

Industry position on the conformity assessment of the hygienic suitability of products in contact with drinking water

Design of delegated and implementing acts under Article 11 of Directive EU 2184/2020 (EU Drinking Water Directive)

EXECUTIVE SUMMARY

“European Drinking Water” (EDW) welcomes the 4 Member States Initiative (4MSi) which contributes to EU-wide harmonized requirements for materials and products in contact with drinking water. This technical paper aims to provide input for the process of specifying the provisions of Article 11 from an industry perspective and mainly concerns the procedures for product classification and product conformity assessment. While the principle of proportionality has been sufficiently addressed in the requirements for metallic materials in the 4MSi approach, this is not the case for other materials, especially plastics and other organic materials.

CONCISE PRODUCT CLASSIFICATION PROCEDURE

A concise classification procedure based on the potential of products to adversely influence drinking water quality should be introduced. This ensures that the requirements for individual products are easily defined and follow the principle of proportionality. With a comprehensible application for all involved stakeholders, three different product classes are sufficient for defining conformity assessment requirements for final products, while a fourth class for preliminary products is suggested for final materials as used by multiple product manufacturers.

A PROPORTIONATE CONFORMITY ASSESSMENT FRAMEWORK FOR ALL PRODUCTS

A conformity assessment according to the 1+ system is suitable and well accepted for all products with a high potential impact on the water quality from source to tap. These are primarily pipes and fittings in distribution networks.

A differentiated approach targeting products with a low impact on drinking water quality considers the principle of proportionality. Such products are typically installed in low numbers along the flow path (e.g., water meters or pumps). A conformity assessment procedure combining modules B and C of Regulation (EC) No 768/2008 is appropriate for products of lower impact. The assessment includes a review of the product’s technical design to guarantee the use of certified final materials and proper manufacturing. This EU type examination is conducted by a notified body and is based on the technical documentation, a recognized quality management system (i.e., ISO 9001) and requirements for good manufacturing practice according to Regulation (EC) No 2023/2006.

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INDUSTRY INITIATIVE EUROPEAN DRINKING WATER

EDW is an alliance of European trade associations representing industries supplying products or materials used in drinking water applications and municipal drinking water supply within the European Union European single market.

EDW works to ensure the harmonised implementation of the provisions of Article 11 of Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (hereinafter referred to as “DWD”), establishing hygiene requirements for materials that come into contact with water intended for human consumption.

EDW promotes the harmonisation of EU regulatory requirements of products and materials used in drinking water applications, and supports:

- the establishment of an EU harmonised positive list for starting substances to produce organic materials, developed using existing EU legislation (Regulation (EU)10/2011) and EU national lists (including the 4MSi proposal) implemented equally by European Member States
- test methods based on European standards
- a proportionate system for the product conformity assessment, which ensures safety of materials and products in contact with drinking water in the European single market

IMPLEMENTING A SYSTEM TO SAFEGUARD THE HYGIENIC SAFETY OF PRODUCTS IN ALL MEMBER STATES OF THE EUROPEAN UNION

This paper is meant to inform relevant stakeholders involved in the process of specifying the provisions of Article 11(2)(c) (Implementing Acts) and Article 11(8) DWD (Delegated Acts) of the Drinking Water Directive:

- Implementing Acts to establish “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 “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. [...]”

We accept the invitation expressed in the **4MSi Draft Common Approach on Certification and approval of products in contact with drinking water** and hereby provide industry feedback on its clarity, applicability, and impact. EDW supports the 4MSi draft common approach, which describes proper methods to achieve a harmonization within the European Union and will ensure good quality of materials and products, which are used within drinking water systems.

Based on practical experience gained from requirements already implemented in some Member States, there is opportunity to amend the procedures for product clarification and product conformity assessment to facilitate harmonization. EDW recommends the following:

- **Harmonized protection** for 500 Mio consumers within the European single market relying on safe products in contact with drinking water;
- **Simplified and standardized requirements** that can be uniformly implemented by all Member States;
- **Avoidance of passing on increased production costs to consumers;**
- **Increased safety**, as testing capacities will not be overloaded by redundant assessments and testing;
- **Appropriate requirements** for economic operators that adequately reflect market realities.

