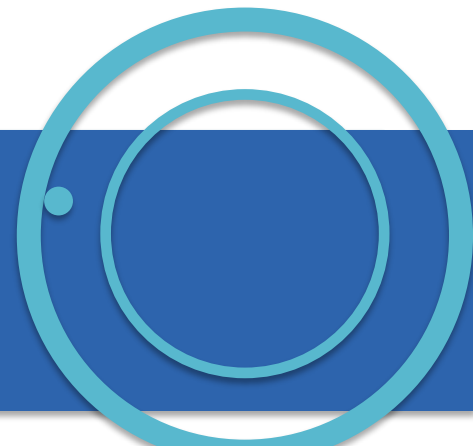


EU Drinking Water Directive: Article 11 in Practice

A pragmatic pathway to safe drinking water, harmonized material, product and substance approval, and legal certainty across Europe



European Drinking Water (EDW) welcomes and promotes the harmonization of EU regulatory requirements of substances, materials and products used in drinking water applications. EDW is committed to helping ensure the consistent and effective implementation of Article 11 of the EU Drinking Water Directive, which establishes minimum hygiene requirements for materials in contact with water intended for human consumption.

To safeguard the continuous production, certification and supply of drinking water contact materials in the EU, EDW proposes targeted amendment to the Directive and certain secondary legislation. EDW is also committed to continued technical cooperation with the European Commission and the Member States.

Challenges



Difficulties for on site-applied materials

The current conformity assessment framework does not fit products made from materials applied on site.



Fragmented transition periods

Article 11 transition periods are applied inconsistently across Member States, while products placed on the EU market after 31.12.2026 without an existing national hygiene certificate are considered “new” and require EU certification.



Missing substances in the EUPL

Existing critical substances are missing from the European Positive Lists (EUPL), which affects the downstream sectors.



Lack of harmonization in testing

Testing methods and validation are not yet sufficiently harmonized across the EU.



Lack of mandatory cost- and data-sharing

Somebody might have to bear all the burdens (including cost and data generation) alone in the EUPL application process.



Uncertain interlinkage between Article 11 and Article 12

It is not clear how the Article 11 could affect the ion exchange resins and filtration membranes under the Directive.

Recommendations and Benefits

Amend Commission Delegated Regulation (EU) 2024/370 to provide a workable assessment route.

Benefits: Certification and installation of on site-applied materials can proceed smoothly, without compromising hygiene.

Apply the Article 11 transition period by default across all Member States and extend it until 2032 for newly placed products, allowing national hygiene certificates alongside the EU certificate.

Benefits: Remove legal uncertainty, ensure consistent EU-wide market access and maintain the availability of newly developed products while preventing supply chain disruptions.

Include the existing critical substances in the EUPL by corrigenda to Commission Implementing Decision (EU) 2024/367.

Benefits: Avoid unexpected disruption and the loss of products made of materials containing these substances.

Industry's commitment to supporting further development and validation of testing methods, together with Member States and laboratories.

Benefits: Reduce gaps in testing methods and improve the mutual acceptance and reliability of test results across the EU.

Introduce a targeted amendment to the Drinking Water Directive to include a mandatory cost- and data-sharing mechanism as seen in REACH Regulation.

Benefits: Ensure the level playing field in the market and encourage industry to invest in production of substances.

Reconsider coherent integration of hygienic evaluation of ion exchange resins and filtration membranes into the framework of Article 11, while preserving the original spirit of Article 12.

Benefits: Promote EU-harmonized treatment of all drinking water contact materials across the EU.

Let's discuss how the targeted amendments can make Article 11 work in practice.