European Drinking Water

Materials & Product In Contact with Drinking Water

- Position of the European Industry

Article 11 of Directive(EU) 2020/2184

EDW strongly supports

- Harmonisation of EU regulatory requirements
- Establishment of a harmonized EU positive list for starting substances
- Proportionate system for product conformity assessment

Proportional & Feasible Implementation

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- Implementing acts (Article 11 (2)(c))

"procedures and methods for testing and accepting final materials as used in a product made from materials or combinations of starting substances, compositions or constituents on the European positive lists"

- Delegated acts (Article 11 (8))

"[…] determining the appropriate conformity assessment procedure applicable to products covered by this Article on the basis of the modules in Annex II to decision No 768/2008/EC […]. […] as starting point the System 1+ of assessment and verification of constancy of performance set out in Annex V to regulation (EU) No. 305/2011, or broadly equivalent procedure, except where it would be disproportionate. […]"

4MSi Approach – Certification and Approval of Products

Certification and approval of products in contact with drinking water

4MSI Draft Common Approach

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 certification and approval of 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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EDW guiding principles

- Achievable
- Feasible
- No significant cost increase for consumers
- Increased safety, through not overloading test capacity by eliminating redundant evaluations
- Appropriate requirements

EDW Position

1. Safety Classes
2. Organic Material certificates for SC2 & SC3
3. Conversion Factors – not to be used for determining product conformity assessment requirements
4. Conformity Assessment

1. Safety Classes

Product	Safety class
Pipes, relining systems, hoses (flexible)	SC1
Fittings *)	SC2
Minor influence products (not falling in SC1 or SC2)	SC3

*) e.g. adapters, expansion adapters, mechanical joint adapters, bell adapters, flange adapters, elbows, couplings, unions, nipples, reducers, tees, caps, plugs, barbs.

**) Products not falling in Safety class 1 or 2 such as for example valves, pumps, water meters, water heaters, water treatment devices, faucets, pressure reducers, anti-backflow devices.

2. Validity of organic material certificates for SC2 and SC3 products

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Test requirements	Material used in products belonging to	
	Safety Class 1	Safety Class 2 & Safety Class 3
Formulation review	Yes	Yes
Specific migration testing (additional requirements)	Yes, on product	Yes, on formulation or (assembled) product, component
Organoleptic testing	Yes, on product	Yes, on formulation or (assembled) product, component
Enhanced Microbial Growth (EMG)	Yes, on product or formulation	Yes, on formulation or component
Total Organic Carbon (TOC)	Yes, on product	Yes, on formulation or (assembled) product, component
Screening of Not Intentionally Added Substances (NIAS)	Yes, on product	Yes, on formulation or (assembled) product, component

Materials can thus be tested as far “upstream” in the supply chain as possible while still adequately maintaining safety requirements. This will help to avoid redundant evaluation and testing, resulting in overloading of testing labs and an unnecessary burden on economic operators/industry.

Material requirements

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D	4MSI	Type	Formulation review		Migration testing		Organoleptic testing		EMG testing		TOC		NIAS screening	
				4MSI		4MSI		4MSI		4MSI		4MSI		4MSI
P1	RG1	Pipes and pipe linings	Yes	Yes	P	P	P	P	M	M	P	P	P	P
P1	RG2	Fittings & Ancillaries			M	M	M	P	M	M	M	P	M	M
P2	RG3	Components thereof (<10%)			M	M	M	M	M	M	M	M	M	M
P3	RG4	Small Components thereof (<1%)	No	No	No	No	M	M	M	M	M	M	M	M

P= moulded parts/ Products
M= Material

3. Conversion Factors – should **not** be used for determining product conformity assessment requirements

Article 11(2)

"[…] the Commission shall adopt implementing acts […]. Those implementing acts shall establish: […] (c) […] Procedures and methods for testing and accepting final materials including (iii) pass/fail criteria for the test results, which take into account, inter alia, conversion factors for substance migration into estimated levels at the tap […]."

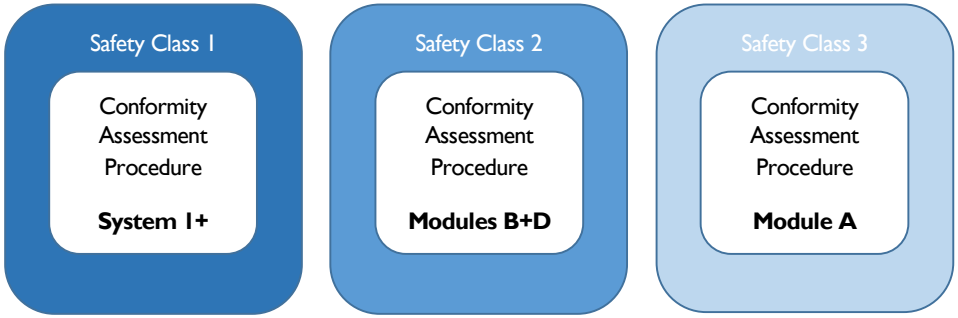
Conversion factors are to be used only and exclusively for this purpose. They are not the appropriate instrument for determining product requirements.

Conformity Assessment – Legal considerations

"[…] determining the appropriate conformity assessment procedure applicable to products covered by this Article on the basis of the modules in Annex II to decision No 768/2008/EC […]. […] as starting point the System 1+ of assessment and verification of constancy of performance set out in Annex V to regulation (EU) No. 305/2011, or broadly equivalent procedure, except where it would be disproportionate. […]"

- CPR System 1+ *vs* 768/2008/EC
- Recital (29) of CPR emphasizes that modules set out in 768/2008/EC are not appropriate
- CPR Revision proposal explicitly takes products in contact with drinking water out of the CPR scope

4. Conformity Assessment (DRAFT / Initial Recomendations)



Conclusion

- EDW strongly supports harmonisation of conformity assessment for products in contact with drinking water
- EDW supports the general 4MSi approach with the highlightede alternations to support feasability, proportionality and implementability
- EDW invites the regulators to engage with industry, so we find the best system to secure safety while also ensuring feasibility and proportionality.