CONFORMITY ASSESSMENT FRAMEWORK PROPORTIONATE FOR ALL PRODUCTS

It is crucial for the legislator to ensure a system that is proportionate when deriving the implementing and delegated acts referred to in the DWD. While Article 11(8) DWD states the System 1+, the assessment and verification of constancy of performance set out in Annex V to Regulation (EU) No 305/2011, shall be considered as the starting point (and thus as default requirement) for materials and products in contact with drinking water, the DWD does not require the application of the System 1+ for all products and materials in contact with drinking water.

EDW agrees that it is appropriate to apply the 1+ system to all products exhibiting a significant potential influence on the tap water quality while it is proportionate to reduce the burden for products with a much lower potential influence. This is in line with the statement in Article 11(8) DWD, saying that the 1+ system, or a broadly equivalent procedure, may not be applied if it would be disproportionate.

Furthermore, Recital 21 states that *[...] In order not to hamper innovation, the Commission should ensure that such procedures are proportionate, and that they do not place an undue burden on economic operators, in particular small and medium-sized enterprises. To the extent possible, such procedures should be aligned with the existing Union product legislation, in order to avoid a double burden obliging economic operators to carry out different conformity assessments for the same product [...].*

EDW believes a differentiated approach considering the individual influence on the drinking water quality of the multitude of product types present in the market is proportionate and reasonable, while fully endorsing the objectives stated in Article 1(2) DWD.

CONCISE PRODUCT CLASSIFICATION PROCEDURE

Assuming that a larger surface area in contact with drinking water is associated with a higher potential of products to adversely influence drinking water quality, this should be considered when establishing conformity assessment requirements. Following the principle of proportionality, an appropriate set of requirements should therefore be established for products based on their potential to influence drinking water quality. For metallic materials and final products made from them, the proportionality

principle has been adequately implemented in the 4 MSi approach and is fully supported by EDW. For final products manufactured from ceramics/enamels, plastics or other organic materials, the idea of proportionality has not been sufficiently addressed.

Therefore, the following aspects focus mainly on organic materials as well as ceramic materials following a similar approach.

In the following, the terms '*preliminary product*' and '*final product*' are used with the following definitions:

Preliminary product

Shall mean final organic materials after completed polymerization, compounding or vulcanization for example in the form of granules, powders or ceramics/ enamels with a specific composition, which are usually marketed under specific brand names and which are used to manufacture final products.

Final product

Shall mean all products in contact with drinking water that are

- (a) an integral part of systems for the abstraction, treatment, or distribution of water; or
- (b) components in assembled products

A clear and concise procedure with different product classes should be introduced to ensure that the requirements for individual products can be easily defined. For the determination of the conformity assessment requirements for final products, we endorse the implementation of three different product classes "F1", "F2" and "F3".

The different product classes and the classification system of the products are described below. An overview on the classes can be obtained from **Table 1 (annex)**.

Preliminary product class P

The introduction of a product class "**P**" for **preliminary products** used in the manufacture of final products is necessary to enable product certifications at an upstream point of the value chain. Preliminary product certificates, held by the final materials' producer, can be the basis for conformity assessments of final products made thereof. A reduction of complexity, time and effort of product conformity assessments of a one-time upstream testing is beneficial, as redundant testing at a downstream stage for numerous products from different manufacturers using the same preliminary product is no longer needed.

Product class F1

Pipes and pipe relining systems have the largest surface area in direct contact with drinking water compared to all other products. This potentially significant influence on the drinking water quality demands for the highest requirement level.

Flexible hoses not falling into the scope of EN 13618 regarding the length, are used, for example, for temporary water distribution.

Product class F2

Fittings are used as connecting elements in distribution systems. Their surface in contact with drinking water is smaller than pipes. In domestic piping systems, their surface is typically around 10% of the surface of the pipes themselves.

Product class F3

Products exhibiting a low surface area in contact with drinking water compared to F1 and F2 are typically not **installed as recurring parts of the distribution network. They exhibit** a low impact on drinking water quality. Typical examples are water meters, pumps, taps, shower heads, sink-connectors and the like. These products are assigned to **Product class “F3”** with a proportionate requirement level.

The assignment of a product to the applicable product class is mandatory prior to its product conformity assessment. Such assessment should be simple for all parties involved to facilitate its implementation in every EU Member State. This would increase the willingness to move from the individual, fragmented procedures, to a harmonized way of consumer protection.

