

Product Evaluation Guideline

for certification of multilayer piping systems
PE-X /AI, PE-RT/AI, PP-R/AI and PP-RCT/AI
intended for transport of hot and cold drinking water
inside buildings
in accordance with EN ISO 21003 Multilayer piping systems for
hot and cold water installations inside buildings

Preface

This product evaluation guideline (PEG) has been approved by the Board of Stakeholders (BoS), wherein all the relevant parties in the field of Plastics piping systems of PE-X/Al, PE-RT/Al, PP-R/Al and PP-RCT/Al intended for the transport of hot and cold drinking water are represented.

The BoS was established with the purpose of implementing certification in a co-operation between certification bodies.

The co-operation is based on the General Rules for Product Certification (GRPC) wherein the mutual recognition of surveillance reports from accredited inspection bodies as well as the acceptance of test reports of accredited test laboratories is specified.

The BoS also supervises the certification activities and where necessary require the evaluation guideline to be revised. The BoS also guides the performance of certification and updates this evaluation guideline in case necessary. Wherever the term "Board of Stakeholders" is used in this PEG, the above mentioned Board of Stakeholders is meant.

This PEG for piping system certification is based on the corresponding EN ISO piping system standard(s) in combination with the hygienic requirements.

It sets requirements for type testing as well as ongoing quality surveillance by third party inspection.

The certification bodies will use this evaluation guideline in conjunction with the General Rules for Product Certification (GRPC).

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References

- GRPC General Rules for Product Certification
- EN ISO 21003-1, *Multilayer piping systems for hot and cold water installations inside buildings – Part 1: General*
- EN ISO 21003-2, *Multilayer piping systems for hot and cold water installations inside buildings – Part 2: Pipes*
- EN ISO 21003-3, *Multilayer piping systems for hot and cold water installations inside buildings – Part 3: Fittings*
- EN ISO 21003-5, *Multilayer piping systems for hot and cold water installations inside buildings – Part 5: Fitness for purpose of the system*
- CEN ISO/TS 21003-7:2008 + Amd:2010, *Multilayer piping systems for hot and cold water installation inside buildings - Part 7: Guidance for the assessment of conformity*
- EN ISO 228-1, *Pipe threads where pressure-tight joints are not made on the threads – Part 1 Dimensions, tolerances and designation*
- EN ISO 527-1, *Plastics — Determination of tensile properties — Part 1: General principles*
- EN ISO 527-2, *Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics*
- EN ISO 1167-1, *Thermoplastics pipes, fittings and assemblies for the conveyance of fluids – Determination of the resistance to internal pressure - Part 1: General method*
- EN ISO 1167-2, *Thermoplastics pipes, fittings and assemblies for the conveyance of fluids – Determination of the resistance to internal pressure — Part 2: Preparation of pipe test pieces*
- EN ISO 1167-3, *Thermoplastics pipes, fittings and assemblies for the conveyance of fluids - Determination of the resistance to internal pressure - Part 3: Preparation of components*
- EN ISO 1167-4, *Thermoplastics pipes, fittings and assemblies for the conveyance of fluids - Determination of the resistance to internal pressure - Part 4: Preparation of assemblies*
- EN ISO 2578, *Plastics — Determination of time-temperature limits after prolonged exposure to heat*
- EN ISO 3126, *Plastics piping systems — Plastics components — Determination of dimensions*
- EN ISO 6259-1, *Thermoplastics pipes — Determination of tensile properties — Part 1: General test method*
- EN ISO 7686, *Plastics pipes and fittings — Determination of opacity*
- EN ISO 9080, *Plastics piping and ducting systems - Determination of the long-term hydrostatic strength of thermoplastics materials in pipe form by extrapolation*
- EN ISO 13760, *Plastics pipes for the conveyance of fluids under pressure — Miner's rule — Calculation method for cumulative damage*
- EN ISO 15874-2, *Plastics piping systems for hot and cold water installations – Polypropylene (PP) Part 2: Pipes*
- EN ISO 15874-3, *Plastics piping systems for hot and cold water installations Polypropylene (PP) Part 3: Fittings*
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EN ISO 15874-5; *Plastics piping systems for hot and cold water installations Polypropylene (PP) - Part 5: Fitness for purpose*

EN ISO 15875-2:2003, *Plastics piping systems for hot and cold water installations Crosslinked Polyethylene (PE-X) - Part 2: Pipes*

EN ISO 15875-3, *Plastics piping systems for hot and cold water installations Crosslinked polyethylene (PE-X) – Part 3: Fittings*

EN ISO 15875-5, *Plastics piping systems for hot and cold water installations Crosslinked polyethylene (PE-X)- Part 5: Fitness for purpose*

EN ISO 15876-2, *Plastics piping systems for hot and cold water installations Polybutylene (PB) Part 2: Pipes*

EN ISO 15876-3, *Plastics piping systems for hot and cold water installations Polybutylene (PB) Part 3: fittings*

EN ISO 15876-5, *Plastics piping systems for hot and cold water installations Polybutylene (PB) Part 5: Fitness for purpose*

EN ISO 22391-2, *Plastics piping systems for hot and cold water installations Polyethylene of raised temperature resistance (PE-RT) Part 2: Pipes*

EN ISO 22391-3, *Plastics piping systems for hot and cold water installations Polyethylene of raised temperature resistance (PE-RT) | Part 2: Fittings*

EN ISO 22391-5, *Plastics piping systems for hot and cold water installations Polyethylene of raised temperature resistance (PE-RT) Part 5: Fitness for purpose*

