are approved because of the presence of the material on the relevant composition list considering the application in the drinking water supply.

Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials '[7]	Risk group
Pipes, metal, copper, with external protection	Distribution Installations	A1: 20 A1: 20	A	RG1
Pipes, metal, copper, with internal tin layer	Distribution Installations	A1: 20 A1: 20	A	RG1
Pipes, metal, copper, with skinny pipe wall and with external protection	Distribution Installations	A1: 20 A1: 20	A	RG1
Pipes, metal, cast iron	Abstraction Treatment Storage Distribution	A2: 10 A2, A3: 10, 5 A2, A3: 10, 5 A2, A3: 10, 5	A	RG1
Pipes, metal, carbon steel	Abstraction Treatment Storage Distribution	A2: 10 A2, A3: 10, 5 A2, A3: 10, 5 A2, A3: 10, 5	A	RG1
Pipes, metal, stainless steel	Abstraction Treatment Storage Distribution	A2: 10 A2, A3: 10, 5 A2, A3: 10, 5 A2, A3: 10, 5	A	RG1
Cascades	Treatment – Aeration	B4: 0.05		RG3
Coatings, for application on metalic and mineral materials	Abstraction (raw water reservoirs) Treatment (pipes) Storage (reservoirs) Distribution (pipes)	E2: 1 A1, A2, A3: 20, 10, 5 F2.1: 1 A2, A3: 10, 5		RG2 RG1, RG2 RG2 RG1
Compensators	Distribution	D3: 0.005		RG4
Doors (watertight), stainless steel	Storage	F1.2: 0.04	C.1	RG3
Nozzles	Treatment (several processes)	D4: 0.0005		RG5
Foils (HDPE, LDPE and plasticized PVC)	Abstraction (raw water) Storage (drinking water)	E2: 1 E2: 1		RG2 RG2

Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials [7]	Risk group
Fittings, cement bounded, concrete	Distribution	B3: 0.5		RG2
Fittings, cement bounded, internal cement lining for steel and cast iron fittings	Abstraction Treatment Storage Distribution	B5: 0.005 B4: 0.05 F1.2: 0.04 B1, B2, B3: 2, 1, 0.5		RG4 RG3 RG3 RG2
Fittings, organic materials	Abstraction Treatment Storage Distribution	B5: 0.005 B4: 0.05 F1.2: 0.04 B1, B2, B3: 2, 1, 0.5		RG4 RG3 RG3 RG2
Fittings, metal, cast iron	Abstraction Treatment Storage Distribution	B2: 1 B2, B3: 1, 0.5 B2, B3: 1, 0.5 B2, B3: 1, 0.5	B	RG2
Fittings, metal, press, pinch and stick in fittings	Abstraction Treatment Storage Distribution Installations	B2: 1 B2, B3: 1, 0.5 B2, B3: 1, 0.5 B2, B3: 1, 0.5	B	RG2
Fittings, metal, fittings with explosion cartridge	Abstraction Treatment Storage Distribution Installations	B2: 1 B2, B3: 1, 0.5 B2, B3: 1, 0.5 B2, B3: 1, 0.5 B1: 2	B	RG2
Fittings, metal, press fittings for use in combination with copper pipes	Abstraction Treatment Storage Distribution Installations	B2: 1 B2, B3: 1, 0.5 B2, B3: 1, 0.5 B2, B3: 1, 0.5 B1: 2	B	RG2
Check valves	Abstraction Treatment Distribution	B5: 0.005 D4: 0.0005 D1, D2, D3: 0.02, 0.01, 0.005		RG4 RG5 RG4
Kits (for dilatation seams)	Storage	F2.2: 0.01		RG4

Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials '[7]	Risk group
Ball valves	Abstraction Treatment Storage Distribution Installations	B5: 0.005 C4: 0.005 F2.2: 0.01 B1, B2, B3: 2, 1, 0.5 2		RG4 RG4 RG4 RG2 RG2
Valves, stop valves	Installations	2		RG2
Valves, connection valves	Distribution	2		RG2
Valves, service valves	Distribution	2		RG2
Valves, tap valves	Installations	2		RG2
Welding agents	Abstraction Treatment Storage Distribution Installations	C2: 0.1 C2, C3: 0.1, 0.05 C2, C3: 0.1, 0.05 C2, C3: 0.1, 0.05 C1: 0.2	C2	RG3
Glues, for epoxy and other materials	Abstraction Treatment Storage Distribution Installations	D5: 0.00005 D4: 0.0005 F2.2: 0.01 D2, D3: 0.01, 0.005 D1: 0.02		RG5 RG5 RG4 RG4, RG5 RG4
Glues, for PVC(-C)	Abstraction Treatment Storage Distribution	D5: 0.00005 D4: 0.0005 F2.2: 0.01 D2, D3: 0.01, 0.005		RG5 RG5 RG4 RG4, RG5
Man holes (water tight), stainless steel	Storage	F1.2: 0.04	C.1	RG3
Materials for artificial infiltration ('normal' infiltration, deep infiltration and dune infiltration)	Treatment (artificial infiltration is being seen as a part of the treatment of water)	See 'Abstraction'		See 'Abstraction'
Controlling devices, sensors for pressure, flow and temperature, level, pH (quartz glass)	Abstraction Treatment Storage Distribution	D5: 0.00005 D4: 0.0005 F2.2: 0.01 D1, D2, D3: 0.02, 0.01, 0.005		RG5 RG4 RG3 RG4, RG3

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Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials [7]	Risk group
Membrane filtration elements, for UF, NF and RO, and ceramic elements	Treatment – Membrane filtration	To be added		To be added
Membrane filtration, modules and pressure pipes	Treatment – Membrane filtration	To be added		To be added
Micro sieves (stainless steel)	Treatment	B4: 0.005	C	RG4
Sampling materials (stainless steel)	Abstraction Treatment Storage Distribution Installations	D2: 0.01 D2, D3: 0.01, 0.005 D2, D3: 0.01, 0.005 D2, D3: 0.01, 0.005 D1: 0.02	C2	RG4
Pall rings	Treatment (several processes)	D4: 0.0005		RG5
Plate aerators	Treatment – Aeration	B4: 0.05		RG3
Pumps, distribution pumps, submersible pumps	Abstraction Treatment Distribution Installations	B5: 0.005 C4: 0.005 D3: 0.005 2		RG4 RG4 RG4 RG2
Relining systems	Distribution	A1, A2, A3: 20, 10, 5		RG1
Reparation clamps	Distribution	D1, D2, D3: 0.02, 0.01, 0.005		RG4
Reservoirs, site applied concrete (without coating)	Storage	F2.1: 1		RG2
Reservoirs, metal, stainless steel	Storage	E1: 4	To be added	RG1
Reservoirs, organic material (coating or covering boarding)	Storage	F2.1: 1		RG2
Mixing devices	Treatment – Coagulation and flocculation	C4: 0.005		RG4
Gate valves	Abstraction Treatment Storage Distribution Installations	B5: 0.005 C4: 0.005 F2.2: 0.01 B1, B2, B3: 2, 1, 0.5 2		RG4 RG4 RG4 RG2 RG2

Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials [7]	Risk group
Solder agents	Distribution Installations	C1, C2: 0.2, 0.1 C1: 0.2	C1	RG3
Flushing nozzles	Treatment – Filtration (rapid and slow sand filtration) Treatment – Softening	D4: 0.0005 D4: 0.0005		RG5 RG5
Aeration nozzles	Treatment – Aeration	D4: 0.0005		RG5
Static mixers	Treatment	D4: 0.0005		RG5
Tanks	Storage (Installations)	E1: 4		RG1
Tower aerators	Treatment – Aeration	B4: 0.05		RG3
Stairs (stainless steel)	Storage	F1.2: 0.04	C.1	RG3
Vibration dampers	Distribution	D1, D2, D3: 0.02, 0.01, 0.005		RG4
UV-disinfection devices	Treatment – Disinfection (physical)	B4: 0.05		RG3
Butterfly valves	Abstraction Treatment Storage Distribution Installations	B5: 0.005 C4: 0.005 F2.2: 0.01 B1, B2, B3: 2, 1, 0.5 2		RG4 RG4 RG4 RG2 RG2
Flow limiters	Distribution Installations	D1, D2, D3: 0.02, 0.01, 0.005 2		RG4 RG2
Filter body materials	Treatment	B4: 0.04		RG3
Water meters	Distribution (ID < 80 mm) Distribution (80 mm ≤ ID < 300 mm)	2 1	B B	RG2 RG2
Materials for the abstraction of raw surface water	Abstraction	F2.3: 0.001		RG5
Shower outlets	Installations	2		RG2
Shower hoses	Installations	2		RG2
Pressure flushing valves	Installations	2		RG2
Thermostatic mixing taps	Installations	2		RG2

