



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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## Contents

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 µg/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 &lt; 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
<b>BPP in pg ATP/cm<sup>2</sup></b>	1000	1000	1000
<b>V<sub>biofilm</sub> in ml/800 cm<sup>2</sup></b>	≤ 0.05 ± 0.02	≤ 0.12 ± 0.03	≤ 0.20 ± 0.03
<b>MDOD* in mg O<sub>2</sub>/l</b>	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; criterium:

- 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  $\text{MTC}_{\text{tap}}$  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

$C_{\text{tap}}$  = Concentration at the tap after maximum at 30<sup>st</sup> day of migration.

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

No testing is needed if migration calculation or modelling is performed, showing that the  $\text{MTC}_{\text{tap}}$  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)	$MTC_{tap} = N.D. (DL = 0.1 \mu\text{g/l})^1$

<sup>1</sup> Method should have a LOD of 0.1 µg/l

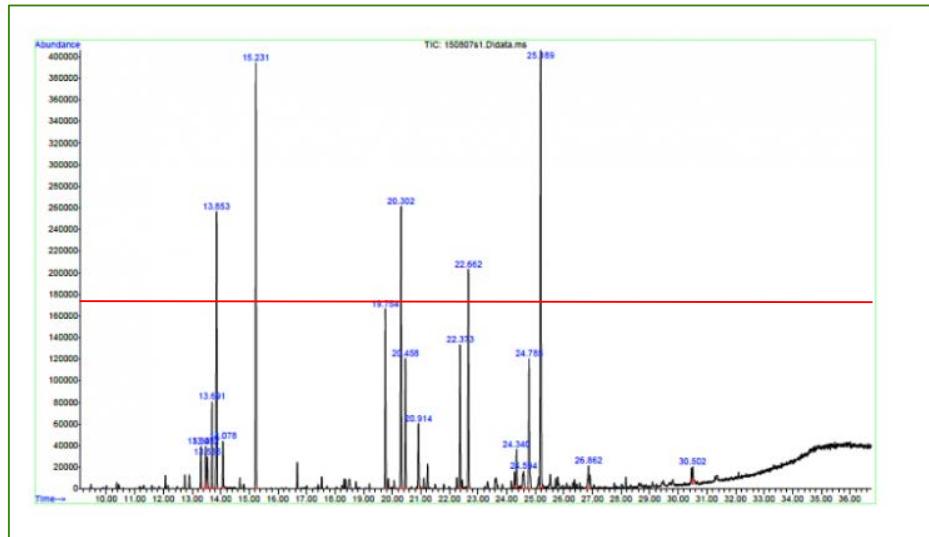
### Rubbers

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



# GC/MS-screening on NIAS

## NIAS: Not-Intentionally-Added Substances



— estimated 1 µg/L line

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

$C_{\text{tap}} \leq 1.0 \text{ } \mu\text{g/l}$  per peak; e.g.  $\leq 5 \text{ } \mu\text{g/l}$  (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 10<sup>th</sup> day, or 31<sup>st</sup> 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  $C_{\text{tap}}$  with MTC's

Calculation of  $C_{\text{tap}}$ :

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

Where MT = migration rate, n= migration period

All requirements fulfilled? PDW is compliant.



Thank you for your attention!