EN 681-1, *Elastomeric seals — Materials requirements for pipe joint seals used in water and drainage Applications — Part 1: Vulcanized rubber*

EN 681-2, *Elastomeric seals — Materials requirements for pipe joint seals used in water and drainage Applications — Part 2: Thermoplastic elastomers*

EN 712, *Thermoplastics plastics piping systems — End-load bearing mechanical joints between pressure pipes and fittings — Test method for resistance to pull-out under constant longitudinal force*

EN 713, *Plastics piping systems — Mechanical joints between fittings and polyolefin pressure pipes — Test method for leak tightness under internal pressure of assemblies subjected to bending*

EN 1254-3, *Copper and copper alloys — Plumbing fittings — Part 3: Fittings with compression ends for use with plastics pipes*

EN 10088, *Stainless steels — Part 1: List of stainless steels*

EN 10226-1, *Pipe threads where pressure tight joints are made on the threads — Part 1: Taper external threads and parallel internal threads; Dimensions, tolerances and designation*

EN 12293, *Plastics piping systems — Thermoplastics pipes and fittings for hot and cold water — Test method for the resistance of mounted assemblies to temperature cycling*

EN 12294, *Plastics piping systems for hot and cold water — Method of test for leaktightness under vacuum*

EN 12295, *Plastics piping systems — Thermoplastics pipes and associated fittings for hot and cold water — Test methods for resistance of joints to pressure cycling*

ISO 2859-1, Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptable quality level (AQL) for lot-by-lot inspection

ISO 3951, Sampling procedures and charts for inspection by variables for percent nonconforming

ISO 10508, *Plastics piping systems for hot and cold water installations — Guidance for classification and design*

ISO 17454, *Plastics piping systems — Multilayer pipes — Test method for the adhesion of the different layers using a pulling rig*

ISO 17455, *Plastics piping systems — Multilayer pipes — Determination of the oxygen permeability of the barrier pipe*

ISO 17456, *Plastics piping systems - Multilayer pipes - Determination of long-term strength*

Standards for hygiene testing and assessment methods

EN 1420, *Influence of organic materials on water intended for human consumption - Determination of odour and flavour assessment of water in piping systems;*

EN 1484, *Water analysis - Guidelines for the determination of total organic carbon (TOC) and dissolved organic carbon (DOC);*

EN 1622, *Water quality - Determination of the threshold odour number (TON) and threshold flavour number (TFN)*

EN 12873-1, *Influence of materials on water intended for human consumption - Influence due to migration - Part 1: Test method for factory-made products made from or incorporating organic or glassy (porcelain/vitreous/enamel) materials*

EN 13052-1, *Influence of organic materials on water intended for human consumption - Organic materials; Determination of colour and turbidity of water in piping systems - Part 1: Test method*

EN 15768, *Influence of materials on water intended for human consumption - GC-MS identification of water leachable organic substances*

CEN/TR 16364, *Influence of materials on water intended for human consumption - Influence due to migration - Prediction of migration from organic materials using mathematical modelling*

EN 16421, *Influence of materials on water for human consumption - Enhancement of microbial growth (EMG)*

EN ISO 7027, *Water quality - Determination of turbidity*

EN ISO 7887, *Water quality - Examination and determination of colour*

Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

Regulation which lays down the conditions of the Approval Scheme in Portugal for products in contact with water intended for human consumption (EU Notification number 2015/234/P)

1. SCOPE

This PEG is applicable to a multilayer piping systems of PE-X /Al, PE-RT/Al, PP-R/Al and PP-RCT/Al which is intended to be applied for hot and cold drinking water installation inside building at a design pressure (= maximum operating pressure) of 4, 6, 8 or 10 bar.

Note: Observe national pressure requirements in drinking water installations

The application class covered by this document is listed in Table 1.

Table 1: Temperature profile during 50 years

	Temperature [°C]	Lifetime	Design coefficient
T _{operation}	70	49 years	1,5
T _{max}	80	1 year	1,3
T _{malfunction}	95	100 hours	1,0

Note: This temperature profile is in accordance with application class 2 of EN ISO 21003-1.

All systems which satisfy the conditions specified in Table 1 shall also be suitable for the conveyance of cold water for a period of 50 years at a temperature of 20 °C and a design pressure of 10 bar.

Further the multilayer pipe of the piping system is composed of 5 layers as follows:

- Inner layer made of PE-X, PP-R, PP-RCT or PE-RT with a thickness of at least 0,5 mm.
- Adhesive layer
- Aluminum layer
- Adhesive layer
- Outer layer made of thermoplastic material (including PE-X)

The total wall thickness of the pipe consists at least of 60% plastic material.

2. TERMS AND SYMBOLS

2.1. Terms

For the purposes of this PEG, the terms given in EN ISO 21003-1, CEN/ISO/TS 21003-7, the GRPC and the following apply:

Applicant: the party that applies for a certificate

Piping system: the set of pipes and fittings including transition fitting (thread adaptors) as well as optionally sealing, expansion pieces and other piping components.

Remark: Installation tools are not part of the system.

2.2. Symbols

For the purposes of this PEG, the terms given in EN ISO 21003-1, CEN/ISO/TS 21003-7, the “Internal regulation for product certification” and the following apply:

BoS	Board of Stakeholders
PEG	Product Evaluation Guideline
GRPC	General Rules of Product Certification
FPC	Factory production control
BRT	Batch release test
PVT	Product verification test
4MS-Group:	Collaboration of 4 European Member States (MS) France, Germany, the Netherlands and the United Kingdom Great Britain
PE-X	cross-linked polyethylene
PE-RT	Polyethylene of raised temperature resistance
PP-R	Polypropylene random copolymer
PP-RCT	Polypropylene random crystallinity temperature

3. CONDITIONS FOR CERTIFICATION

The issuing of a certificate requires that the applicant commits himself to follow the GRPC and this PEG.