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Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials ’[7]	Risk group
Low pressure mechanical mixing taps	Installations	2		RG2
Electronic opening and closing sanitary taps	Installations	2		RG2
Extractable outlets for sink and basin mixers	Installations	2		RG2
Extractable shower hoses for sanitary tapware for supply systems	Installations	2		RG2
Single taps	Installations	2		RG2
Combination taps	Installations	2		RG2
Flow rate regulators	Installations	0.2		RG3
Automatic shut-off valves	Installations	2		RG2
Mixing valves, mechanical	Installations	2		RG2
Stopvalves, copper alloy	Installations	2		RG2
Ball valves, manually operated, copper alloy and stainless steel	Installations	2		RG2
Hydraulic safety groups	Installations	2		RG2
Expansion groups	Installations	2		RG2
Pressure safety valves	Installations	2		RG2
Combines temperature and pressure relief valves	Installations	2		RG2
Expansion valves	Installations	2		RG2
Inline hot water supply tempering valves	Installations	2		RG2
Water pressure reducing valves	Installations	2		RG2
Combination water pressure reducing valves	Installations	2		RG2
Controllable backflow preventer	Installations	2		RG2

Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials ’[7]	Risk group
Unrestricted air gap	Installations	2		RG2
Air gap with non-circular overflow (unrestricted)	Installations	2		RG2
Air gap with submerged feed incorporating air inlet plus overflow	Installations	2		RG2
Air gap with injector	Installations	2		RG2
In-line anti-vacuum valves	Installations	2		RG2
Pipe interrupter with atmospheric vent and moving element	Installations	2		RG2
Pipe interrupter with permanent atmospheric vent	Installations	2		RG2
Hose union backflow preventer	Installations	2		RG2
Pressurized air inlet valves	Installations	2		RG2
Automatic diverter	Installations	2		RG2
Air gap with circular overflow (restricted)	Installations	2		RG2
Air gaps with minimum circular overflow (verified by test or measurement)	Installations	2		RG2
Hose union anti-vacuum valves	Installations	2		RG2
Mechanical filters	Installations	2		RG2
Water conditioning equipment inside buildings	Installations	2		RG2
Flexible hose assemblies	Installations	2 (20 for the inner hose)	B	RG2 (RG1 for the inner hose)
unvented (closed) storage water heaters	Installations	2		RG2
Anti-pollution check valves	Installations	2		RG2

Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials [7]	Risk group
Inlet valves for flushing cisterns with internal overflow	Installations	2		RG2
Non-controllable backflow preventer with different pressure zones	Installations	2		RG2
Stirrers	Treatment Storage	To be added	To be added	RG4
Backflow prevention valves	Abstraction Treatment Storage Distribution Installations	To be added	To be added	RG4 RG4 RG4 RG4
Baffle curtains	Treatment Storage	To be added	To be added	RG2
Baffle curtain fixings	Treatment Storage	To be added	To be added	RG4
CCTV cameras and fixings	Treatment Storage	To be added	To be added	RG4
Cementitious anchors	Storage	To be added	To be added	RG4
Brick construction materials	Treatment Storage	To be added	To be added	RG4
Clay pipes		To be added	To be added	RG4
Crack injection sealants (non-water contact) in water retaining structures	Storage	To be added	To be added	RG4
Expansion joint filler boards	Storage	To be added	To be added	RG4
Expansion joints	Storage	To be added	To be added	RG4
External pipe repairs (e.g. collars)	Distribution	To be added	To be added	RG4
Line stops, bungs, plugs	Storage Distribution	To be added	To be added	RG4

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Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials [7]	Risk group
Mobile and temporary sensors	Abstraction Treatment Storage Distribution	To be added	To be added	RG4
Pumps, turbine generators and associated fittings, materials and lubricants	Abstraction Distribution	To be added	To be added	RG4
Radio frequency identification devices (RFID)	Abstraction Treatment Storage Distribution	To be added	To be added	RG4
Scum boards	Treatment	To be added	To be added	RG4
Security devices	Treatment Storage Distribution	To be added	To be added	RG4
Taps – not installations	Abstraction Treatment Storage Distribution	To be added	To be added	RG4
Touch-up coatings	Abstraction Treatment Storage Distribution	To be added	To be added	RG4
Penstock, butterfly valves	Abstraction Treatment Storage Distribution	To be added	To be added	RG4
Weir plates	Abstraction Treatment Storage	To be added	To be added	RG4
Well casings and screens	Abstraction	To be added	To be added	RG3

