

Q&A

Questions and Answers on materials and products in contact with drinking water

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¹ The Commission published a proposal on the Revision of the Mutual Recognition Regulation on 19 December 2017
<https://ec.europa.eu/docsroom/documents/26975>

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19. How long would harmonisation take?
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22. Can an environmental legislation, such as the Drinking Water Directive², lead to harmonisation?
23. What would be the relationship between the Drinking Water and product legislation?
24. Which are the alternatives to harmonisation under the Drinking Water Directive?

² The Drinking Water Directive falls under the Environmental Chapter of the Treaty on the Functioning of the European Union ([Art. 191 TFUE](#)) of which the objective is to guarantee a high level of health and environmental safety.

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I. Overview on Materials and products in contact with drinking water

1. What are products in contact with drinking water?

According to the DWD, products in contact with drinking water are manufactured items used for fixed water supply equipment. These include:

- Pipes.
- Pipes fittings, i.e. items used to connect pipes.
- Products used to measure water, to control water pressure, flow or temperature - such as valves, sensors, pumps, water meters and water heaters.
- Water storage systems.
- Taps and other appliances delivering water for human consumption.
- Water treatment devices.
- Water treatment chemicals.
- Vending machines up to the backflow device.

2. Which products do not fall under the scope this definition?

Products that are not part of the fixed water supply system do not fall under the definition above.³ For instance, the DWD does not classify bottles, glasses or drinking straws as products in contact with drinking water. The latter are considered as food contact materials and articles and are regulated under the [Food Contact Materials Framework Regulation](#) (Regulation (EC) No 1935/2004).

3. What are materials in contact with drinking water?

Materials in contact with drinking water are the produced form of a substance or a combination of substances, suitable for use in the manufacturing of products. Products in contact with drinking water are made from one or more materials.

4. What are the main materials in contact with drinking water?

There are three main types of materials:

- Cementitious materials, i.e. materials including cement in their composition.
- Metallic material, including metals (e.g. copper, nickel, chromium and iron), metallic alloys (e.g. brasses, stainless steel, etc.) and platings.
- Organic materials, including plastics, rubbers, silicones, and coatings.

5. How many companies are involved in the production of materials and products in contact with drinking water?

In the EU, around 2500 companies manufacture materials in contact with drinking water, while 5000 manufacture products in contact with drinking water. Most of these companies are SMEs. Over 100.000 people are directly employed in the manufacturing of products in contact with drinking water. The sector generates sales up to 40 billion euros a year.⁴

³ According to the General Food Law (Regulation (EC) No 178/2002), water after the point of compliance set in Art. 6 of the is not subject to the obligation stemming from drinking water legislation, but is covered by food legislation.

⁴ Ian Naismith and others, "Study on materials in contact with drinking water" (February 2017), p. 29.

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II. EU current Regulatory framework

6. What is the current EU regulatory framework?

As of today, materials and products in contact with drinking water are not harmonised at the EU level. That means that it is the responsibility of Member States to set hygienic requirements. This situation stems from the existing Article 10 of the [Drinking Water Directive](#) (DIRECTIVE 98/83/EC) – currently under revision – according to which:

‘ Member States shall take all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in water intended for human consumption in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive’

7. What are the consequences arising from the current EU regulatory framework?

The current Article 10 has led to the proliferation of different national requirements on materials and products in contact with drinking water. Member States have implemented Article 10 in vastly different ways whilst some have no specific provisions. Such a lack of harmonisation has significant **negative impacts** on European consumers and companies:

- **Differences in the level of consumer health protection and in drinking water quality.**
- **Fragmentation of the EU internal market and barriers to intra-EU trade.**
- **High administrative and financial burden** for the producers of these products (amounting to roughly 1.208 billion euros a year in the EU-28).⁵ These estimates do not include the costs for the petition of the same substances across different Member States: average costs amount to several million euros for only one substance.⁶ Companies need to test and assess the conformity of the same material or product multiple times in different Member States. This is especially a burden for small and medium enterprises that do not often have enough resources to cope with different national provisions.
- **Obstacles to innovation:** European manufacturers have fewer incentives to invest in innovative products (e.g. products having a longer lifetime) since they do not have the legal certainty that they can sell their products to the whole European market.⁷

⁵ Ian Naismith and others, “Study on materials in contact with drinking water” (February 2017), p. 63

⁶ Food Contact Additives (FCA), Cefic Sector Group, own estimates.

⁷ This is even more for the case for assembled products, i.e. products in contact with drinking water made from a number of different materials (e.g. plastics and metal, cement and metals, etc.): before assembled products are approved across the EU, every material that constitutes these products needs to be approved by every and each EU Member State. This situation significantly increases the legal uncertainty for European companies that want to put innovative products on the market.