4. APPLICATION FOR A CERTIFICATE

The applicant shall use the application form from the CB to choose the requested certification. This application form shall be send to one of the chosen certification bodies.

The application shall include:

- Reports covering type tests and initial inspection according to clause 7.1 and description of each component intended to be covered in the certificate. Technical specifications and when appropriate, drawings can be used. Type test reports or any other reports should preferably be presented in English language.
- Specification of the raw material used in pipes and fittings including the name of its manufacturer.
- If applicable information concerning manufacturer and type of the sealing rings, together with documentation that the sealing ring material meets the requirements of the relevant standard, EN 681-1, either by a valid certificate or with test reports from an accredited body.
- Description of the manufacturer´s internal quality control system (quality plan) and instructions for factory production control of the relevant product according to clause 7.2.
- Sample of existing marking on the product.-
- Installation manual

Certificates can only be issued to the supplier of the piping system.

Note: The applicant may purchase externally parts of the complete piping system (e. g pipes, fittings or other components) which are in the scope of the certification. In such case, the supplied parts shall either be certified by the supplier under his own brand, or they shall be considered as subcontracted products and shall be certified as such under the applicant's brand.

5. CERTIFICATE

The certificate can be granted when all requirements of this document are met, including the requirements of the GRPC. The certificate may include information about the production sites of the certified pipes and fittings.

6. PERFORMANCE REQUIREMENTS

The pipes, fittings and joints of the piping system as specified in clause 1 shall be tested with regard to their proper functioning.

All requirements of the tests in EN ISO 21003 part 1, 2, 3 and 5 have to be fulfilled, see Annex A.

For metal parts the 4MS requirements apply.

All organic components of the installation system in contact with drinking water have to fulfill the hygienic requirements of Annex B.

7. TESTING AND INSPECTION

7.1 General

Testing and inspection include:

- type testing and initial inspection, clause 7.2
- factory production control (BRT, PVT), clause 7.3
- periodical inspection and audit testing (AT), clause 7.4
- Change in design, compound, production method, production site and extension of product range, clause 7.5

For testing and inspection the grouping, i.e. the pressure groups, the size groups and the type of fittings groups, according to NWIP CEN ISO/TS 21003 part 7 (2015) applies.

Table 2

Pressure group	Operating pressure, p_{op} bar
1	4; 6
2	8; 10

Table 3

Size group	1	2	3
Nominal outside diameter, d_n , mm	≥ 10 and ≤ 26	> 26 and ≤ 63	> 63

Fittings are divided into groups according to Table 4.

or..to Table 3 of CEN ISO/TS 21003-7:2008 + Amd:2010

Table 4

Fitting group	Fitting type
1	Elbows, tees, reducers, couplers, end caps
2	Unions, flange adaptors, transition fitting, adaptor pieces and/or their plastics parts, plus others

Note: The fitting groups are according to NWIP CEN ISO/TS 21003 part 7 (2015).

7.2 Type testing and initial inspection

7.2.1 Type testing

Type testing shall be carried out on material/compound, pipes and fittings, which are to be included in the certificate and to the extent stated in Table A.1, A.2, A.3, A.4 and A.5.

For characteristics which require third party involvement, the testing shall be carried out by a testing laboratory according to the GRPC.

The type test report shall confirm that all requirements are fulfilled with regard to the relevant material/compound and pipes/fittings and verify that the manufacturers test results are available and fulfils the requirements in this PEG. The type test report shall state the designation of material from which the pipes and fittings are made.

7.2.2 Initial inspection

The initial inspection shall be carried out by an inspection body according to the GRPC.

The initial inspection shall verify that the manufacturers system for quality assurance for relevant products at the production site(s) is according to EN ISO 9001.

Note: The use of a common CCB check list for the initial inspection list is preferred.

7.3 Factory production control (FPC), batch release test (BRT) and process verification test (PVT)

The manufacturer is responsible for demonstrating through described procedures and written instructions that pipes and fittings fulfill the requirements of this PEG.

The manufacturer is responsible for ensuring that the instructions concerning the internal quality inspection are available for the personnel in the language of the manufacturing country concerned.

Records of the internal control shall be dated, traceable and available to the external inspector according to clause 7.4.

The records shall include information of - or traceability to

- Type of raw material
- Certificate of raw material
- Recipe identification / designation
- Batch number
- Date of production

7.3.1 Batch release test (BRT)

Batch release testing is carried out by the producer and includes determination of the characteristics listed in tables A.6 and A.7 with the specified minimum sampling frequencies. Documentation from the control should be kept at least for 5 years.

The manufacturer shall specify a batch or lot in his quality plan.

A batch or lot shall only be released for supply when all the relevant tests and inspections have been carried out at least once at the specified frequencies and the requirements have been met.

If a product fails in respect of any characteristic given in Table A.6 and A.7, as applicable, the batch or lot shall be rejected or the retest procedure shall be performed for the characteristic on which the product failed.

The retest procedure shall be given in the manufacturer's quality plan.

7.3.2 Product Verification test (PVT)

Product verification testing is carried out by the producer and includes determination of the characteristics listed in tables C.8 and C.9 with the specified minimum sampling frequencies.

