Für Mensch & Umwelt

Umwelt Bundesamt

Materials in Contact with Drinking Water

4MSI Draft Common Approach on Certification and Approval of Products

Thomas Rapp
Section II 3.4 / Distribution of drinking water

Overview

1 MATERIAL SPECIFIC REQUIREMENTS

2 ATTESTATION OF CONFORMITY

3 4MSI COMMON APPROACH ON CERTIFICATION AND APPROVAL OF PRODUCTS

Material Specific Requirements

	Metallic	Organic	Cementitious	Enamel / Ceramics
4MSI Common Approach available	*yes*	*yes*	*yes*	*Proposal*
Positive List for	*Compositions*	*Starting Substances*	*Constituents*	*Compositions*
Risk Based Approach	*Product groups*	*Conversion Factor*	*Conversion Factor*	*Conversion Factor*

Material Specific Requirements

Conversion Factor (CF)

- **Used for the alignment of test results**
  - $c_{tap} = \frac{CF}{S/V*t} * c_{measured}$

- **Determines the risk group (testing requirements)** *new*

Risk group*	Conversion factor*	Formulation review	Specific migration testing	Organoleptic testing	EMG	TOC	Unknowns
RG1	≥ 4	Yes	Yes	Yes	Yes	Yes	Yes
RG2	≥ 0.4 and < 4	Yes	Reduced	Yes	Reduced	Yes	Reduced
RG3	≥ 0.04 and < 0.4	Yes	Reduced	Reduced	Reduced	Reduced	Reduced
RG4	≥ 0.004 and < 0.04	no	no	Reduced	Reduced	Reduced	Reduced
RG5	< 0.004	no	no	no	no	no	no

Material Specific Requirements

Conversion Factor (CF)

	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)	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**			
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**			
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**			
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

Attestation of Conformity for Products

Principles

Approval	Certification	Self-Declaration
Issued by governmental institution	Issued by private third party	Issued by producer

Surveillance required

Attestation of Conformity for Products

Assessment and Verification of Constancy of Performance according to CPR (Regulation (EU) No 305/2011)

System 1+:

(a) the manufacturer shall carry out:

(i) factory production control;

(ii) further testing of samples taken at the factory in accordance with the prescribed test plan;

(b) the notified product **certification body** shall issue the certificate of constancy of performance of the product on the basis of:

(i) determination of the product-type on the basis of **type testing** (including sampling), type calculation, tabulated values or descriptive documentation of the product;

(ii) **initial inspection of the manufacturing plant** and of factory production control;

(iii) **continuous surveillance, assessment and evaluation of factory production control**;

(iv) **audit-testing of samples** taken before placing the product on the market.

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Principles

- Approval / Certification according to 1+ system
- Risk Based Approach

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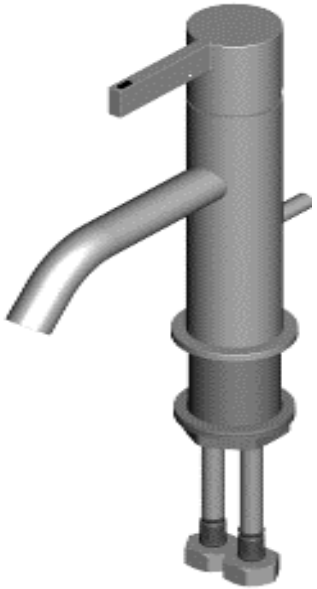
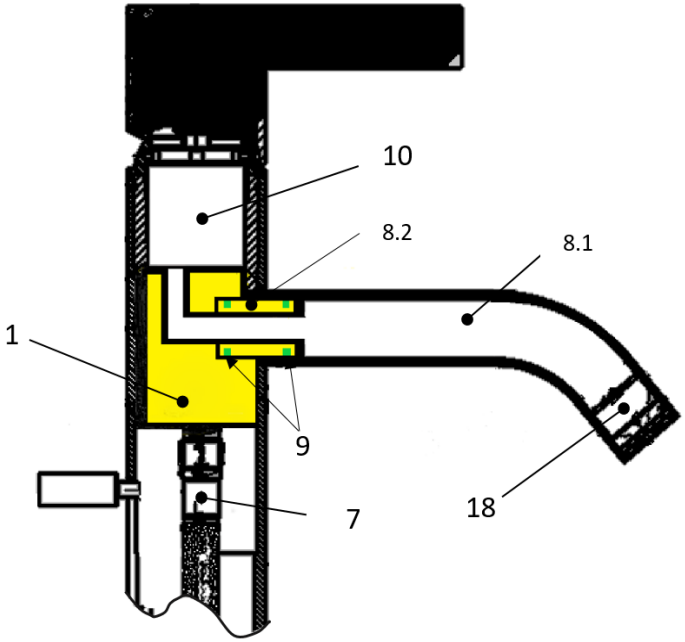
Assembled Products