CONFORMITY ASSESSMENT PROCEDURE FOR PRELIMINARY PRODUCT CLASS P

EDW strongly supports establishing a procedure that enables producers of preliminary products to obtain full confirmation of conformity with the requirements of the implementing act based on specifications of Article 11 2(c) DWD (e.g., test requirements, pass/fail criteria for the test results) on the basis of material tests for their products (e.g., plastic granules) specified therein. The material testing options for organic and ceramic materials are described more in detail in **Table 2 (annex)****Fehler!**
Verweisquelle konnte nicht gefunden werden..

EDW considers that confirmations of conformity of a preliminary product (certificate) can be used, in whole or in part, depending on the requirements specified in the respective product classes F1-F3, for the subsequent conformity assessment of a final product if the following aspects are fulfilled in the conformity assessment procedure of the preliminary product:

- the formulation of the preliminary product must comply with the requirements of the positive lists of the starting substances
- the production of the test specimens with defined process parameters is supervised by an accredited third-party
- sampling of the test specimens and further transportation is the responsibility of the accredited third-party
- based on the results of the material tests, the certificate must clearly state the applications for which the preliminary product is suitable for

The future requirements should not restrict the producers of preliminary products in their decision-making powers as to whether they seek confirmation of conformity for their products. This decision rests solely with the respective producer of the preliminary product.

CONFORMITY ASSESSMENT PROCEDURE FOR PRODUCT CLASSES F1 AND F2

General requirements

Considering our initial statements, EDW shares the view of the 4MSi that the starting point for products with a potentially high influence on drinking water quality should be the 1+ system set out in Regulation (EU) No 305/2011, as the objectives and purposes of the DWD are met by default. It shall be possible to obtain certificates of conformity for product families consisting of comparable products (e.g., same materials, comparable design, different sizes).

Material specific requirements

Product class F1

With respect to the material-specific requirements, EDW agrees with the 4MSi opinion, saying that most of the requirements must be assessed with tests on the final product level. Provided a certificate is available for the preliminary product used, the evaluation of the formulation and the enhancement of microbial growth shall no longer be required at the final product level.

Product class F2

If confirmations of conformity for all preliminary products used in the manufacture of the final product are available, only the requirements for Total Organic Carbon (TOC) and organoleptic requirements shall be verified at the final product level. All other requirements shall be covered by the preliminary product certificate, if provided.

If a manufacturer uses a preliminary product to manufacture a final product for which no confirmation of conformity is available or decides to deviate from the processing specifications given there, he is obliged to carry out the requirements of conformity assessment on the final product.

CONFORMITY ASSESSMENT PROCEDURE FOR PRODUCT CLASS F3

General requirements

EDW recommends that a combination of modules B and C of Regulation (EC) No 768/2008 is proportionate – with Module B covering the design level and Module C covering the production level. Module B includes a review of the technical design of the product by a notified body (EU type examination), which focusses on the wetted surfaces of the product and the documentation of the suitability of materials.

EDW stresses that it is proportionate to assess the technical design of the product based on the technical documentation only. The technical documentation should contain all necessary information about the hygienic suitability of the product. Conformity at production level shall be ensured by internal manufacturing control based on a recognized management system (e.g., ISO 9001) in combination with good manufacturing practice (GMP) based on the requirements from Regulation (EC) No 2023/2006. It should be possible to obtain certificates of conformity for product families consisting of comparable products (e.g., same materials, comparable design, different sizes).

Material specific requirements

With reference to the draft of the 4MSi ("*Requirements and test methods for products made of Organic Materials in Contact with Drinking Water - 4MSi Draft Common Approach on Organic Materials- Part C*"), EDW stresses that the assessment of hygienic suitability at the preliminary product level ensures

a sufficient level of safety without further testing for final products with minor influence on drinking water. A recent study by the German Environment Agency (UBA) investigated whether the production of different components from the same preliminary product at different locations has an impact on the quality of plastic components. For this purpose, components from various manufacturers of drinking water products were compared with material test plates from producers of preliminary products (granules). No significant differences were found for the three different polymer types tested.

The study results indicate it may be possible to reduce testing requirements for components intended for products with minor influence on drinking water if certification is done for the preliminary product.