Documentation from the control should be kept at least for 5 years.

If a product does not conform to the requirements in respect of any characteristic given in Table A.8 and A.9, as applicable, the retest procedure detailed in the manufacturer's quality plan shall be performed.

If the retest procedure does not confirm conformity of the product to the requirements, then the process shall be investigated and corrected in accordance with the procedures given in the manufacturer's quality plan, as well as to verify the characteristics given in Table A.7 to Table A.8, as applicable.

A test performed as an AT does not need to be repeated as a PVT.

7.3.3 Indirect testing

Generally, testing shall be performed using the test methods referred to ISO 21003. Indirect testing may be used for BRT characteristics as given in Table A.6 and Table A.7. Indirect testing shall not be used for TTs, PVTs or ATs.

The indirect test method used and the correlation or safe relationship of the indirect testing to the specified testing shall be documented in the manufacturer's quality plan. The continuing validity of the indirect testing shall be checked at regular intervals.

In cases of dispute, the BRT as specified in Table C.6 and Table C.7 shall be used.

The indirect testing shall be accepted by certification body.

7.4 Periodical audit and audit testing

Periodical audit and the audit testing of all system components (materials/compounds, multilayer pipes as well as fittings made of plastic and metallic materials), as part of the current certificate shall be carried out according by an inspection body and testing laboratory according to the specifications defined in the GRPC.

The periodical audit shall verify that the manufacturers FPC system for the relevant products at the production site(s) is according to this PEG.

If the requirements are not fulfilled the certification body decides, if necessary in consent with the inspection body/testing laboratory concerned, which actions shall be taken.

Deficiencies in the internal control and/or in the test results may result in a cancelling of the approval marking temporarily or definitely until actions are taken to state correct quality. The certification body may even extend the number of testing to be carried out within a fixed period.

Note:

See the GRPC

7.5 Change in design, compound, production site, production method and extension of product range

Relevant type testing shall not only be carried out on new systems, but whenever there is a change in design, compound, production site or production method, other than routine in-process adjustments, and/or whenever there is an extension of the product range.

In all these cases the characteristics according to NWIP CEN ISO/TS 21003 part 7 (2015) has to be tested.

The applicant shall in advance inform the certification body of any relevant change.
Only products with changes approved by the CB can be certified.

8. MARKING

Pipes and fittings included in the certificate shall be marked with:

- Information according to EN ISO 21003-2 clause 16 or EN ISO 21003-3 clause 12 respectively.
- The conformity mark according to the specific rules of the CB, see the table 2 of the GRPC
- If relevant, the certificate number

9. REGISTER

Register of approved systems according to this product evaluation guideline can be found on the homepage of each certification bodies of this co-operation, see GRPC, table 1.

ANNEX A

Extent of testing

A.1 Type testing (TT)

Table A.1.1 — Characteristics of PE-X /AI, PE-RT/AI, PP-R/AI and PP-RCT/AI pipes that require type testing (TT)

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 5

The hygiene requirements find in Annex B of this document.

Table A.1.2 — Characteristics of plastic fittings that require type testing (TT)

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 7

The hygiene requirements find in Annex B of this document.

Table A.1.3 Metal fittings - Characteristics of metal fittings that require type testing (TT)

Characteristic	Reference to part and clause or subclause of ISO 21003 2008	Conditions requiring test ^b					Sampling procedure	
		I	D	M1	P	E	Manufacturer	Certification body; b
Influence on water intended for human consumption see Annex B	-	+	-	+	+	+ _d	-	See table C.5 1 test piece of smallest diameter
Material : Brass/Red Brass: EN 12163- EN 12168 EN 1982 Stainless steel: EN 10088 EN 10283 Fittings: EN 1254-3 EN 1254-6 EN 1254-8	Part 3, Clause 5.3	+	-	+	+	-	One evaluation per material	Evaluation checked by certification body
Sealing elements according to EN 681-1	Part 3 Clause 9.3	+	+	+/-	-	+ -		One evaluation acc. to EN 681-1:2006-11, table 3e
Appearance	Part 3, Clause 6.1	+	+	+	+	+	5 test pieces/ size/fitting type ^f	5 test pieces of one diameter/ size group/ fitting type
Dimensions	Part 3, Clause 7	+	+	+	+	+	5 test pieces/ size/fitting type ^f	5 test pieces of one diameter/ size group/ fitting type
Resistance to internal pressure	Part 3, Clause 8	+	+	+	-	+	3 test pieces/ size/ fitting type for the relevant design pressure and appropriate class of application ^f	3 test pieces of one diameter/ size group/ fitting type for the relevant design pressure and appropriate class of application
Marking	Part 3, Clause 11	+	+	+	+	+	5 test piece/ size/ fitting type ^f	5 test piece of one diameter/ size group/ fitting type
^b I: initial type test; D: change in design; M1: change of material; P: change of production site (same product) E: extension of product range; +: test to be carried out. ^d Recommended sampling procedure for a testing laboratory working for a certification body ^e Positive list compliance (see table C.5) does not need to be repeated if the fitting is made from the same material as the pipe. ^f Only if the extension of product range consist of introducing a reference of a smaller diameter. (increase in S/V)								

Table A.1.4 — Characteristics of fitness for purpose of the system that require type testing (TT)

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 8

The hygiene requirements find in Annex B of this document.

A.2 Batch release testing (BRT)

Table A.2.1 - Characteristics of pipes and minimum sampling frequencies for BRT

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 9

The hygiene requirements find in Annex B of this document.