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Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials [7]	Risk group
Bowsers and tanks (limited use for temporary supply) max usage 90 days	Distribution	To be added	To be added	RG3
Liner bags (1000L) (limited use for temporary supply) single use	Distribution	To be added	To be added	RG3
In-situ tubular linings for pipes	Distribution	To be added	To be added	RG1
In-situ applied epoxy resin linings for pipes	Distribution Installations	To be added	To be added	RG1
In-situ applied polyurethane linings for pipes	Distribution Installations	To be added	To be added	RG1
Flexible covers and lining for water retaining structures	Abstraction Storage	To be added	To be added	RG3 RG2
Cementitious linings for water retaining structures	Abstraction Storage	To be added	To be added	RG3 RG2
Cementitious repair materials for water retaining structures	Abstraction Storage	To be added	To be added	RG4 RG3
Membranes – filter cartridges	Treatment Distribution Installations	To be added	To be added	RG2 RG1 RG1
Membranes – PVDF	Treatment	To be added	To be added	RG2
Membranes – PP	Treatment	To be added	To be added	RG2
Membranes – ceramic	Treatment	To be added	To be added	RG2
Membranes – cloth filter	Abstraction	To be added	To be added	RG3
Membrane housings and associated fittings	Treatment Distribution Installations	To be added	To be added	RG3 RG2 RG2
Electrodialysis	Treatment	To be added	To be added	RG3
Filter media containing vessels	Treatment Installations	To be added	To be added	RG3 RG2
Underdrains	Treatment	To be added	To be added	RG3

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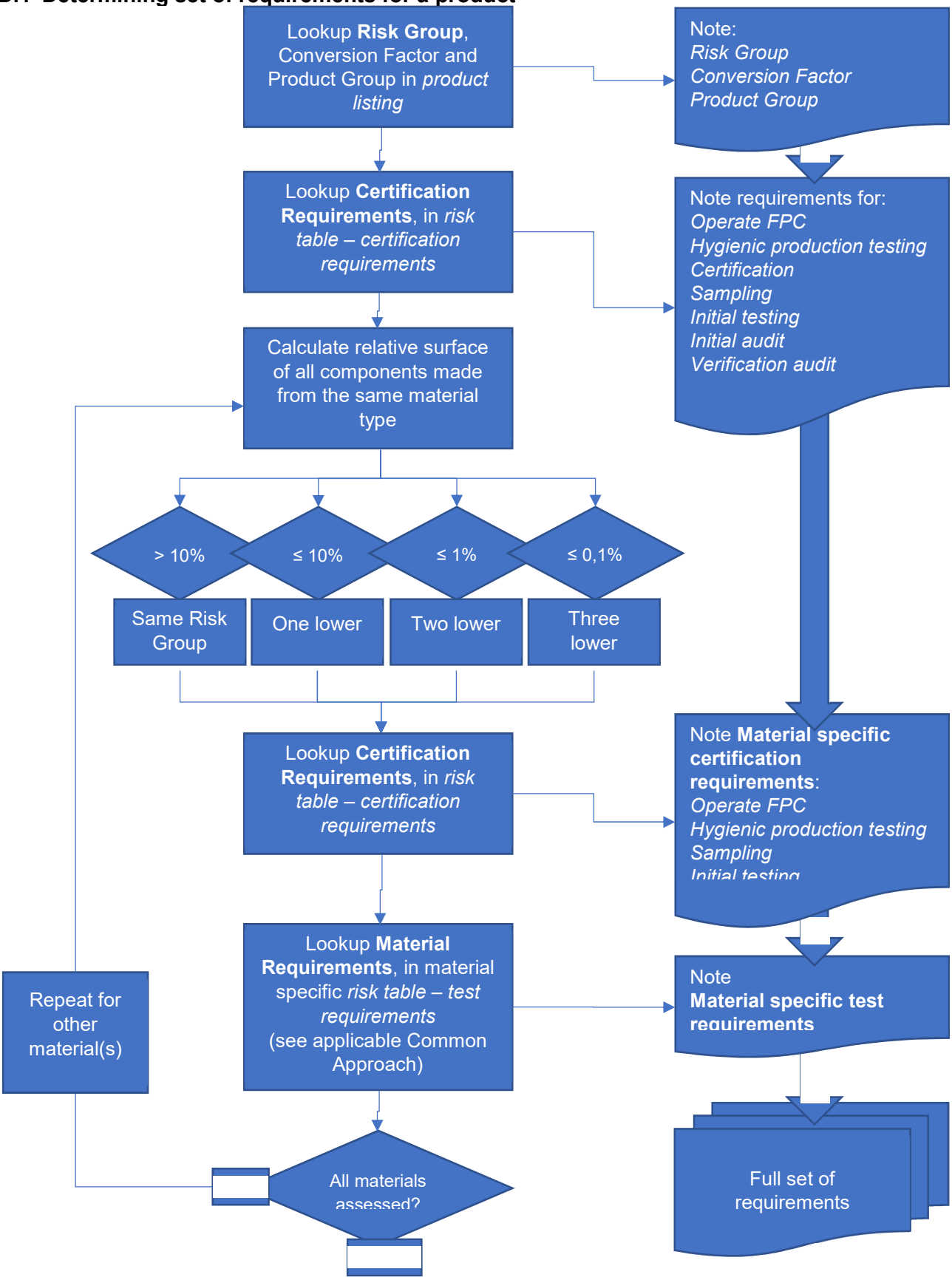
Product	Application area	Conversion factor for organic, cementitious and assembled products (day/dm)[6]	Product group for metallic materials [7]	Risk group
Pressure vessels	Treatment	To be added	To be added	RG3
Dewatering screw press – water returns to process	Treatment	To be added	To be added	RG3
Lamellas	Treatment	To be added	To be added	RG3
Pontoons – temporary platforms	Abstraction Treatment Storage	To be added	To be added	RG4 RG3 RG3
Ion exchange resins	Treatment	To be added	To be added	RG2
Suspended ion exchange resins	Treatment	To be added	To be added	RG2
Dissolved air flotation (DAF) systems	Treatment	To be added	To be added	RG3

Annex D Flow schemes

D.1 Determining set of requirements for a product



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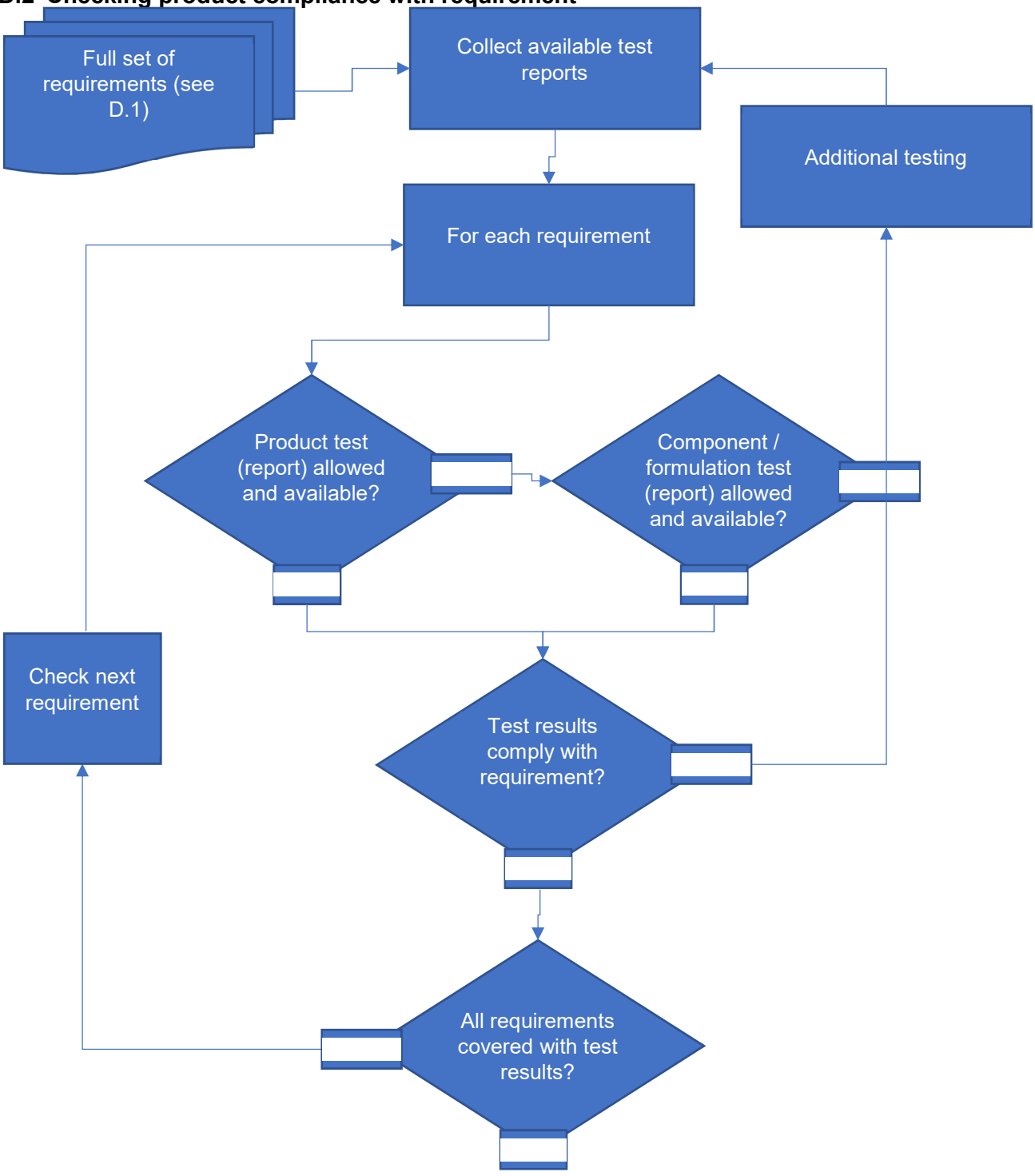
D.2 Checking product compliance with requirement



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Annex E Examples

E.1 Case 'Flexible hose'

E.1.1 General description

Flexible hoses for connection of sanitary tapware to the drinking water system for in-house installations.

E.1.2 Risk group, conversion factor and product group

According to the product listing, flexible hoses fall in risk group RG2 with conversion factor 2 and product group B. An exception applies to one component: the inner hose is to be assessed according to Risk Group RG1, with conversion factor 20. No product group applies to the inner hose, as it is made from organic material(s).

E.1.3 Certification requirements

For the RG2 risk group, the following certification requirements apply:

Operate FPC	yes
Hygienic production testing	None
Certification	Certification
Sampling	Yes initial and regular by third party
Initial testing	Yes by third party
Regular testing	TOC, organoleptics yearly; specifics, EMG, unknowns, formulation review every 5 years
Initial audit	Yes by third party
Regular audit	Yearly by third party

E.1.4 Wetted parts list

The following information on the composition of the product is available.

Components	Size	Material	Wetted Surface	
			(mm^2)	(%)
Seal 1	1/2"	EPDM 1	113	0,83
End fitting 1	20 mm	Brass	377	2,78
Hose	500 mm	PEX	12571	92,77
End fitting 2	20 mm	Brass	377	2,78
Seal 2	1/2"	EPDM 2	113	0,83

E.1.5 Summing the relative contact area of all components made from the same composition

For each material type, the relative surface area is summed.

Components	Size	Material	Wetted Surface		Summing
			(mm^2)	(%)	
Seal 1	1/2"	EPDM 1	113	0,83	Add to Seal 2
End fitting 1	20 mm	Brass	377	2,78	Add to End fitting 2
Hose	500 mm	PEX	12571	92,77	92,77
End fitting 2	20 mm	Brass	377	2,78	2,78 + 2,78 = 5,56
Seal 2	1/2"	EPDM 2	113	0,83	0,83 + 0,83 = 1,66

E.1.6 Material risk groups

The flexible hose falls in Risk Group RG2. Based on the summed wetted surfaces, the following Risk Groups apply. The inner hose is an exception.

Components	Size	Material	Wetted Surface		Summing	Risk Group
			(mm^2)	(%)		
Seal 1	1/2"	EPDM 1	113	0,83	Add to Seal 2	
End fitting 1	20 mm	Brass	377	2,78	Add to End fitting 2	
Hose	500 mm	PEX	12571	92,77	92,77	RG1
End fitting 2	20 mm	Brass	377	2,78	2,78 + 2,78 = 5,56	RG3
Seal 2	1/2"	EPDM 2	113	0,83	0,83 + 0,83 = 1,66	RG3

E.1.7 Material requirements

Based on the Risk Groups for the various materials, the following test requirements apply.