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Assembled Products

Part No.	PART	Qty.	MATERIAL	% Wetted surface
1	Body	1	Metal 1	40,96%
2	Slider	1	Plastics 1	0,71%
3	Seal	1	Elastomer 1	0,06%
4	Screen	1	Metal 2	1,46%
5	Control slider	1	Ceramics 1	0,54%
6	Control disc	1	Ceramics 2	1,80%
7	Gasket	1	Elastomer 1	0,69%
8	Bottom	1	Plastics 2	6,98%
9	Seal	2	Elastomer 1	0,04%
10	Seal	1	Elastomer 1	0,35%
11	Adaptor	1	Plastics 3	25,29%
12	Flow regulator	1	Plastics 1	1,57%
13	Slider	1	Plastics 1	1,86%
14	Seal	2	Elastomer 1	1,08%
15	Seal	2	Elastomer 1	0,47%
16	Mousseur	1	Multicomponent	9,22%
17	Water Guide	1	Plastics 1	5,09%
18	Water Guide	1	Plastics 1	1,84%
				100,00%

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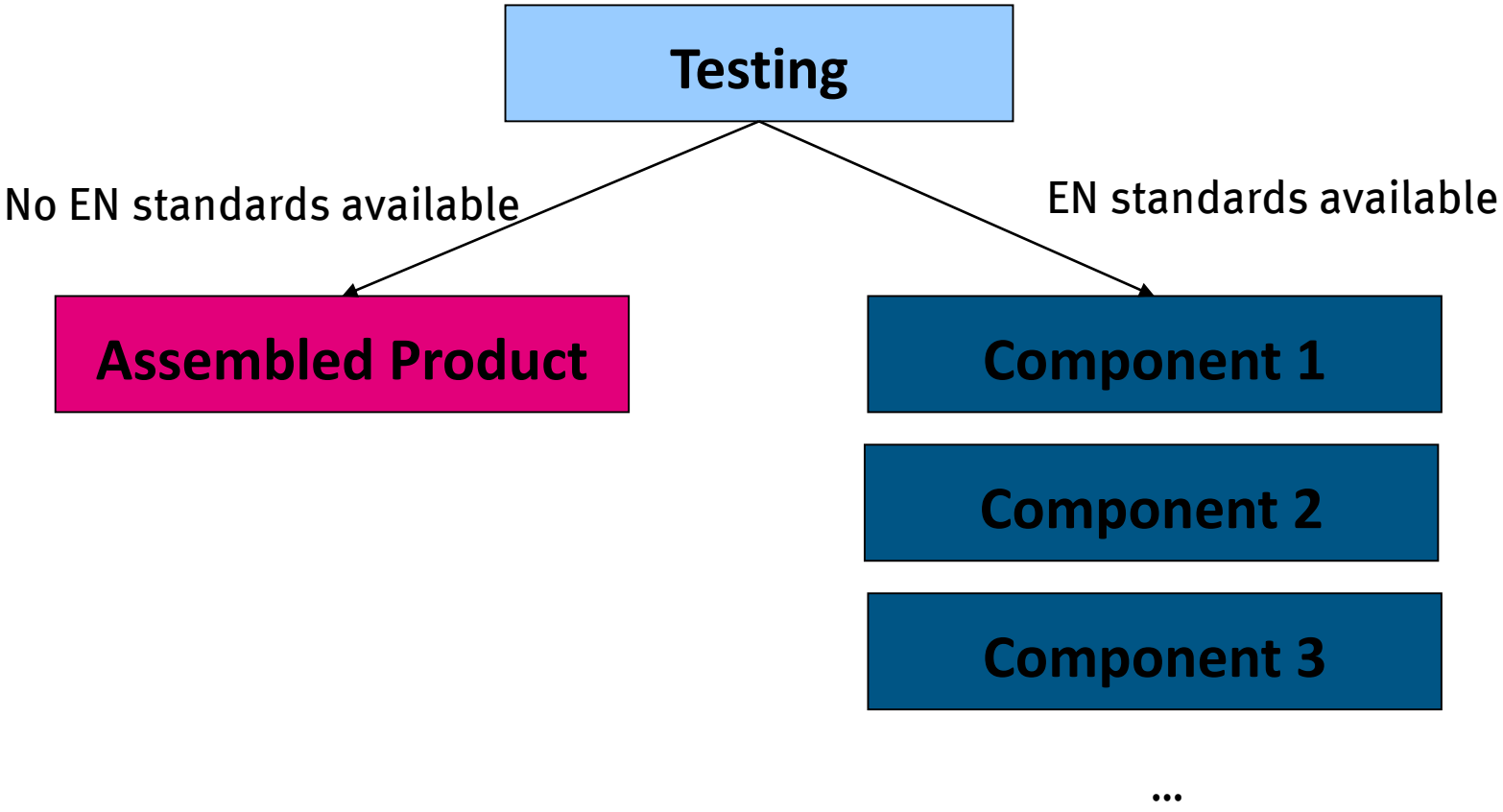
Assembled Products



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Assembled Products – Testing of Components

Reducing the effort for organic materials by:

a) Approval / Certification of components (Risk Group 2):

- Combining of components (even for different products)

b) Approval / Certification of formulations (Risk Group 3):

- All components made of the same **formulation** are covered

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Assembled Products

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				100,00%