Table A.2.2 — Characteristics of fittings and minimum sampling frequencies for BRTs

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 9

The hygiene requirements find in Annex B of this document.

A.3 Process Verification Test (PVT)

Table A.3.1 Characteristics of pipes and minimum sampling frequencies for PVT

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 10

The hygiene requirements find in Annex B of this document.

Table A.3.2 Characteristics of fittings and minimum sampling frequencies for PVT for fittings

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 10

The hygiene requirements find in Annex B of this document.

A.4 Audit test (AT)

Table A.4.1 Characteristics of pipes and minimum sampling frequencies for AT

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 11

The hygiene requirements find in Annex B of this document.

Table A.4.2 Characteristics of fittings and minimum sampling frequencies for AT

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 11

Characteristic	Reference to part and clause or subclause of ISO 21003	Minimum sampling frequency
Influence on water intended for human consumption		One test piece per 5 years
Positive list compliance a		One test piece per years
TOC		One test piece per years

Details for the hygiene requirements find in Annex B of this document

Table A.4.3 Characteristics for fitness for purpose and minimum sampling frequencies for AT

See CEN ISO/TS 21003-7:2008 + Amd 1:2010, table 11

The hygiene requirements find in Annex B of this document.

ANNEX B

Approval scheme for organic products in contact with water intended for human consumption

1 Scope

The pipes, fittings and joints of the piping system as specified in clause 1 “Scope” shall be suitable for the transport of water intended for human consumption. This annex lays down the assessment scheme for this characteristic, and is applicable to products made completely or partly from plastic materials.

Note 1: This Annex is a concrete implementation of the Article 10 of the Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption and is based on the scheme notified to the European commission (Notification number 2015/234/P).

Note 2: As long as no European hygienic scheme is in place, only the characteristics relevant for the EU member state for which the approval is requested, shall be tested.

This Annex does not apply to elastomers prepared from natural or synthetic rubber materials, nor to metals.

2 Definitions and Abbreviations

2.1 Definitions

For the purpose of this scheme of assessment, the following definitions shall apply:

- a) ‘Additive’ means a substance which is intentionally added to plastics materials to achieve a physical or chemical effect during processing of the plastic or in the final material or product; it is intended to be present in the final material or product;
- b) ‘Production aid’ shall mean any substance which initiates polymerization and/or controls the formation of the macromolecular structure and/or provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or products nor has a physical or chemical effect in the final material or-product;
- c) ‘Ancillary substances, means all substances other than additives and/or monomers and starting substances;
- d) ‘Maximum reference concentration’ shall mean the maximum allowable concentration of a substance in water intended for human consumption, which shall correspond to Drinking Water directive 98/83/EC or in reference bibliography;
- e) ‘Maximum tolerable concentration at the tap (MTC_{tap}) shall mean the maximum permitted amount of a substance that may migrate to tap water, in order to ensure that the material in contact with the water does not pose a risk to the health of consumers;
- f) ‘Component’ shall mean a part manufactured out of a specific material, placed on the market as a product, part of an assembled product or as a separate part. Components may be considered as products and be individually approved (e.g. O-ring, gaskets) or tested in the final product (e.g. valve);
- g) ‘Composition’ or ‘Chemical formulation’ shall mean the description of the nature and proportions of the different chemical substances found in a material;
- h) ‘Conversion Factor’ ‘FC’ shall mean the factor used to convert the result obtained in the migration test carried out on the product to be approved, for an average concentration representative of the real situation. The concentration is calculated and subsequently compared against the maximum tolerable concentration of the analyte in the water intended for human consumption;

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- i) 'Positive List' shall mean a list of chemical substances accepted for the manufacture of a material or product to be used in contact with water intended for human consumption, after being assessed and in compliance with the criteria laid down in the clause 7 of this Scheme of Assessment;

Note: As long as the 4MS group has not finalized a common and mutual recognized positive list (i. e. the so-called "4MS Plastic Core List"), the applicable reference documents are listed in clause 7

- j) 'Material' shall mean the prepared form of a substance or combination of substances, in a specific formulation and suitable for use in a manufacturing process;

Note: The word "Compound" or "Formulation" is often used as an alternative to "Material".

- k) 'Product' shall mean the manufactured item or component thereof, which is clearly identified and in its finished form shall be submitted by the product supplier to the certification and/or approval process. The product may be a component or equipment which is in contact with water throughout the entire water supply system from the source, treatment and distribution network to the consumer's tap;
- l) 'Substance' shall mean a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.
- m) 'Product type' may be the following: a product consisting of a single material or of different materials; a multicomponent product (a product assembled with two or more components, possibly of different materials, such as meters, taps, showers); a multilayer product (a product including two or more layers which are interlinked to form a single item).
- n) 'Product supplier' is the person, company or organisation placing the product on the market in the European Union and responsible for its compliance certification.
- o) 'Material or component supplier' is the person, company or organisation supplying a material or component which is used in the construction of the product by the product supplier.
- p) 'Certification body' is the accredited third-party organisation responsible for conducting the relevant procedures for demonstrating compliance with this certification scheme
- q) Programme of Requirements shall mean the programme prepared by the certification body, prior to its implementation, which contains the product conformity assessment requirements in accordance with this scheme of assessment.
- r) Coated means the finished materials, prepared mainly from plastic materials, applied to form a layer/film on a substrate in such a way as to create a protective layer and/or to impart a technical performance

2.2 Abbreviations

CF	Conversion Factor
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
C _{Tap}	Concentration of the substance in tap water
DoC	Declaration of Conformity
DWPLL	Drinking Water Positive List Limit
MTC	Maximum Tolerable Concentration
NIAS	Non-Intentionally Added Substance
SML	Specific Migration Limit
TOC	Total Organic carbon

3. Conformity of the material

All the organic⁽¹⁾ materials (compounds/formulations) used in the manufacture of products in contact with water, shall be subject to the confirmation of conformity of the chemical substances which they are made of, in accordance with the following requirements:

(1): Non organic materials, such as metallic parts of a fitting, shall also comply with the applicable regulation in the place of use.

a. The toxicological assessment of the complete formulation shall be realized with following limits:

- Pipes and fittings 0,1%
- O-rings and other fitting components 0,5%

b. For the conformity assessment, the material or component supplier shall confirm to the product supplier or the certification body that all monomers, and additives used in the material are included on the positive list of substances (clause 7). However substances with specific migration limits shall be disclosed.

In the following cases only, disclosure of the identity of a substance in the DoC is not mandatory if the certification body is informed on the presence of non-disclosed substances, and the certification body confirms that:

- i) the substance is not migrating in detectable concentrations, with indication of the detection limit⁽²⁾, if the material is used under the conditions of use explicitly specified in the DoC. or
- ii) one tenth of the restriction cannot be exceeded up to a given material layer thickness or concentration of material in a blend, provided the conditions of use for which compliance is calculated or tested are clearly specified, or
- iii) the residual concentration is so low that one tenth of the restriction is not exceeded on the basis of worst case calculation or modelling or migration data.

Sub- paragraphs (i) (ii) and (iii) can be refined based on the appropriate level of communication, allowing the certification body to prove on the basis of the information received on the other materials supplied from the same or other suppliers that the SML cannot be exceeded

(2): The detection limits can be an experimental value or a threshold used from modelling or worst case calculation. The detection limit of the analytical method has to be below the applicable restriction of the given substance

c. Substances used in materials may contain impurities originating from their manufacturing or extraction process. These impurities are non-intentionally added together with the substance (non-intentionally added substance – NIAS) [1]. As far as they are relevant for the risk assessment the main impurities of a substance should be considered and if necessary be included in the specifications of a substance. However it is not possible to list and consider all impurities in the authorisation. Therefore they may be present in the material or product but not included in the positive list of substances (clause 7)

Also, during the manufacture and use of materials and products, reaction and degradation substances can be formed. These reaction and degradation substances are non-intentionally present in the material (NIAS). As far as they are relevant for the risk assessment the main reaction and degradation substances of the intended application of a substance should be considered and included in the restrictions of the substance. However it is not possible to list and consider all reaction and degradation substances in the authorisation. Therefore they should not be listed as single entries in the positive lists of substances (clause 7).

Any potential health risk in the final material or product arising from use of production aids which are not listed in the clause 7, or from reaction and degradation substances should be assessed by the certification body in accordance with internationally recognised scientific principles on risk assessment.

d. Monomers and other precursors, production aids and additives shall be of good technical quality and not used in amounts exceeding those strictly required for the production of the product. Substances used in the manufacture of plastic layers in plastic materials and products shall be of a technical quality and a

purity suitable for the intended and foreseeable use of the materials or products. The composition shall be known to the manufacturer of the material and made available to the product supplier or certification body on request.

- e. The positive lists (clause 7) are not exhaustive and do not exclude the use of other substances. A substance not included in the lists may be accepted in the approval of the product, if demonstrated, on a case-by-case basis, by migration tests or validated mathematical modelling (e.g. Piringer) and using a suitable conversion factor, that the expected concentration of the substance in the water is lower than 0.1 µg/l at the tap. Based on this evidence the substances can be used without the need to add these substances to the positive list. The concentration level 0.1 µg/l for C_{tap} may be raised to 2.5 µg/l if the genotoxicity tests show no genotoxic effect [2].
- f. In the assessment to be carried out, it shall be recognised that not all chemical substances used in the manufacture of the product will migrate to the water. Some substances form the stable part of a polymer and others will disappear during production, while others will completely decompose.

The conformity assessment of the chemical formulation of the product shall constitute a precondition for defining the migration tests of the effects on water quality. On basis of the data of the toxicological conformity assessment of the chemical formulation of the material, the Programme of Requirements shall be established to define at least the following elements:

- Collection conditions and preparation of the samples to be tested;
- Assessment tests of the effects on water quality;
- Identification of the relevant substances/parameters to be checked in the migration water;
- Assessment criteria of the laboratory results;
- Product acceptance criteria

4 Assessment of the effects on water quality

The product shall be submitted to tests in order to assess the organoleptic influence of the material and the migration of chemical substances to water, using the test methods and conditions of Table 1.

Tests shall be carried out on a sample, collected randomly in a batch of a product, if applicable, representative of the family of products intended to be placed on the market, provided that their chemical constitution and manufacturing and packaging conditions are identical or deemed to be equivalent.