In case certificates for all preliminary products used in the manufacture of the final product are available and the manufacture is in line with the specifications of the preliminary product, no additional tests to assess hygienic suitability as part of initial certification (EU type examination) shall be required on the final product level.

If a manufacturer uses a preliminary product to manufacture a final product for which no confirmation of conformity is available or decides to deviate from the processing specifications given there, they are obliged to carry out the requirements of conformity assessment on the final product.

An overview on the conformity assessment procedure for the different product classes is given in **Table 3 (annex)**.

FINAL REMARKS

EDW recommends engagement with manufacturers and producers to identify the best system to secure safety, while also ensuring feasibility and proportionality. EDW is confident that the proposed way forward delivers on the DWD objectives and contributes to the safety of drinking water products for 500 Mio people within the European single market. This will be achieved on basis of clear and easy-to-apply product classes for products in contact with drinking water and suitable conformity assessment procedures having regard to the potential impact of products on drinking water quality. This should be based on a common and unique test method to be used in the EU27.

ANNEX

Table 1: Overview of the product classes

Product category	Product class	Products
Preliminary products	P	Plastic granules, compounds, ceramics/enamels
Final products	F1	Pipes, relining systems, Flexible hoses out of scope of EN 13618
	F2	Pipe connectors, fittings such as adapters, expansion adapters, mechanical joint adapters, bell adapters, flange adapters, elbows, couplings, unions, nipples, reducers, tees, caps, plugs, barbs.
	F3	All other products not falling in Product class F1 or F2 such as valves, pumps, water meters, water heaters, water treatment devices, taps, pressure reducers, anti-backflow devices and flexible hoses within scope of EN 13618.

Table 2: Options for organic materials and ceramic materials /enamels testing for final products according to Article 11(8) DWD

Material group	Test requirements	Product class F1	Product class F2	Product class F3
Ceramic Materials/ Enamels Organic Materials	Formulation review (based on starting substance positive lists)	yes	yes	yes
Organic Materials	Enhancement of Microbial Growth (EMG)	Final product or component	Component	Component
		Preliminary product	Preliminary product	Preliminary product
Organic Materials	Total organic carbon (TOC)	Final product	Final product or component	Final product or component
				Preliminary product
Organic Materials	Organoleptic testing (TON)	Final product	Final product or component	Final product or component
				Preliminary product
Ceramic Materials/ Enamels Organic Materials	Additional requirements (Specific migration limits)	Final product	Final product or component	Final product or component
			Preliminary product	Preliminary product

If more than one option is specified, where the tests can be performed it is only necessary to perform the tests at one indicated option, not at all.

Table 3: Product conformity assessment requirements according to Article 11(8) DWD based on product classes

Product category	Preliminary Products	Final products		
Product class	P	F1	F2	F3
Products	Plastic granules, powders, compounds; Ceramics/enamels	Pipes, relining systems	Pipe connectors, fittings, flexible hoses	All products not being F1, F2, P
Conformity assessment procedure	Supervised test specimen production	System 1+	System 1+	Module B + C of 768/2008/EC
Operate quality management system/ Factory production control (FPC)	ISO 9001 + 2023/2006/EC	FPC according 305/2011/EU	FPC according 305/2011/EU	ISO 9001 + 2023/2006/EC
Sampling	Yes	Yes	Yes	No
Product testing	Every 5 years	Every 5 years for TOC, TON and additional requirements	Every 5 years for TOC and TON	No, product conformity based on certified/approved materials
Verification testing	No	Annually for TOC and TON	Annually for TOC and TON	No
Initial production audit	No	Yes, by hygiene inspector	Yes, by hygiene inspector	No
Verification audit	Within ISO 9001 audit	Yes, by hygiene inspector	Yes, by hygiene inspector	Within ISO 9001 audit
Frequency of verification audit	ISO 9001 frequency	Annually	Annually	ISO 9001 frequency
Product certificate	Certificate based on test results of specimen	Certificate based on product test and inspection	Certificate based on product test and inspection	Type approval based on document review **)
Validity of certificate *)	Valid for 5 years	Valid for 5 years	Valid for 5 years	Valid for 5 years

*) earlier in case of changes

**) comparable to French ACS type approval