



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

4MSI Draft Common Approach for organic materials in contact with drinking water

Part C- Testing and Accepting

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1. Principles
2. Tests needed
3. Pass/fail criteria
4. Test protocols



Common Approaches Organic Materials

Part A: Methodologies for Testing and Accepting Starting Substances to be Included in the Positive List

What data are required? How to evaluate? How to set an MTC?

Part B: Positive List of Starting Substances for Organic Materials

For which material, in what function, what is the MTC?

Part C: Procedures and Methods for Testing and Accepting Products Made of Organic Materials

Which compliance tests, how to perform, what are the pass/fail criteria?

Common Approaches are available at the [4MSI-website](#)



Principles and Scope

Products (PDW's) can affect the quality of drinking water by:

- Substances leaching at levels that endanger human health
- Enhancement of microbial growth
- Causing organoleptic / appearance problems

Scope of the document:

All products from source to tap, except:

- Membrane filtration products
- Ion exchange resins



Procedure compliance testing of products

1. Formulation check: all starting substances on Positive Lists?
2. Tests on the migration water:
 - Odour (TON), flavour (TFN), colour, turbidity, foaming
 - Total Organic Carbon (TOC)
 - MTC_{tap} for formulation related substances (PLs & DWD substances)
 - Additional requirements on specific materials
 - GC/MS-screening
3. Enhancement of Microbial Growth (EMG) on product surface
4. Additional testing on the material (QM/QMA)

Compliance check: Check results with the acceptance criteria



Risk groups and their requirements

	Conversion factor*	Formulation review	Specific migration testing	Organoleptic testing	EMG	TOC	screening of NIAS
RG1	≥ 4	Yes	Yes	Yes	Yes (1)	Yes	Yes
RG2	≥ 0.4 and < 4	Yes	Yes (3)	Yes (2)	Yes (4)	Yes (2)	Yes (3)
RG3	≥ 0.04 and < 0.4	Yes	Yes (3)	Yes (3)	Yes (4)	Yes (3)	Yes (3)
RG4	≥ 0.004 and < 0.04	No	No	Yes (3)	Yes (4)	Yes (3)	Yes (3*)
RG5	< 0.004	No	No	No	No	No	No

(1) on product or formulation; for pipes and coatings in domestic installations: on the product

(2) on (assembled) product or component (* except for rigid plastics)

(3) on (assembled) product, component or formulation

(4) on component or formulation



Requirements for the formulation

Only substances can be used that are listed in:

- Union List of Reg 10/2011 (plastic FCM),
- 4MSI-Positive Lists

In addition:

- Salts of listed acids, alcohols and phenols
- Polymeric additives of listed substances >1000 Da
- Prepolymers of listed monomers
- Substances, not monomers, not CMR-listed, not nano, that will not give rise to migration $> 0.1 \mu\text{g/l}$ (substance, its reaction product or impurity)
- Pigments and colorants that are authorized on national level
- Solvents that disappear, if not listed as CMR



Formulation check

The full formulation must be provided

The cut-off value for the formulation is:

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

A cut-off value is set, below which details of the formulation are not required.



Migration testing; odour, flavour, appearance, TOC

Parameter	Immersion Methods		Analytical Methods	Acceptance Criteria (cold and warm/hot water)
	Pipes	Tanks		
Odour and flavour (TON/TFN)	EN 1420	EN 14395-1	EN 1622	<u>Pipes < 80 mm</u> ≤ 8.0 after 31 days, AND ≤ 16.0 after 10 days <u>All other products:</u> ≤ 2.0 after 31 days AND ≤ 4.0 after 10 days In warm/hot water: limits 2x higher
Colour	EN 13052-1	EN 14395-1	EN ISO 7887	≤ 5 mg/l Pt/Co
Turbidity	EN 13052-1	EN 14395-1	EN ISO 7027	≤ 0.5 NFU
TOC	EN 12873-1 EN 12873-2	EN 12873-1 EN 12873-2	EN 1484	TOC ≤ 0.5 mg/l AND TOC ≤ 2.0 mg/l after 10 days AND no increasing trend



Enhancement of Microbial Growth (EMG)

	All non-elastomers	elastomers with large contact area	elastomers with small contact area
BPP in pg ATP/cm ²	1000	1000	1000
V _{biofilm} in ml/800 cm ²	≤ 0.05 ± 0.02	≤ 0.12 ± 0.03	≤ 0.20 ± 0.03
MDOD* in mg O ₂ /l	2.39	2.39	2.39

* only for chlorinated water

BBP= Biomass production potency;

MDOD = Mean dissolved Oxygen difference

Additional guidance needed on which test(s) for which specific situations

No biocidal properties allowed; has to be verified by biofilm method or cytotoxicity test.



Substance specific migration

Testing required for; **criterion**:

- Substances used in the formulation; $C_{\text{tap}} < \text{MTC}$ or $< [\text{SML}/20]$
- Degradation/reaction products of substances in the formulation, for which an SML or MTC_{tap} has been set in the PL; $C_{\text{tap}} < \text{MTC}$ or $[\text{SML}/20]$
- Metal elements if present; $C_{\text{tap}} < \text{MTC}$ in Annex D
- Trihalomethanes (THMs); $C_{\text{tap}} < 10 \mu\text{g/l}$ (sum of 4 THM's) only in chlorinated water

C_{tap} = Concentration at the tap after maximum at 30st day of migration.

If $C_{\text{tap}} > 10\%$ of MTC_{tap} , a decreasing trend has to be shown.

No testing is needed if migration calculation or modelling is performed, showing that the MTC_{tap} can not be exceeded.



Additional requirements

Substances listed with a QM or QMA on the PL

Concentration in the end product must be analytically verified.

Material specific requirements

Plastics and coatings:

Parameter	Restriction
Sum of Primary Aromatic Amines (PAA)	$MTC_{\text{tap}} = \text{N.D. (DL = 0.1 } \mu\text{g/l)}^1$

¹ Method should have a LOD of 0.1 $\mu\text{g/l}$

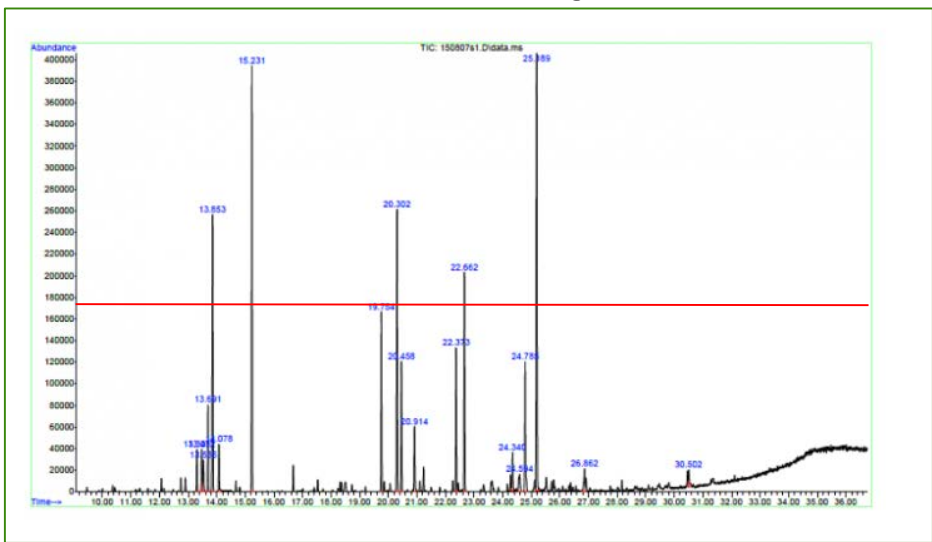
Rubbers

Parameter	Restriction
Sum of Primary Aromatic Amines (PAA)	$MTC_{\text{tap}} = \text{N.D. (DL = 0.1 } \mu\text{g/l)}$
Sum of secondary amines ¹	$MTC_{\text{tap}} = 250 \mu\text{g/l}$
Sum of N-nitrosamines ²	$MTC_{\text{tap}} = 0.3 \mu\text{g/l}$



GC/MS-screening on NIAS

NIAS: Not-Intentionally-Added Substances



— estimated 1 µg/L line

$C_{\text{tap}} \leq \text{MTC}$ (known substances)

$C_{\text{tap}} \leq 1.0 \mu\text{g/l}$ per peak; e.g. $\leq 5 \mu\text{g/l}$ (sum) for unknowns.

MTC as set in PL, or derived from a TDI of EFSA.

Only to be tested in cold water; decreasing trend might be needed



Migration testing

CEN standards are used; some additional decisions:

- Compliance with acceptance criteria at 10th day, or 31st day the latest.
- Use migration water of 23°C (cold), and depending on the intended use of product, also at 60 °C (warm) and 85 °C (hot water).
- Perform at least 2 migration tests per product; either:
 - one with, one without chlorination
 - two migration tests with non-chlorinated water (only for MS that do not have chlorinated water)
- Waiving of analytical testing of specific substances is possible by a worst case (100%) or modelled migration showing $C_{\text{tap}} < MTC_{\text{tap}}$



Compliance check of MTC's

Comparing C_{tap} with MTC's

Calculation of C_{tap} :

$$C_{\text{tap}_n} [\mu\text{g/l}] = MT_n [\mu\text{g}/\text{dm}^2/\text{day}] \times CF [\text{day}/\text{dm}]$$

Where MT = migration rate, n= migration period

All requirements fulfilled? PDW is compliant.



Thank you for your attention!