**Table 1 - Hygienic requirements and test methods
for products in contact with water intended for human consumption**

Characteristic ^(a)	Test Method	Assessment Method	Test conditions	Recommended Acceptance criteria	
Organoleptic aspects					
Odour	EN 1420	EN 1622	23°C	≤ 8	
Flavour	EN 1420	EN 1622	23°C	≤ 8	
Colour	EN 13052-1	EN ISO 7887	23°C	≤ 10 mg/l PtCo	
Turbidity	EN 13052-1	EN ISO 7027	23°C	Max 0.5 NTU increase	
migration of substances to water ^(b c)					
TOC ^(d)	EN 12873-1 ^(e)	EN 1484	23°C and 60°C	C _{tap} ≤ 2 mg/l C	
Parameters Drinking Water Directive		Accredited method to determine the substance to be analysed	23°C and 60°C	C _{tap} ≤ 20 % of the parametric value set out in Drinking Water Directive [3]	
Specific substances of positive list	Migration modelling	CEN/TR 16364	23°C and 60°C	C _{tap} < limit specified in the Positive List	
	Or				
	EN 12873-1 ^(e)	Accredited method			
Unsuspected substances	Migration modelling	EN/TR 16364	23°C	^(f)	
enhancement of microbial growth					
EMG	EN 16421	method 2 (biofilm volume)	23°C	a) products with ≤(0,05+0,02)ml/ 800cm ² b) large area sealing < (0,12+0.03) ml / 800 cm ² c) small area sealing < (0,20+0.03) ml / 800 cm ²	
<p>a) As long as no European hygienic scheme is in place, only the characteristics relevant for the EU member state for which the approval is requested, shall be tested.</p> <p>b) For organic materials, dissemination models for the estimated calculation of the level of migration of a substance under certain conditions, avoid more complex, time consuming and costly tests. Instead of the migration test, mathematical models such as the Piringer model may preferably be used to calculate the estimated level of migration of substances from materials in water intended for human consumption. Conditions are described in CEN/TR 16364 (Prediction of migration from organic materials using mathematical modelling).</p> <p>c) Conversion factors shall be applied to migration results to calculate the estimated concentration at the tap (see 5.1)</p> <p>d) The value obtained in the TOC test may be used to demonstrate that the levels of total organic carbon are so low that the concentration limits of a particular substance in the tap water cannot be exceeded.</p> <p>e) Unless the acceptance criteria is met before, the assessment should be based on the 30th day migration exposure (ie 9th migration in cold water and 22nd migration in hot water)</p> <p>f) Unsuspected substances acc. EN 15768 is not listed due missing evaluation criteria</p>					

5 Acceptance criteria

Product approval shall only be given provided that there is compliance with all the applicable requirements in the country where the product will be placed on the market.

5.1 Conversion factors

Conversion factors shall be used to convert the migration test result into an average concentration representative of the real situation. The calculated concentration shall be subsequently compared with the MTC (in mg/l or µg/l) of the substance in the tap water set out in the Positive List.

In accordance with the requirements set out at European level, any CF is composed of a geometric factor (F_g , which depends on the surface area/volume ratio stated in dm^{-1}) of the product and an operational factor (F_o , residence or contact time of the water, stated in days).

Table 8 – Criteria applied to the conversion factors

Product group: Piping	$F_g = S/V$ (dm^{-1})	$F_o = t$ (days)	$CF = F_g \times F_o$ (days. dm^{-1})
Building network: (10 mm ≤ ID < 160 mm)	Max 40 ^(a)	0.5	Max 20
Distribution network: (80 mm ≤ ID < 300 mm)	Max 5 ^(a)	2	Max 10
(a) use real S/V of the smallest dimension, max. 40, max, 5			

In Table 9 CFs for product groups are shown, depending on their application.

Table 9 – Conversion factors per product group

Product group		CF (day.dm-1)
A.	Pipes and their internal coating	
A1	Hot & cold (building networks, buildings)	20
A2	ID < 300 mm (distribution network)	10
B	Fittings	
B1	Hot & cold (building networks, buildings)	4
B2	80 mm ≤ ID < 300 mm (distribution network)	2
C	Ancillary components (a)	
C1	ID < 80 mm (building networks, buildings)	0.4
C2	80 mm ≤ ID < 300 mm (distribution network)	0.2
(a) Group C includes fitting components such as o-rings and other parts, if tested separately. If a product is tested as a unit then the CF of Group B shall apply..		

Notes:

(1) If a series of different products is made from the same raw material and the same ancillary materials under the same manufacturing process (the so-called product family), and the product with the highest S/V is assessed and approved, then the whole range of products shall be permitted to be used for all areas of application within the product group without requiring additional testing.

For process verification and audit tests other than the smallest pipe diameter may be tested. If, in this case the field concentration C_{tap} exceeds MTC_{tap} and half the value of the last measured concentration does not exceed MTC_{tap} the test shall be repeated on a pipe sample made of the same material but smaller diameter, e.g. worst case ID = 10 mm.

(2) Fittings are considered to be a complete functional unit made up of one or more components or materials, which may be in contact with water, e.g. taps, valves, meters pipe links, flexible fittings.

5.2 Calculation of the expected concentration of the substance in water

The migration of substances from materials to water depends on the type of material and migration conditions (temperature, contact time, S/V ratio and hydraulic condition of the water). The (S/V) ratio of the tested sample and contact time in the migration test, carried out in accordance with EN 12873-1 are different from the real use of the product in situations of normal operation.

The migration speed (M_n) of the test substances for water should be calculated as specified in the migration testing standards:

$$M_n = C_n / (S/V \times t), \text{ stated in } (\text{mg} \cdot \text{dm}^{-2} \cdot \text{d}^{-1})$$

To assess product conformity, the results of the maximum concentration of substances (in mg/l or $\mu\text{g/l}$) obtained at laboratory-scale should be converted to real-scale by applying a CF.

The results obtained in the n th migration period (at 23 °C and high temperatures) are used to estimate the concentration of the substance in tap water (C_{tap}):

$$C_{\text{tap}} = M_n \times \text{CF}, \text{ stated in } (\text{mg/l or } \mu\text{g/l}),$$

where:

- M_n is the migration speed of migration period n
- n is the sequence number of the migration period (1, 2, 3, ...22). (Period 22 corresponds to day 30 at 60°C and 85°C)
- C_n is the concentration of the substance measured in mg/l for migration period n
- S/V is the ratio of the surface area by volume in dm^{-1}
- t is the duration of the migration period in days (1 or 3 days)

In the case of a low risk product, conformity may be demonstrated, without the need for migration tests, by calculating the estimated concentration of the substance to the migration water, from the assessment of its chemical formulation presented with the level of specification of 0.1 % (m/m). For this purpose, the product supplier or certification body shall demonstrate the conformity assessment of the product and provide all the relevant information on the application thereof, as follows:

- Average amount used in the application of the product;
- Potential disappearance of solvents due to evaporation;
- Possible interaction between substances;
- Configuration of the piping systems, such as number of connections;
- Contact surface;
- Volumes of water in the system.

The estimated concentration of the migration of substances to the water may be calculated by one of the following methods:

- Analytical determination of the substance in the migration water, using an appropriate method of analysis, with a limit of detection of at least 0.1 $\mu\text{g/l}$;
- Mathematical modelling recognised by the 4MS Group
- Calculation of the average migration of the amount of the substance, used in the manufacture of the product, to the migration water over 100 days, based on the "wetted thickness" [5] of the plastic material in contact with water, which is specified as 100 μm for polyolefin and 50 μm for all other plastic products:

$$C (\mu\text{g/l}) = Q (\%) \times (S/V) \times E_w \times D \times 10^6 / (100 \times 100)$$

where:

- C - Average concentration over 100 days of the migrant into the water in µg/l
- Q - Content of the migrant in the organic material in %
- S/V - surface/volume ratio of the product in dm⁻¹
- E_w - Wetted thickness (m). It is 100 µm for polyolefin and 50 µm for other materials
- D - Density of the product in kg/m³
- 10⁶ - Factor due to the conversion of concentration in g/l into µg/l
- 100 - Factor due to the expression of the concentration in %
- 100 – 100. Migration (24h)

Using the following mathematical relation, the maximum concentration of a migrant in the plastic material can be calculated for having an average worst-case migration over 100 days equal to 0.1 µg/l.

$$Q(\%) = 0.1 (\mu\text{g/l}) \times 10^{-2} / [E_p \times (S/V) \times (D_{\text{pol}}/D_w)]$$

where:

- Q – content of the migration substance in the plastic or silicone material
- E_p - the total thickness of the plastic or silicone material
- S/V - the surface/volume ratio
- D_{pol} – density of product
- D_w – density of water

However, this assessment does not apply to substances classified, proven or suspected, as carcinogenic, mutagenic or toxic to reproduction (CMR), if not authorized by the Commission.

5.3 Assessment of product conformity

When assessing product conformity, the following requirements shall be applied:

- The toxicological conformity of the materials of the product with the criteria set out in the positive lists of clause 7.
- Products must fulfil the requirements for the organoleptic aspects set out in accordance with clause 4.1 after three, respective nine migration periods for cold water and after seven, respective twenty-two migration periods for warm and hot water, as far as relevant to the product concerned.
- The concentration of the substance in the water should not increase during the migration test. If more than three migration periods are necessary to demonstrate the downward trend of the concentration of the substance in the water, the total migration test time may be extended to nine migration periods for cold water and 22 for warm or hot water.
- The expected concentration of the substance at the tap (C_{tap}), determined by migration tests in accordance with the standards specified in this Scheme for Assessment [4] and after the conversion factor has been applied, should be compared to the maximum tolerable concentration at the tap (MTC_{tap}): $M_n \leq (MTC_{\text{tap}} / CF)$; $C_{\text{tap}} \leq MTC_{\text{tap}}$.
- If the C_{tap} value is not in accordance with the MTC_{tap} value on day 9 of the migration time, (3rd migration at 23°C, or 7th migration at 60°C [4] and if it is expected that the migration speed of the substance shall decrease over time, the migration test may be extended to a total migration time of up to 9 migration periods in cold water and twenty-two for 60°C, in compliance with that specified in the migration testing standard.
- To assess the level of impact of the product on water quality, an assessment must be carried out of the results of the maximum concentration of the substances analysed in the water (C_{tap}), after the application of the CF as set out in this Annex, applying the criteria given in Table 1.

6 Positive lists for plastic products

As long as the 4MS group has not finalized a common and mutual recognized positive list (I.e. the so-called “4MS Plastics Core List”), the assessment of the compound/formulation shall be done by the use of one of the following documents from clause 7.1 to clause 7.4.

6.1-Applicable published documents of the 4MS group

- 4MS Common Approach, Positive Lists for Organic Materials, Part A – Compilation and management of a suite of Positive Lists (PLs) for organic materials [2]
- 4MS Common Approach, Positive List for Organic Materials Part B – Assessment of products for compliance with Positive List requirements [4]
- 4MS Group Combined Positive List of Organic Substances in Contact with Drinking Water

Note: The latest issues are published at:

<http://www.umweltbundesamt.de/en/topics/water/drinking-water/distributingdrinking-water/approval-harmonization-4ms-initiative>

6.2 Applicable Dutch positive lists)

To be filled in later

6.3 Applicable French positive lists

To be filled in later

6.4 Applicable German positive lists

To be filled in later