Material	% Wetted surface	Risk Group
Plastics 1	11,1%	RG 2
Plastics 2	7,0%	RG 3
Plastics 3	25,3%	RG 2
Elastomer 1	4,3%	RG 3

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Risked Based Approach

Risk group*	Conversion factor*	Operate FPC	Hygienic production testing	Certification	Sampling	Initial testing	Verification testing (material)			Initial audit	Verification audit
							Organic	Metal	Cementitious		
RG1	≥ 4	Yes	Yes	Yes	Yes	Yes	Yes	*To be added*	*To be added*	Yes	Yes
RG2	≥ 0.4 and < 4	Yes	no	Yes	Yes	Yes	Yes	*To be added*	*To be added*	Yes	Yes
RG3	≥ 0.04 and < 0.4	Yes	no	Yes	Yes	Yes	Reduced	*To be added*	*To be added*	Yes	Reduced
RG4	≥ 0.004 and < 0.04	Yes	no	Yes	Reduced	Yes	Further reduced	*To be added*	*To be added*	no	no
RG5	< 0.004	Yes	no	Reduced	no	no	no	*To be added*	*To be added*	no	no

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Conclusion

- Most products are assembled products
- Certification/Approval of parts and pre-products simplifies the certification/approval of assembled products
- Certification/Approval of metallic parts is simple
- Risked based approach reduces testing and certification requirements

Thank you for your attention

Thomas Rapp
thomas.rapp@uba.de

www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen