Requirements and test methods for products made of Organic Materials in Contact with Drinking Water

4MSI Draft Common Approach on Organic Materials– Part C

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 accepting organic materials and 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 procedure for the assessment of acceptance of products made of organic materials in contact with drinking water (PDW) in respect to their effect on water quality. It describes requirements, methods and limits. It will not describe the conformity procedure. It has been prepared in accordance with the 4MS 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 document as a starting document for a common basis for implementing the concept for the assessment of organic materials and products in their national regulations. The document provides an overview of requirements that can be included in the set of requirements for products and materials that come into contact with drinking water. A decision on the complete set of requirements and the pass/fail criteria to be set has not been taken yet, and therefore no fully agreed Common Approach is available at the moment. The document is subject to revisions agreed by the 4MSI.

Furthermore, this document 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 organic materials and products 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 acceptance of organic materials and products.

Abbreviations

BPP - Biomass Production Potential
C_{tap} – The calculated concentration of a substance at the tap
CF – Conversion Factor
DWD – Council Directive 98/83/EC - Drinking Water Directive
EMG - Enhancement of Microbial Growth
EN – European Standard
GC-MS - Gas Chromatography-Mass Spectrometry
ID – Internal Diameter
JMC – Joint Management Committee (4MS Common Approach)
MDOD - Mean Dissolved Oxygen Difference
MS – Member State
MTC_{tap} – Maximum Tolerable Concentration at the tap
$MTC(T)_{tap}$ – Maximum Tolerable Concentration of a group of substances at the tap
n – Sequence number of the migration period
NIAS - Not Intentionally Added Substances
PDW – Product coming into contact with Drinking Water
PL – Positive List
POD – Point of Departure
PV – Parametric Value (in the DWD)
QM – Quantity Maximum (see definitions)
QMA – Quantity Maximum per unit Area (see definitions)
RG – Risk Group
SML – Specific Migration Limit
S/V – Surface area-to-Volume ratio
t – Duration of the migration period in days
TDI – Tolerable Daily Intake
TFN – Threshold Flavour Number
TOC – Total Organic Carbon
TON – Threshold Odour Number
TRP – Toxicological Reference Point
TTC – Threshold of Toxicological Concern
WHO – World Health Organization

Table of contents

1. Background
1.1. General

Products that are made of organic materials and which are in contact with drinking water (DW) could impair the drinking water quality by:

- Leaching of substances at levels that pose a potential risk to human health;
- Enhancement of microbial growth (EMG);
- Organoleptic problems.

Council Directive 98/83/EC on the Quality of Water Intended for Human Consumption (DWD) establishes a high level of protection for the consumer and requires Member States to ensure that substances and materials used in preparation and distribution of drinking water do not reduce that level of protection. The Directive's point of compliance is at consumers' taps. This implies a need for control of all products in contact with drinking water (PDW), including pipes and ancillaries within consumers' premises.

The definitions as given in the "4MSI Common Approach - Management of the Positive Lists for Organic Materials" are applicable.

1.2. Principles of the acceptance procedure for PDW

Requirements for the acceptance of PDW depend on the risk group in which the product or component is categorized. The requirements for each risk group are described in Section 2.
The requirements can be found in Section 3 (parameters and pass/fail criteria) and the methods for testing in Section 4. In Section 5 the evaluation of the results is described.

The procedure for acceptance of organic PDW is based on:

- The compliance of the formulation with the Positive Lists;
- The migration testing and the compliance of the results with the acceptance criteria
    - Odour (TON), flavour (TFN), colour, turbidity, foaming
    - Total Organic Carbon (TOC)
    - Maximum Tolerable Concentration at the tap (MTC_{tap}) for formulation related substances
    - Formulation specific requirements on specific materials
    - GC/MS-screening
- Enhancement of Microbial Growth (EMG)
- The product certification (this point will be developed in a separate document).

A schematic overview of the testing procedure is included in Annex A, and a summary of parameters and acceptance criteria is in Annex E.

1.3. Scope

The Common Approach described in this document applies to all products and components in contact with drinking water made of organic materials, except for:

- membrane filtration products
- ion exchange resins,

as for these products, migration tests and requirements are different and are described in separate future documents.

2. Risk groups

Requirements for the acceptance of PDW depend on the risk group in which the product or the component is categorized. The assessment of the product is carried out type of material specific, which means that for a product made of different organic materials and metallic parts, the risk groups apply for the components of a specific organic polymer. For categorization into risk groups, all components of a product that are made of the same polymer, have to be considered together.

The applicable requirements result from the use of materials in individual products or for components in accordance with a risk-based approach. The conversion factors (see Annex B) of the products or components to be applied serve as the basis for the classification.

In Table 1 the requirements for approval of products or components in contact with drinking water are summarized. The table is comprised of rows with risk groups RG1 to RG5, and columns with the approval requirements. For further details see “Common Approach on Certification and approval of products in contact with drinking water”.

Table 1: Risk based testing program for products

Risk group*	Conversion factor*	Formu-lation review	Specific migration testing (formulation related requirements****)	Organoleptic testing	EMG	TOC	screening of NIAS
RG1	≥ 4	Yes	Yes, on product	Yes, on product	Yes, on product or formulation**	Yes, on product	Yes, on product
RG2	≥ 0.4 and < 4	Yes	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
RG3	≥ 0.04 and < 0.4	Yes	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
RG4	≥ 0.004 and < 0.04	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
RG5	< 0.004	No	No	No	No	No	No

* see product listing for applicable risk group and conversion factor

** For pipes and coatings on pipes in domestic installations (products with a CF of 20 day/dm) EMG needs to be tested on the product

*** Except for the following materials: rigid plastics

**** Sometimes also referred to as “additional requirements” due to additional testing depending on the specific material

3. Requirements for products made of organic materials

The requirements mentioned in this section are directly linked to the test methods described in Section 4**.** The requirements mentioned in the current section apply to materials used in products or components that are in risk group RG1. The requirements for products in risk groups RG2 through RG5 can be different, as less tests will be required (see table 1).

3.1. Requirements for the formulation

Only the substances listed in the Union List of Regulation (EU) No 10/2011, and in the 4MSI-Positive Lists may be intentionally used in the manufacture of PDW, taking into account the specific material (for example plastic, rubber, coating, silicon, thermoplastic elastomer (TPE) and lubricant). Substances that are in the Union List of Reg. (EU) No 10/2011 may be used in all types of materials in contact with drinking water, when used with the same function as the function listed for the plastic. With “4MSI Positive Lists”, the 4MSI Core List is meant, and for a transitional period, also the 4MSI Combined List, where permitted.

In addition, the following substances not included in the lists mentioned above can be used intentionally:

(a) all salts of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of listed acids, phenols or alcohols;

(b) mixtures obtained by mixing authorised substances without a chemical reaction of the substances;

(c) when used as additives, natural or synthetic polymeric substances of a molecular weight of at least 1000 Da[1], except macromolecules obtained from microbial fermentation, complying with the requirements for formulations of PDWs, if they are capable of functioning as the main structural component of final products;

(d) when used as monomer or other starting substance, pre-polymers and natural or synthetic macromolecular substances, as well as their mixtures, except macromolecules obtained from microbial fermentation, if the monomers or starting substances required to synthesize them are listed;

(e) substances for which no migration of the substance, its impurities and/or its reaction and degradation products into drinking water occurs at concentrations at or above 0.1 µg/l at the consumer’s tap. This only applies to substances that do not belong to either one of the following categories:

- substances classified as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B, in accordance with CLP Regulation No. 1272/2008;
- substances intentionally in nanoform;
- monomers of the main polymer in the material

It has not yet been decided on whether a restriction on the maximum weight percentage of use in the formulation will be added to these substances. When making this decision, the performance of the screening method for migration of 'Not Intentionally Added Substances' (NIAS) could be taken into account.

(f) pigments and colorants, as long as they comply with purity criteria as defined in Annex C, and do not migrate at or above 0.1 µg/l.

(g) solvents which are not classified as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B, in accordance with CLP Regulation No. 1272/2008, and are completely removed during the manufacturing process as confirmed with testing if required, taking into account boiling point, temperature of manufacturing process and use of the product.

[1] 1500 Da in case of perfluorinated compounds

Substances that are listed shall only be in the formulation when used in the function for which they are listed, and when this is in compliance with the specific requirements mentioned in the positive lists. The restrictions and specifications in the Union List of Reg. (EU) No 10/2011 are also applicable to the use of the substances in the formulations of PDW's.

Pigment and fillers must comply with the purity criteria as defined in Annex C. Substances with an intentional nano structure have to be assessed for the nano structure and be listed accordingly in the respective positive list. Biocides used as in-can preservatives (Product Type 6) can only be used when their use is allowed under Commission Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products, and if no antimicrobial activity is carried out on the surface of the PDW.

In case of multi-layer products with a total barrier (for example, an aluminium layer), only the layers on the drinking water contact side have to comply to the requirement that the substances used are listed in positive lists.

The full formulation of the organic materials must be provided. A cut-off value is set, below which details of the formulation (i.e. chemical composition of ingredients) are not required. The cut-off value, expressed as weight percentage in the formulation is:

- 0.02% for one substance (and/or mixture), and
- 0.1% for the sum of all such substances (and/or mixtures).

3.2. General requirements for migration water

The following criteria are applicable to the migration water that is derived by testing of the product or component. The method of migration testing is described in 4.3.2.

3.2.1. ***Odour, flavour, colour, turbidity and foaming***

Products or components shall not give rise to a perceivable change to the odour, flavour, colour, turbidity or foaming of the water. The following acceptance criteria are set for the migration water:

- for odour (TON) and flavour (TFN) (see 4.3.3.2 for testing method):

1°) Pipes with internal diameter (ID) < 80 mm:

After 10 days (3rd migration period in cold, and 7th migration period in warm/hot water testing):

- if TON ≤ 8.0 and TFN ≤ 8.0, the product is deemed to have passed and the test can be stopped.
- if TON and/or TFN > 16.0 then the product is deemed to have failed.
- if TON or TFN > 8.0 and ≤ 16.0, then the testing can be continued to 31 days.

After 31 days (9th migration period in cold, and 22nd migration period in warm/hot water testing):

- if TON ≤ 8.0 and TFN ≤ 8.0, then the product is deemed to have passed.
- if TON or TFN > 8.0 then the product is deemed to have failed.

These thresholds apply to cold, warm and hot water tests.

2°) Other products:

After 10 days (3rd migration period in cold, and 7th migration period in warm/hot water testing):

- if TON≤ 2.0 and TFN ≤ 2.0, the product is deemed to have passed and the test can be stopped.
- if TON and/or TFN > 4.0 then the product is deemed to have failed.
- if 2.0 < TON/TFN ≤ 4 then the testing can be continued to 31 days.

After 31 days (9th migration period in cold, and 22nd migration period in warm/hot water testing):

- if TON≤ 2.0 and TFN ≤ 2.0 then the product is deemed to have passed.
- if TON≤ 2.0 or TFN > 2.0 then the product is deemed to have failed.

- for colour (see 4.3.3.3. for testing method):

C_{tap} ≤ 5 mg/l Pt/Co at 10 days (3rd migration period in cold water, 7th migration period in warm/hot water), or at 31 days (9th migration period in cold water, 22th migration period in warm/hot water) in case of extended testing.

- for turbidity (see 4.3.3.4. for testing method):

Turbidity ≤ 0.5 NFU at 10 days (3rd migration period in cold water, 7th migration period in warm/hot water), or at 31 days (9th migration period in cold water, 22th migration period in warm/hot water), in case of extended testing.

- for foaming (see 4.3.3.5. for testing method)
No visual foaming.

3.2.2. ***Total Organic Carbon (TOC)***

Products or components may not release more than 0.5 mg/l Total Organic Carbon (TOC) into the water (see 4.3.3.1 for testing method) expressed as C_{tap}. In addition, it is required to show that there is no increasing trend (in time / migration periods). However, if the TOC in the last migration period is below 0.1 mg/l expressed as C_{tap}, no trend-analysis is required.

This means the following test requirements apply:

After 10 days (3rd migration period in cold, and 7th migration period in warm/hot water testing):
- if C_{tap} ≤ 0.5 mg/l and 'no increasing trend' is shown, then the product is deemed to have passed and the test can be stopped.
- if 0.1 mg/l < C_{tap} ≤ 0.5 mg/l but 'no increasing trend' has not been shown, the testing can be continued up to 31 days.
- if 0.5 mg/l < C_{tap} ≤ 2.0 mg/l, the testing can be continued up to 31 days.
- if C_{tap} > 2.0 mg/l, then the product is deemed to have failed

After 31 days (9th migration period in cold, and 22nd migration period in warm/hot water testing):
- if C_{tap} ≤ 0.5 mg/l and 'no increasing trend' is shown, the product is deemed to have passed.
- If C_{tap} > 0.5 mg/l and/or the trend is increasing, the product is deemed to have failed.

The trend of the measured TOC values is considered increasing if the following criteria are met at the same time:
- the measured TOC concentration in the migration period relevant to the assessment is above 0.1 mg/l, and
- the measured TOC concentration in the migration period relevant to the assessment has doubled significantly compared to the lowest measured concentration (higher than the measurement uncertainty), and
- the measured concentration in the migration period relevant for the assessment is the highest measured value of the last three migration periods.

The criterion of 'no increasing trend' is considered to be fulfilled if:
- The slope of a linear fit of the TOC values in migration water has been significantly lower than zero (i.e. taking into account measurement uncertainty).

In all other cases, the trend cannot be decided on and therefore the duration of the test should be extended to 31 days.

3.3. Enhancement of Microbial Growth (EMG)

Products shall not enhance microbial growth. For Enhancement of Microbial Growth (EMG) testing (for method see paragraph 4.4), the following requirements apply:

- Biomass production potency (BPP) ≤ 1000 pg ATP/cm^2, or
- Biofilm volume ≤ 0.05 ± 0.02 ml/800 cm^2, or
- Mean dissolved oxygen difference (MDOD) ≤ 2.39 mg O_2/l (only for MS with chlorinated water)

For elastomers, special criteria are proposed, At the moment, the proposal is as follows:

For elastomers with large contact area:
- BPP ≤ 1000 pg ATP/cm^2, or
- Biofilm volume ≤ 0.12 ± 0.03 ml/800 cm^2, or
- MDOD ≤ 2.39 mg O_2/l (only for MS with chlorinated water)

For elastomers with small contact area:
- Biofilm volume ≤ 0.20 ± 0.03 ml/800 cm^2, or
- MDOD ≤ 2.39 mg O_2/l (only for MS with chlorinated water)

No change in S/V-ratio is permitted in the MDOD test. Values may be different for materials that are to be in contact with chlorinated and non-chlorinated water.

Unusual suppression of microbial growth is not allowed for the materials. Material may not show biocidal properties, as to be verified with the biofilm method or with a cytotoxicity test.

3.4. Formulation specific requirements

3.4.1. ***General***

In Table 1 “Risk based testing program for products” it is defined which products, according to applicable risk group, shall be subject to formulation specific testing and what type of test sample needs to be used for the test.

The formulation of a material or product may contain substances that are subject to specific requirements. In which documents these requirements are set, depends on the (type of) substance. In the following sections, the documents and different types of substances are described. In addition to restrictions defined in Positive List entries, specific requirements as set out in section 3.4.3 have to be tested for and must be fulfilled by the respective material or product.

3.4.2. ***Substance specific restrictions***

Substances listed in the 4MSI Positive Lists

For substances that are listed in the 4MSI Core List or 4MSI Combined List, the MTC_{tap} – if any – given in the lists apply. Migration limits might have been set to the substance itself, and/or for impurities, degradation products and/or reaction products of the substance. The list can also contain other substance specific requirements, e.g. in the form of restrictions on the use percentage of the substance, or on the maximum amount of impurities, or as a maximum residual content in the material (QM) or per area (QMA).

Substances listed in Regulation (EU) No 10/2011

For substances with a specific migration limit (SML) listed in the Union List of Regulation (EU) No 10/2011 the MTC_{tap} is set at: 1/20 * SML * 1 kg/l for all substances with a migration restriction. Other restrictions and specifications in the Union List are also applicable to the use of the substances in the formulations of PDW.

For substances that are listed in both in Union List of Reg. (EU) No 10/2011 and the 4MSI positive list for the relevant type of material, the MTC_{tap} and specifications and restrictions in the 4MSI positive lists prevail.

Polymeric additives and prepolymers

For polymeric substances and prepolymers, the MTC_{tap} of their monomers apply. In addition, for prepolymers with a Mw <1000 Da (or Mw < 1500 Da in case of perfluorinated prepolymers) for which an MTC_{tap} is available or can be derived, MTC_{tap} of the prepolymers (if available) also apply.

Metal elements and minerals

Metal elements and minerals might be constituents of an additive (e.g. stabilizers) or impurities (found in coloring agents and pigments, for example) of substances included in the Positive Lists. MTC_{tap} values for metal elements and minerals are listed in Annex D.

Salts of listed acids, phenols and alcohols

All salts of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of listed acids, phenols or alcohols are permitted to be used. For some of these minerals an MTC_{tap} has been set as 10% of the parametric value in DWD. For other cations, in parallel of Reg. (EU) No 10/2011, an MTC_{tap} is set at 1/20 of SML or 1/10 of WHO-guideline value. MTC_{tap} values for metal elements and minerals are listed in Annex D.

DWD-substances

For substances having a parametric value (PV) set in Directive 98/83/EC, the quantities migrating from the materials should not exceed 10% of the PV (see 4MSI Common Approach – Management of Positive Lists for Organic Materials), except for epichlorohydrin and vinyl chloride, for which 100% of the PV applies, as is determined by Note 1 of Annex 1- Part B of Directive 98/83/EC.

Trihalomethanes (THMs):

If the material releases organic substances, they may react with chlorine and form THMs or other disinfection by-products. At least the following four compounds should be analyzed (for method, see 4.3.3.6): chloroform, bromoform, dibromochloromethane and bromodichloromethane. The MTC_{tap} for the sum of these four compounds is set at 10 µg/l (as 10% of DWD-value).

3.4.2.1. Substance specific migration restrictions (MTC_{tap})

For all substances in the formulation of a product or component for which an MTC_{tap} is applicable, or for which an MTC_{tap} is set on one of its degradation or reaction products, it has to be demonstrated that:

- the expected concentration at the tap (C_{tap}) is at or below the Maximum Tolerable Concentration at the tap (MTC_{tap}), and
- the migration does not show an increasing trend (in time / migration periods).

This means that for a product or component the migration into water has to be assessed for each of the following substances:

- Substances that are intentionally added for which an MTC_{tap} applies.
- Impurities, degradation or reaction products of the intentionally added substances, for which an MTC_{tap} have been set in the entry of the intentionally added substance in the positive list.
- Substances that are not listed but intentionally added, as is permitted by paragraph 3.1 under (e), as well as their impurities and foreseeable degradation and reaction products. For these substances an MTC_{tap} of 0.1 µg/l applies.
- All substances for which an MTC_{tap} applies that are used in polymeric additives and prepolymers in the formulation.
- Metal elements and minerals that are present in the formulation, e.g. as constituent, salt or impurity.
- In case additional material and product specific criteria apply (see 3.4.3): all substances (or group of substances) for which an MTC_{tap} has been set.
- In case of migration into chlorinated water: the four trihalomethanes as mentioned in 3.4.2.

The following requirement applies to the cold water migration test:
$C_{tap} \leq MTC_{tap}$ for the 3rd migration period; or, in case extended testing is needed, at the latest for the 9th migration period. It has to be shown that there is no increasing trend in the C_{tap} in time.

The following requirement applies to the warm/hot water migration test:
$C_{tap} \leq MTC_{tap}$ for the 7th migration period; or, in case extended testing is needed, at the latest for the 22nd migration period. It has to be shown that there is no increasing trend in the C_{tap} in time.

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

There is an increasing trend of measured concentrations, if the following criteria are met at the same time:
- The measured concentration in the assessment-relevant migration period is over 1/10 of the migration restriction, and
- The measured concentration in the assessment-relevant migration period has doubled significantly (higher than the measurement uncertainty) compared to the lowest measured concentration, and
- The measured concentration in the assessment-relevant migration period is the highest measurement of the last three migration periods.

The criterion of 'no increasing trend' is considered to be fulfilled if:
- The slope of a linear fit of the TOC values in migration water is significantly lower than zero (i.e. taking into account measurement uncertainty).

In all other cases, the trend cannot be decided on and therefore the duration of the test should be extended to 31 days.

3.4.2.2. Restrictions on residual content of substances (QM and QMA)

In the 4MSI - PL and in the Union List in Reg. (EU) No 10/2011, there are substances for which a QM or QMA limit has been set. QM is the residual content in the polymer based on the mass of the polymer (in mg substance / kg polymer), and QMA is the residual content in the polymer based on the contact area (in mg substance per 6 dm^2). These values need to be checked in the component or product.

If it is not possible to analyze the substance in the migration water (e.g. isocyanates are hydrolyzed in water), the analysis of the residual content of the substance in the product is required. The QM and QMA limits apply independently of the product group of organic materials.

Where a substance with a QMA-limit can be determined in the migration water, the requirement may also be tested via migration testing. In these cases, the MTC_{tap} value is determined considering an "SML" value that is derived from the QMA value by assuming 1 kg of food is packed in a cube with a surface area of 6 dm^2 (SML = QMA × 6 dm^2/kg). The formula for calculation of an MTC_{tap} from QMA is: $MTC_{tap} = {}^{1}/_{20} \times QMA \times 6\ dm^2/kg \times 1\ kg/l$. This is however not applicable for substances that are listed with both a restriction in the form of QMA and an SML or MTC; in these cases, the MTC_{tap} as listed, or derived from the listed SML, prevails. Only one of the restrictions (QMA or MTC_{tap}) has to be tested; preference should be given to checking the MTC_{tap} value.

3.4.3. ***Material specific requirements***

For certain materials and products, specific requirements are set, e.g. to cover reaction products that are usually found to migrate from that type of material, and which are not directly related to a specific substance. In the following sections these requirements are detailed.

3.4.3.1. Plastics & Coatings

Requirements for plastics:
Stabilizers (e.g. antioxidants) are common constituents of plastics. The release of stabilizers into drinking water is rather low. However, for stabilizers bearing alkylphenol structural moieties (see some examples below table 2) there is evidence from migration water and drinking water testing, for release of related degradation products which might be of concern. In the case that these kind of stabilizers are used in the formulation, it is therefore required to have migration waters of plastics analyzed for the common degradation products specified in table 2.

Table 2: Degradation products of stabilizers with alkylphenol structural moieties required to be tested for in plastic products made from relevant formulations

I	4-Ethylphenol (CAS No 123-07-9)	MTC_{tap} = 0.1 µg/l
II	p-tert-Butylphenol (CAS No 98-54-4)	MTC_{tap} = 2.5 µg/l [1]
III	2,6-Di-tert-butyl-p-benzoquinone (CAS No 719-22-2)	MTC_{tap} = 2.5 µg/l
IV	2,4-Di-tert-butyl phenol (CAS No 96-76-4)	MTC_{tap} = 250 µg/l [1]
V	3,5-Di-tert-butyl-4-hydroxy styrene (CAS No 19263-36-6)	MTC_{tap} = 0.1 µg/l
VI	3,5-Di-tert-butyl-4-hydroxy benzaldehyde (CAS No 1620-98-0)	MTC_{tap} = 2.5 µg/l
VII	3,5-Di-tert-butyl-4-hydroxy acetophenone (CAS No 14035-33-7)	MTC_{tap} = 2.5 µg/l
VIII	7,9-Di-tert-butyl-1-oxaspiro[4.5]deca-6,9-diene-2,8-dione (CAS No 82304-66-3)	*to be defined* [2]
IX	3-(3,5-Di-tert-butyl-4-hydroxyphenyl)methyl propionate (CAS No 6386-38-5)	MTC_{tap} = 50 µg/l [3]
X	3-(3,5-Di-tert-butyl-4-hydroxyphenyl)propionic acid (CAS No 20170-32-5)	

[1] Possible revision of MTC_{tap} due to the pending ECHA re-evaluation.

[2] Restriction not yet defined due to insufficient toxicological study data; an additional study is in progress. A preliminary MTC_{tap} of 2.5 µg/l has been derived.

[3] As sum for both substance IX + X.

Determination of substance concentrations in migration waters shall be accomplished by quantitative analysis with individual standards. Both cold and warm water migration testing shall be performed.

For example, the following substances in Regulation (EU) No 10/2011 are alkylphenols:

- 1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene
  (FCM substance No 428, CAS No 0001709-70-2);
- octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
  (FCM substance No 433, CAS No 0002082-79-3);
- pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]
  (FCM substance No 496, CAS No 0006683-19-8);
- phosphorous acid, tris(2,4-di-tert-butylphenyl)ester
  (FCM substance No 671, CAS No 0031570-04-4;
- 2,2′-oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]
  (FCM substance No 739, CAS No 0070331-94-1)

Please note: tabulated restrictions (MTC_{tap}) reflect current preliminary consent among 4MSI responsible bodies, which was achieved following consultations based on a scientific opinion prepared by the German Environment Agency. The opinion document has been consolidated in December 2020 and is available on request. Due to ongoing national considerations in study validation, risk assessment and definition of analytical standards, restrictions may be adapted.

Requirements for plastics and coatings:
Primary aromatic amines (PAA) can be formed during the manufacturing of certain types of materials. Therefore, products or components made of plastics, or of materials coated with polyamide or polyurethane resin coatings, need to be tested on PAA.

Table 3: Requirement on PAA for plastics and coatings

Parameter	Restriction
Sum of Primary Aromatic Amines (PAA)	MTC_{tap} = N.D. (DL = 0.1 µg/l)[1]

[1] Method should be improved to have a LOD of 0.1 µg/l.

3.4.3.2. Rubbers

Table 4: Requirements on amines and nitrosamines for rubbers

Parameter	Restriction
Sum of Primary Aromatic Amines (PAA) (a.o. aniline, o-toluidine)	MTC_{tap} = N.D. (DL = 0.1 µg/l)
Sum of secondary amines[1]	MTC_{tap} = 250 µg/l
Sum of N-nitrosamines[2]	MTC_{tap} = 0.3 µg/l

[1] sum of dibutylamine, diethylamine, dimethylamine, dicyclohexylamine, cyclohexylethylamine, diphenylamine, dibenzylamine, benzyl-N-methylamine, benzylidenebenzylamine, N-methylaniline, N-ethylaniline, N-butylaniline

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

For rubbers made by use of stabilizers bearing alkylphenol structural moieties, migration waters have to be analyzed for the ten degradation products tabulated in table 2, section 3.4.3.1, subheader “requirements for plastics..

3.4.3.3. Lubricants

For lubricants that leave no (significant) residue after flushing, no migration requirements apply. For other lubricants, only the following requirements apply:

- TON/TFN
- TOC
- Formulation dependent requirements
- Enhancement of Microbiological Growth

3.5. Unsuspected and Not Intentionally Added Substances (NIAS)

Not Intentionally Added Substances (NIAS) should not be released into the water in unacceptable levels, as measured by the GC/MS screening method (see 4.3.3.7). Testing for NIAS has to be performed in samples obtained by cold water migration testing.

- For identified substances with a known MTC_{tap}, the requirement is $C_{tap} \leq MTC_{tap}$.
- For identified substances without a known $MTC_{tap,}$ a toxicological reference point (TRP)[2] can be used (if available) to calculate a provisional limit value. A TRP can be, for instance, a TDI as derived by EFSA, resulting in a provisional MTC_{tap} of: 10% * TDI * 60 kg bw / 2 l/d * 1 kg/l.
- It is not yet decided if publicly available toxicological information[2] can be used to derive a Point of Departure (POD; like a NOAEL or BMDL for the most critical effect) for a risk assessment, taking into account common toxicological principles, including application of uncertainty factors on a case by case basis. For instance, for a substance that is assessed not to be genotoxic by EFSA, a provisional MTC_{tap} of 2.5 µg/l could be applied. If a suitable TRP or POD is not available or could not be derived, or if it is not permitted to be used, then $C_{tap} \leq 1.0$ µg/l applies.
- For unidentified substances, the requirement is $C_{tap} \leq 1.0$ µg/l per peak, based on the response of the closest internal standard. The sum of unidentified substances (unidentified peaks) shall be restricted, e.g. ≤ 5 µg/l.

The above requirements apply to the 3rd migration period; or, in case extended testing is needed, at the latest for the 9th migration period.

[2] can only be used if derived or evaluated by an institute that is generally recognized

4. Test methods for products made of organic materials

4.1. General

The influence of products or components on the quality of drinking water is tested according to standardized test methods (EN standards). In this section the relevant methods and standards are described.

For testing assembled products as complete products no EN testing standard is currently available. Alternatively, components made of organic materials have to be tested separately.

Note: The 4MSI Common Approach for Certification describes a procedure to accept the testing of one component representing different components made of the same pre-product (granulate) and even used for different assembled products.

Multilayer products are made of different, firmly attached layers. In this case the testing and the assessment is made for the product. For the formulation review the individual layers (layers between drinking water and total barrier) have to be assessed in terms of each material. The determined MTCtap values of all layers shall be assessed. Multilayered products with a total barrier are exempt. In this case, only the layers facing the drinking water need to be assessed. The total barrier itself need not be assessed as a material.

4.2. Procedure for the assessment of the formulation

The applicant must disclose 100% of the formulation of each material of the product or component:

- list of all ingredients (substances or blend of substances) used in the formulation to produce the material (all monomers, additives, pigments, fillers, catalysts etc.)
- their respective percentage in the formulation.

Based on the information provided by the applicant, the notified body has to obtain the chemical compositions of each ingredient (compound / masterbatch / preparation / mixture). In this approach, each ingredient supplier needs to be contacted. In case an ingredient contains no specific brand name (but the name of the substance), the supplier has to confirm it is only one substance (including impurities) or whether the substance contains intentionally added additives. If it is only one substance, no further information is requested and it is compared to the PLs. If the ingredient contains one or more additives, the notified body reviews this additionally supplied information and verifies that it is also permitted.

The results of the formulation evaluation should be documented. An example of the form to document the formulation, is given:

Level 1	Level 2	Level 3	Level 4
Commercial mixture 1	**Commercial mixture 1.1**	**Commercial mixture 1.1.1**	Substance 15
			Substance 16
		Substance 9	
		Substance 10	
	Commercial mixture 1.2	Substance 11	
		Substance 12	
	Substance 2		
Commercial mixture 2	Substance 3		
	Substance 4		
Substance 1			
Filler 1	Substance 5		
	Substance 6		
Masterbatch 1	Pigment 1		
	Pigment 2		
	Commercial mixture 3	Substance 13	
		Substance 14	
	Commercial mixture 3'	substance 13	
		substance 17	
		substance 18	
Aid to polymerisation 1	Substance 7		
	Substance 8		

Based on this information, the applicable test requirements and respective test methods can be determined for that product or component. This 'program of requirements' lists all parameters, including limit values, that need to be examined for that product or component.

Requirements defined as percentage use restrictions for the substance, or as maximum amount of impurities have to be assessed by the formulation review.

Pigments and fillers or listed substances with a specification on purity and/or nanostructure, for example carbon black, must be verified to fulfil the requirements by a certificate of analysis provided by the supplier. Supporting documentation may require the inclusion of a test report.

4.3. Migration testing

For substances in the PDW that are restricted with an MTC_{tap}, it shall be ensured that migration is within MTC_{tap}. Therefore, a migration test should be carried out, with the exception of certain types of organic materials, where generally recognized diffusion models (based on experimental data) allow the estimation of the migration level of a substance under certain conditions. If these models show the migration of the substance complies with the MTC_{tap}, migration testing for these substances will not be necessary. If compliance is not shown by using the models, migration testing can still be performed.

4.3.1. ***Mathematical modelling***

Instead of actual migration testing performed by a laboratory, mathematical modelling can be used to show compliance with parameters. If modelling for a certain parameter shows compliance with the parametric value no further (practical) testing for that parameter is necessary.

The following varieties of modelling are permitted:

- Migration modelling according to CEN/TR 16364, simulating a migration test according to the EN 12873 series
- Full transfer calculation, simulating full transfer of a substances during a migration test according to the EN 12873 series from the product to the migration water

4.3.1.1. Migration modelling (CEN/TR 16364)

Migration modelling shall be performed according to CEN/TR 16364.

4.3.1.2. Full transfer calculation

The amount of substance liable to migrate is calculated on the assumption that all of the substance in the material, i.e. 100%, can migrate:

Cmax = Q*S/V*Lp*D

where:

- **C_{max}** (in mg/l) is the maximum possible migration of the substance,
- **Q** (in mg/kg of product) is the quantity of substance in the finished product, or alternatively the quantity of substance used to manufacture 1 kg of product,
- **S/V** (in dm^{-1}) is the ratio of surface area of the product or component to the water volume,
- **Lp** (in dm) is the thickness of the product,
- **D** (in g/cm^3) is the density of the product.

4.3.1.3. Waiving specific migration testing by using TOC compliance

If the SML in Regulation (EU) No. 10/2011 is higher than 10 mg/kg for a specific substance, or if the MTC_{tap} in 4MSI PL is higher than 0.5 mg/kg, demonstration of compliance with the requirement on Total Organic Carbon (TOC) might be sufficient to guarantee that the MTC_{tap} for that substance is not exceeded. The following formulas can be used to check if specific migration testing for the substance is required. The specific migration does not need to be assessed if:

$$SML \times \frac{M_{Carbon}}{\mathrm{M}_{\mathrm{total}}} \geq 10 \frac{mg}{kg} \qquad or \qquad MTCtap \times \frac{M_{Carbon}}{\mathrm{M}_{\mathrm{total}}} \geq 0.5\ mg/kg$$

where:

- M_{total} = molecular weight of the substance,
- M_{Carbon} = molecular weight of only the carbon atoms in the substance

4.3.2. ***Test setup for migration testing***

4.3.2.1. Migration standards

For migration of organic and inorganic substances and TOC testing, the relevant EN 12873 series of standards shall be applied. For migration of taste and odour, EN 1420 shall be applied.

These European standards offer several options for test conditions:

- the type of test water (chlorinated or chlorine-free),
- the number of tests for each type of test water,
- the number of migration periods.
- test temperature

For these options, choices may be made either through national regulations or product standards. In the following sections the choices for the 4MSI countries are listed.

4.3.2.2. Sample selection and preparation

Samples have to be the product or component itself (pipe, fitting, o-ring, …) or representative of the product (e.g. coating), or, but only in case of products from risk groups RG3 and RG4, representative of the formulation (test sheet). This can only be used where there is no processing change required to

make this a final product. For example, for components and products of RG3 and RG4 it is sufficient when test specimens are tested that are made of the granulate, if the granulate is not further cross linked in the final product. If the test specimens comply, the granulate is certified.

4.3.2.3. Temperature of testing

All products shall be tested at 23 °C ± 2°C (cold water test condition). Additionally, products that are normally used for warm or hot applications shall be tested at 60 °C ± 2°C or 85 °C ± 2°C, respectively. For this purpose, warm water corresponds to normal operating temperatures between 30 and 70 °C and hot water corresponds to operating temperatures exceeding 70 °C.

4.3.2.4. Type of test water

If the water is generally chlorinated in the country, it will be necessary to undertake the migration tests in chlorinated and chlorine-free water. For warm and hot water tests however, only chlorine-free water shall be used. Table 5 below shows which Member States tests are required with chlorinated water, in addition to tests with chlorine-free water.

Table 5 - Required type of test waters in each Member State for cold water testing

Member State	Chlorinated water	Chlorine-free water
France	X	X
Germany		X
The Netherlands		X
United Kingdom	X	X
Portugal	X	X
Denmark		X

4.3.2.5. Migration periods

For several parameters, requirements are defined for more than one migration period. Depending on results from the first of these migration periods, analysis of subsequent periods may not be required. Standards for migration testing determine which migration periods may be analyzed.

For testing with cold water, the migration samples of the 1st, 2nd and 3rd migration period according to standards shall be analyzed. If extended testing is needed, the 5th, 7th and 9th period shall be analyzed. The compliance with the acceptance criteria should be assessed at the 3rd migration period (10th day), or at the latest at the 9th migration period (31st day) in case an extended testing. The results of the other migration periods allow the laboratory to verify that the testing went smoothly and the results are consistent, and are used to assess the trend (whether it is decreasing or not).
It is not yet decided whether the requirement of analysis of the migration water from the intermediate periods (1st,2nd, and 5th and 7th) shall also apply to the NIAS-testing (GC/MS screening), or to have an exception for that.

For testing with warm or hot water, the migration samples of the 1st, 6th and 7th migration period according to standards have to be analyzed. Note: This is not according to the standard.
If extended testing is needed, the 12th, 17th and 22nd period have to be analyzed. The compliance with the acceptance criteria should be assessed at the 7th migration period (10th day), or at the 22nd migration period (31st day) in case of extended testing; the results of the other migration periods allow the laboratory to verify that the testing went smoothly and the results are consistent, and are used to assess the trend, whether it is decreasing or not.

Extended testing is only required if the migration water did not meet the criteria set after the 3rd migration period for cold water test or after the 7th migration period for warm/hot water test. For multilayer products the warm/hot water migration test may not be stopped before 31 days contact time as substances originating from different layers may only show up later in the test.

4.3.2.6. Number of tests for each type of test water

In Member States where tests with both types (chlorinated and chlorine-free) of test water are required, only a single test for each type of test water is required. In Member States where only testing with chlorine-free water is required, duplicate migration testing is required, but for analysis, both of the corresponding migration waters can be mixed.

4.3.3. ***Analysis of migration water***

In the migration water(s), the relevant parameters are analyzed. In this section the applicable test methods for the parameters are given.

4.3.3.1. Total organic carbon (TOC) (EN 1484)

TOC shall be determined according to EN 1484 (non-purgeable organic carbon).

4.3.3.2. Odour and Flavour testing (EN1622)

Odour and Flavour shall be determined as Threshold Odour Numbers (TON) and Threshold Flavour Numbers (TFN) EN 1622 in combination with the limitations given in EN 1420.

4.3.3.3. Colour testing (EN ISO 7887)

Colour shall be determined according to EN ISO 7887 in the migration water.

4.3.3.4. Turbidity testing (EN ISO 7027)

Turbidity shall be determined according to the EN ISO 7027 in the migration water.

4.3.3.5. Foaming testing (Visual)

Foaming shall be determined visually in migration water according to EN 1420. The migration water is assessed visually for the absence of foaming after shaking.

4.3.3.6. Formulation dependent specific migrants

For each formulation dependent specific migrant, a suitable method shall be used. When available, a generally accepted method, such as EN or ISO standards shall be used. If these are not available, an in-house method can be applied. Any method used should meet the minimal validation requirements, (still to be set).

Migration of metal elements and minerals should be analyzed according to the EN ISO 17294-2[3] Standard, except for mercury, which should be analyzed according to EN ISO 12846, or EN ISO 17852. Analysis of the THM parameter should be performed according to EN ISO 10301 or EN ISO 15680, and only in chlorinated water.

4.3.3.7. GC-MS screening (EN15768)

GC-MS screening shall be conducted according to the EN 15768.

[3] *The NF EN ISO 17294-2 Standard specifies a testing method for the following 62 elements: aluminium, antimony, arsenic, barium, beryllium, bismuth, boron, cadmium, caesium, calcium, cerium, chromium, cobalt, copper, dysprosium, erbium, europium, gadolinium, gallium, germanium, gold, hafnium, holmium, indium, iridium, lanthanum, lead, lithium, lutetium, magnesium, manganese, molybdenum, neodymium, nickel, palladium, phosphorus, platinum, potassium, praseodymium, rubidium, rhenium, rhodium, ruthenium, samarium, scandium, selenium, silver, sodium, strontium, terbium, tellurium, thorium, thallium, thulium, tin, tungsten, uranium, vanadium, yttrium, ytterbium, zinc and zirconium.*

The S/V ratio used should be large enough to be able to verify, for the relevant threshold in the method (the threshold value of 2 µg/l is the concentration below which detection and/or identification is not guaranteed, see EN 15768), the value corresponding to the MTC_{tap} in the migration water:

Product categories		MTC_{tap} (µg/l)	CF	M^{T}_{n} (µg/dm²/day)	S/V (dm^{-1})	C^{T}_{n} (µg/l)	EN 15768 Threshold value (µg/l)
Group A Pipes and their linings	Domestic installations, buildings (Ø < 80 mm)	1	20	0.05	5* 14 40	0.75 2.1 6	2
	Service piping (80 mm ≤ Ø < 300 mm)	1	10	0.1	5* 7 40	1.5 2.1 12	2
	Mains piping (Ø ≥ 300 mm)	1	5	0.2	5 40	3 24	2

***** S/V ratio values where the MTC_{tap} of 1 µg/l cannot be verified due to analytical constraints.

GC-MS results obtained by this screening method are semi-quantitative and may underestimate substance concentrations from case to case. By applying individual calibration standards, the method will also allow quantification in specific migration testing. To cover a wider range of substances that can be detected, parallel runs in appropriate MS modes may be necessary.

4.3.3.8. Reduced testing for comparable materials and products

For a material or product that has only minor modifications as compared to a material or product that has already been fully approved, reduced or simplified testing is possible. Details have still to be specified.

4.4. Enhancement of Microbial Growth (EMG) testing

EMG testing shall be performed according to EN 16421.

5. Evaluation of test results against requirements

5.1. General

The results obtained via the test methods described in section 4 are used to assess the requirements given in section 3. For some test methods a direct comparison of the test result against the requirements is possible. For others a conversion is necessary.

5.2. Conversion of migration rates to C_{tap}

Migration rates (M^{T}_{n}) are converted to the expected concentration at the consumer's tap ($C_{tap, n}$), using the conversion factor (CF) that applies to the product, according to the following formula:

$C_{tap, n}$ [µg/l] = M^{T}_{n} [µg/dm^2/day] x CF [day/dm]

Conversion factors (CF) have been defined depending on product type and area of application. The values adopted by the 4MSI are given in Annex B. The background on the use and derivation of conversion factors can be found in Appendix 1.

If $C_{tap} \leq MTC_{tap}$ the requirement is considered to be met.

Annex A - Procedure for evaluation of the acceptability of products

Review of formulation against respective Positive Lists, including the purities of starting substances

⇩

Determination of required testing and performance depending on:

- Formulation
- Material (material depending by-products = specific requirements)
- Product group
- Intended use of product (cold water, warm or hot water)

⇩

Performance of tests:

1. Migration test EN 12873 series	⇨	○ TOC ○ Substances with an MTC_{tap} ○ Material specific requirements ○ GC-MS-screening (EN 15768)
1a Experimental determination or modeling of migration of substances with an MTC_{tap} (specific requirements have to be tested by analytical methods)	⇨	Substances with an MTC_{tap}
2. Migration test EN 1420	⇨	○ TON/TFN (EN 1622) ○ Appearance
3. EMG test EN 16421	⇨	EMG
4. Additional tests	⇨	QM/QMA

Annex B – Conversion Factors - CF's

Product groups and its conversion factor (CF); as derivation from F_g and F_o. ($CF = F_g \times F_o$)

	Product group	CF (in day/dm)	F_g = S/V (in dm^{-1})	F_o = t (in days)
A	**Pipes and pipe linings**			
1	ID < 80 mm (domestic installations, buildings) [1]	20	40	0.5
2	80 mm ≤ ID < 300 mm (service piping)	10	5	2
3	ID ≥ 300 mm (mains piping)	5	1.25	4
B	**Fittings, ancillaries [2]**			
1	ID < 80 mm (domestic installations, buildings)	2	4	0.5
2	80 mm ≤ ID < 300 mm (service piping)	1	0.5	2
3	ID ≥ 300 mm (mains piping)	0.5	0.125	4
4	Housing of treatment steps and their coatings	0.05	0.0125	4
5	Water abstraction devices	0.005	0.00125	4
C	**Components of fittings, ancillaries [3]**			
1	ID < 80 mm (domestic installations, buildings)	0.2	0.4	0.5
2	80 mm ≤ ID < 300 mm (service piping)	0.1	0.05	2
3	ID ≥ 300 mm (mains piping)	0.05	0.0125	4
4	Components of housing of treatment steps and their coatings	0.005	0.00125	4
5	Components of water abstraction devices	0.0005	0.000125	4
D	**Small Components of fittings, ancillaries [4]**			
1	ID < 80 mm (domestic installations, buildings)	0.02	0.04	0.5
2	80 mm ≤ ID < 300 mm (service piping)	0.01	0.005	2
3	ID ≥ 300 mm (mains piping)	0.005	0.00125	4
4	Small components of housing of treatment steps and their coatings	0.0005	0.000125	4
5	Small components of water abstraction devices	0.00005	0.0000125	4
E	**Storage systems (reservoirs)**			
1	In domestic installations, buildings, water volume < 10 l	4	4	1
2	In domestic installations, buildings, water volume ≥ 10 l	2	2	1
3	In water supply	1	0.25	4
F	**Components of storage systems [3]**			
1	In domestic installations, buildings, water volume < 10 l	0.4	0.4	1
2	In domestic installations, buildings; water volume ≥ 10 l	0.2	0.2	1
3	In water supply	0.1	0.025	4
G	**Small Components storage systems [4]**			
1	In domestic installations, buildings; water volume < 10 l	0.04	0.04	1
2	In domestic installations, buildings; water volume ≥ 10 l	0.02	0.02	1
3	In water supply	0.01	0.0025	4
4	Elements of raw water basins, covering < 1‰ of the total surface	0.001	0.00025	4

[1] 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.

[2,3,4] Components (sum of components made of similar materials) of assembled products with a wetted surface fraction

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

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

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

Annex C – Requirements on purity of pigments, colorants and fillers

Pigments and colorants

Colorants and pigments have to comply with the following purity requirements:

a) When extracted with 0.1 N hydrochloric acid, the following elements may dissolve from the colorant or pigment up to the maximum amount, based on the colorant or pigment:
   - antimony 0.05 %
   - arsenic 0.01 %
   - barium 0.01 %
   - cadmium 0.01 %
   - chromium 0.1 %
   - lead 0.01 %
   - mercury 0.005 %
   - selenium 0.01 %

b) The content of primary aromatic amines soluble in 1 M hydrochloric acid must not exceed 0.05 % (calculated as aniline). This limit does not apply to primary aromatic amines containing carboxyl- or sulfo-groups,

   or

   When extracted with 2 N ethanolic hydrochloric acid, a maximum of 0.05% aromatic amines (based on the colorant or pigment) may dissolve from the colorant or pigment.

If the purity requirements under a) and b) are not met or cannot be checked, the migration from the final product in contact with cold or hot water shall be measured for all above mentioned constituents, and in addition cobalt, manganese and nickel. The requirements of $C_{tap} \leq MTC_{tap}$ for metals and aromatic amines apply. The MTC_{tap} values for metal elements can be found in Annex D; the MTC_{tap} for the 'sum of aromatic amines' is 0.1 µg/l.

Fillers

Fillers can be contaminated with impurities. For mineral fillers, the following specification applies:

- After solution in 0.1 M hydrochloric acid, the concentration of the following elements shall not exceed the maximum amount, based on the filler:
  - antimony 0.005%
  - arsenic 0.01%
  - barium 0.01%
  - cadmium 0.01%
  - chromium 0.1%
  - lead 0.01%
  - mercury 0.0005%
  - selenium 0.01%

For example, the following substances that are listed in Union List of Reg. (EU) No 10/2011 can only be used if they meet the requirements on the maximum content of impurities:

- aluminium hydroxide
- aluminium silicate
- barium sulfate
- calcium carbonate
- calcium hydroxide
- calcium oxide
- calcium silicate
- dolomite
- magnesium oxide
- magnesium silicate
- silicon dioxide
- silicon dioxide, silanated
- titanium dioxide
- zinc oxide
- zinc carbonate

Annex D – MTC_{tap} for metal elements

Metal ion		MTC_{tap} [µg/l]	Allocation and Reference
Aluminium	Al	20	10% of Parametric Value [1]
Antimony	Sb	0.5	10% of Parametric Value [1]
Arsenic	As	1	10% of Parametric Value [1]
Barium	Ba	70	10% of WHO-Guideline value [2, 4]
Boron	B	100	10% of Parametric Value [1]
Cadmium	Cd	0.5	10% of Parametric Value [1]
Chromium	Cr	5	10% of Parametric Value [1]
Cobalt	Co	2.5	1/20 SML [3]
Copper	Cu	200	10% of Parametric Value [1]
Iron	Fe	20	10% of Parametric Value [1]
Lead	Pb	1	10% of Parametric Value [1]
Lithium	Li	30	1/20 SML [3]
Manganese	Mn	5	10% of Parametric Value[1]
Mercury	Hg	0.1	10% of Parametric Value[1]
Nickel	Ni	2	10% of Parametric Value [1]
Selenium	Se	1	10% of Parametric Value[1]
Zinc	Zn	250	10% of WHO-Guideline value [2, 5]

[1] A parametric value (PV) is set in Directive 98/83/EC. The quantities migrating from the materials should not exceed 10% of the PV (see 4MSI Common Approach – Management of Positive Lists for Organic Materials)

[2] A Guidance value is set by WHO. The quantities migrating from PDW materials should not exceed 10% of the DW-guidance value (see 4MSI Common Approach – Management of Positive Lists for Organic Materials)

[3] Regulation (EU) No 10/2011

[4] http://www.who.int/water_sanitation_health/dwq/chemicals/barium.pdf

[5] http://www.who.int/water_sanitation_health/dwq/chemicals/zinc.pdf

Annex E – Summary of parameters and acceptance criteria used

<table>
<tr><th rowspan="2">Parameters</th><th colspan="2">Immersion Methods</th><th rowspan="2">Analytical Methods</th><th rowspan="2">Acceptance Criteria</th><th rowspan="2">Units</th></tr>
<tr><th>Pipes</th><th>Tanks</th></tr>
<tr><td>Odour and flavour (TON/TFN)</td><td>EN 1420</td><td>EN 14395-1</td><td>EN 1622</td><td>1) <u>Pipes with internal diameter (ID) < 80 mm:</u>
TON/TFN ≤ 8.0 after 10 days (in cold and warm/hot water test), or
TON/TFN ≤ 16.0 after 10 days AND TON/TFN ≤ 8.0 after 31 days (in cold and warm/hot water test)

<u>All other products:</u>
TON/TFN ≤ 2.0 after 10 days (in cold water test), or
TON/TFN ≤ 4.0 after 10 days AND TON/TFN ≤ 2.0 after 31 days (in cold water test).
In warm/hot water test, the values can be two times higher</td><td>-</td></tr>
<tr><td>Colour</td><td>EN 13052-1</td><td>EN 14395-1</td><td>EN ISO 7887</td><td>≤ 5 at 10 days, or at 31 days in case of extended testing (in cold and warm/hot water test)</td><td>mg/l Pt/Co</td></tr>
<tr><td>Turbidity</td><td>EN 13052-1</td><td>EN 14395-1</td><td>EN ISO 7027</td><td>≤ 0.5 at 10 days, or at 31 days in case of extended testing (in cold and warm/hot water test)</td><td>NFU</td></tr>
<tr><td>TOC</td><td>EN 12873-1
EN 12873-2</td><td>EN 12873-1
EN 12873-2</td><td>EN 1484</td><td>TOC ≤ 0.5 after 10 days and no increasing trend testing (in cold and warm/hot water test); or
TOC ≤ 2.0.after 10 days AND TOC ≤ 0.5 after 31 days, and no increasing trend (cold and warm/hot water testing)</td><td>mg/l</td></tr>
<tr><td>GC-MS screening
Only in cold water</td><td>EN 12873-1
EN 12873-2</td><td>EN 12873-1
EN 12873-2</td><td>EN 15768</td><td>At 10 days or at 31 days in case of extended testing: Ctap ≤ MTCtap.; for substances without MTC_{tap}, and/or for peaks unidentified: Ctap ≤ 1 per peak and C_{tap}≤ 5 for sum of unidentied peaks.</td><td>µg/l</td></tr>
<tr><td>EMG only chlorine-free water</td><td>EN 16421</td><td>EN 16421</td><td>EN 16421</td><td>
<table>
<tr><th></th><th>All non-elastomers</th><th>elastomers with large contact area</th><th>elastomers with small contact area</th></tr>
<tr><td>BPP in pg ATP/cm²</td><td>1000</td><td>1000</td><td>1000</td></tr>
<tr><td>$V_{biofilm}$ in ml/800 cm²</td><td>≤ 0.05 ± 0.02</td><td>≤ 0.12 ± 0.03</td><td>≤ 0.20 ± 0.03</td></tr>
<tr><td>MDOD in mg O_2/l</td><td>2.39</td><td>2.39</td><td>2.39</td></tr>
</table>
</td><td></td></tr>
<tr><td>Substances with MTC_{tap}</td><td>EN 12873-1
EN 12873-2</td><td>EN 12873-1
EN 12873-2</td><td>Analysis or calculation or modelling</td><td>Ctap ≤ MTC_{tap} at 10 days, or at 31 days in case of extended testing and no increasing trend (in cold and warm/hot water test)</td><td>µg/l</td></tr>
<tr><td>Substances as mentioned in §3.1 e), f), and g) (not on PL)</td><td>EN 12873-1
EN 12873-2</td><td>EN 12873-1
EN 12873-2</td><td>Analysis or calculation or modelling</td><td>Ctap ≤ MTC_{tap} = 0.1 at 10 days, or at 31 days in case of extended testing and no increasing trend (in cold and warm/hot water test)</td><td>µg/L</td></tr>
<tr><td>metal elements and minerals by ICP-MS
+
Mercury</td><td>EN 12873-1
EN 12873-2</td><td>EN 12873-1
EN 12873-2</td><td>EN ISO 17294-2
+
EN 1483 or
EN ISO 17852 or
EN 12338</td><td>C_{tap} ≤0.1 x PV (DWD) or C_{tap} ≤ value in Annex D; at 10 days, or at 31 days in case of extended testing and no increasing trend (in cold and warm/hot water test).</td><td>µg/l</td></tr>
<tr><td>THMs (only in chlorinated water)</td><td>EN 12873-1
EN 12873-2</td><td>EN 12873-1
EN 12873-2</td><td>EN ISO 10301 or
EN ISO 15680</td><td>C_{tap} ≤ 10 for the sum, at 10 days, or at 31 days in case of extended testing.(in cold and warm/hot water test)</td><td>µg/l</td></tr>
</table>

“at 10 days, or at 31 days in case of extended testing (in cold and warm/hot water test)” :This means: at 10 days (3rd migration period in cold water, 7th migration period in warm/hot water) or at 31 days (9th migration period in cold water, 22th migration period in warm/hot water) in case extended testing was needed

Appendix 1 - Explanation on Conversion Factors (CF)

The S/V ratio of the test sample and the contact time used in the migration test according to EN 12873 differ from real use of the end products in practice. Therefore, the concentrations determined in the migration test have to be converted. The application of CFs (dimension: day/dm) aims to recognize the level of impact on drinking water quality that will arise from the product in its normal operating situation.

The purpose of a CF is to achieve a comparison between the results of the experimental migration test or modelling with the relevant MTC_{tap}.

CFs are dependent on the application of a product. Therefore, a CF is made up of a geometrical factor (F_g – Surface-to-Volume ratio – dimension: dm^{-1}), which is determined by the PDW, and an operational factor (F_o – dimension: day) which is calculated from the residence or contact time of the water. Thus:

$$CF = F_g \times F_o \qquad [d\ dm^{-1}] \qquad (1)$$

In accordance with EN 12873-1 the results of the experimental migration test are calculated as follows:

$$M_n = C_n / (S/V \times t) \qquad [mg\ dm^{-2} d^{-1}] \qquad (2)$$

where

M_n is the migration rate for the n^{th} migration period
n is the sequence number of the migration period (1, 2, 3,…..10)
C_n is the concentration of the measured substance in mg/l for the n^{th} migration period

t is the duration of the n^{th} migration period in days
S/V is the surface area-to-volume ratio in the test setup in dm^{-1}

The estimated concentration at the consumer's tap (C_{tap}) is calculated from:

$$C_{tap} = M_n \times CF = C_n / (S/V \times t) \times CF \qquad [mg\ dm^{-3}] \qquad (3)$$

Equations (2) and (3) imply the assumption that the migration rate is constant during the migration period and independent of the concentration already present in the drinking water, although this is not always the case.

The results of the 3^{rd} migration period (for testing cold water) or the result of the 7^{th} migration period (for testing at warm or hot temperatures) according to EN 12873 are used to estimate the concentration at the tap (C_{tap}). This value is compared with the respective MTC_{tap}. The estimated C_{tap} must be lower than the relevant MTC_{tap}. If results calculated via equation (3) show that the relevant MTC_{tap} cannot be met after three or seven migration periods for cold and warm/hot water testing respectively, and migration over the migration periods was declining in this 10-day test (indicating that the migration rate will decrease over time), migration testing (both for testing at cold and elevated temperatures) can be extended to a total migration time of 31 days at the utmost.

Hot and warm water testing is only needed for products that can come in contact with hot or warm water. The product groups and relevant applicable Conversion Factors (CF) can be found in Annex B.