Material	Risk Group	Formulation review	Specific migration testing	Organoleptic testing	EMG	TOC	Unknowns
PEX	RG1	Yes, on formulation	Yes, on (assembled) product or component	Yes, on (assembled) product or component	Yes, on component or formulation*	Yes, on (assembled) product or component	Yes, on (assembled) product or component
Brass	RG3	Composition	n.a.	n.a.	n.a.	n.a.	n.a.
EPDM	RG3	Yes, on formulation	Yes, on (assembled) product, component or formulation	Yes, on (assembled) product, component or formulation	Yes, on component or formulation	Yes, on (assembled) product, component or formulation	Yes, on (assembled) product, component or formulation

E.2 Case 'Commercial and industrial water meter'

E.2.1 General description

Commercial and industrial water meter for use in distribution. Internal diameter is assumed to be between 80 and 300 mm.

E.2.2 Risk group, conversion factor and product group

According to the product listing, Water Meters fall in risk group RG2 with conversion factor 1 (assuming ID > 80 mm) and product group B.

E.2.3 Certification requirements

For the RG2 risk group, the following certification requirements apply:

Operate FPC	yes
Hygienic production testing	None
Certification	Certification
Sampling	Yes initial and regular by third party
Initial testing	Yes by third party
Regular testing	TOC, organoleptics yearly; specifics, EMG, unknowns, formulation review every 5 years
Initial audit	Yes by third party
Regular audit	Yearly by third party

E.2.4 Wetted parts list

The following information on the composition of the product is available.

#	Components	Material	Wetted Surface (cm^2)	Wetted Surface (%)
1	Meter body	Stainless steel	314	36,14%
2	Flow pipe	Thermoplastic 1	500	57,55%
3	Meter counter housing	Thermoplastic 1	14	1,61%
4	Reflectors	Stainless steel	32,6	3,75%
5	O-ring	Elastomer	8,28	0,95%

E.2.5 Summing the relative contact area of all components made from the same formulation

For each material type, the relative surface area is summed.

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#	Components	Material	Wetted Surface (cm^2)	Wetted Surface (%)	Summing
1	Meter body	Stainless steel	314	36,14%	Add to reflectors
2	Flow pipe	Thermoplastic 1	500	57,55%	Add to meter counter housing
3	Meter counter housing	Thermoplastic 1	14	1,61%	57,55 + 1,61 = 59,16%
4	Reflectors	Stainless steel	32,6	3,75%	36,14 + 3,75 = 39,89%
5	O-ring	Elastomer	8,28	0,95%	0,95%

E.2.6 Material risk groups

The flexible hose falls in Risk Group RG2. Based on the summed wetted surfaces, the following Risk Groups apply.

#	Components	Material	Wetted Surface (cm^2)	Wetted Surface (%)	Summing	Risk Group
1	Meter body	Stainless steel	314	36,14%	Add to reflectors	
2	Flow pipe	Thermoplastic 1	500	57,55%	Add to meter counter housing	
3	Meter counter housing	Thermoplastic 1	14	1,61%	57,55 + 1,61 = 59,16%	RG2
4	Reflectors	Stainless steel	32,6	3,75%	36,14 + 3,75 = 39,89%	RG2
5	O-ring	Elastomer	8,28	0,95%	0,95%	RG4

E.2.7 Material requirements

Based on the Risk Groups for the various materials, the following test requirements apply.

Material	Risk Group	Formulation review	Specific migration testing	Organoleptic testing	EMG	TOC	Unknowns
Thermoplastic 1	RG2	Yes, on formulation	Yes, on (assembled) product, component or formulation	Yes, on (assembled) product or component	Yes, on component or formulation	Yes, on (assembled) product or component	Yes, on (assembled) product, component or formulation
Stainless steel	RG2	Composition	n.a.	n.a.	n.a.	n.a.	n.a.
Elastomer	RG4	no	no	Yes, on (assembled) product, component or formulation	Yes, on component or formulation	Yes, on (assembled) product, component or formulation	Yes**, on (assembled) product, component or formulation