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As recognised by the Commission's own review of the DWD: *'The Article 10 provisions do not work well and represent a long term challenge to the provision of clean and healthy drinking water in the EU'*.⁸

8. Does the mutual recognition principle apply to materials and products in contact with drinking water?

In theory, the principle of mutual recognition should apply to materials and products in contact with drinking water. That means that Member States may not prohibit the sale on its territory of products which are lawfully marketed in another Member State, even where those products were manufactured in accordance with technical rules different from those to which domestic products are subject. The only exceptions to the principle of mutual recognition are restrictions which are justified on the grounds set out in Article 30 of the Treaty (i.e. public morality, public policy or public security; the protection of health and life of humans, animals or plants, etc.) or on the basis of other overriding reasons of public interest.⁹ In practice, "mutual recognition is only rarely admitted"¹⁰ and national authorities and customers do not generally accept materials and products in contact with drinking water coming from other Member States – even more from Member States without a specific national legislation on materials and products in contact with drinking water.

9. Will the ongoing revision of the Mutual Recognition Regulation¹¹ have a significant impact on materials and products in contact with drinking water?

No. While the Commission proposal on mutual recognition streamlines the procedure for companies to demonstrate their compliance with national legislation, the proposal still formulates in broad terms the exceptions to the mutual recognition principle. Thus, the existence of different national requirements will still enable Member States to restrict materials and products in contact with drinking water coming from other Member States.

⁸ European Commission, Staff Working Document "Refit Evaluation of the Drinking Water Directive 98/83/EC", 1 December 2016, p. 42, Available at http://ec.europa.eu/environment/water/water-drink/pdf/SWD_2016_428_F1.pdf

⁹ See [Regulation \(EC\) No 764/2008](#)

¹⁰ European Commission, Staff Working Document "Refit Evaluation of the Drinking Water Directive 98/83/EC", 1 December 2016, p. 15, Available at http://ec.europa.eu/environment/water/water-drink/pdf/SWD_2016_428_F1.pdf

¹¹ The Commission published a proposal on the Revision of the Mutual Recognition Regulation on 19 December 2017 <https://ec.europa.eu/docsroom/documents/26975>

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III. Main elements of the Commission proposal on the Recast of the Drinking Water Directive and EDW reaction

10. What are the main elements of the Commission proposal?

The Commission proposal on the Recast of the Drinking Water Directive – released on 1 February 2018 – deletes current provision on materials and products in contact with drinking water (Article 10 of DIRECTIVE 98/83/EC). The proposal states that the hygienic requirements for materials and products in contact with drinking water should be regulated under the [Construction Products Regulation \(CPR\) \(REGULATION EU 305/2011\)](#).

11. What is the Construction Products Regulation?

The Construction Products Regulation lays down harmonised standards for the marketing of construction products in the EU, with the objective to promote the creation of a single market for construction products. In particular, the CPR outlines the methods (e.g. test methods) and criteria for assessing the performance of construction products. The CPR only applies to construction products, i.e. products incorporated in a permanent manner in buildings.¹²

12. What would be the impact of the Commission proposal on materials and products in contact with drinking water?

In accordance with the Commission proposal, the Commission will issue a mandate to standardisation bodies (CEN) to elaborate harmonised standards outlining the methods and criteria to assess the hygienic performance (e.g. migration of substances) of construction products in contact with drinking water. Once the harmonised standard is published, all manufacturers of such products must use them when marketing their products. These standards do not harmonise the hygienic requirements (e.g. migration limits for substances) applicable to construction products in contact with drinking water.

13. Would the Commission proposal be effective in harmonising hygienic requirements on materials and product in contact with drinking water?

No. The Commission proposal will not ensure full harmonisation for the following reasons:

- The primary objective of European harmonised standards under the CPR is to specify common test methods to assess a certain construction product. **There will be no harmonisation if the hygienic requirements (e.g. lists of approved substances and other general hygienic requirements) continue to differ among Member States.** As also recognised by the Commission review, *“in general, CPR-based harmonised standards are not setting requirements for products’ performance itself”*.¹³

¹² The CPR defines construction products as *“any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works”*

¹³ European Commission, “Report on the Implementation of Regulation (EU) NO 305/211 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC” (7 July 2016), p. 6 <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0445&from=EN>

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- Many products in contact with drinking water (water heaters, pumps, domestic appliances, water meters, hoses, gaskets, some types of valves, taps, etc.) do not fall under the scope of the CPR.¹⁴ Hence, **the Commission proposal excludes a large share of products in contact with drinking water from harmonisation**, creating a legal vacuum that risks to negatively affect drinking water quality.

For all these reasons, the Commission proposal on the Recast of the Drinking Water Directive will not lead to full harmonisation. Instead, the Commission proposal will create additional confusion and a regulatory loophole for a significant share of materials and products in contact with drinking water.

¹⁴ The CPR only applies to construction products, i.e. products incorporated in a permanent manner in buildings. See footnote 11.

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IV.EDW Position**14. What is the EDW position on materials and products in contact with drinking water?**

The EDW supports the development of legally binding EU-wide harmonised hygienic requirements and test methods on all materials and products in contact with drinking water.

15. Which requirements should be harmonised?

Materials and products in contact with drinking water shall:

- Ensure a high level of protection of human health;
- Avoid enhancement of microbial growth
- Avoid alterations in flavour, odour, colour or turbidity of water (organoleptic characteristics) that render it unsuitable for consumer acceptability.

To comply with the conditions above, the following aspects should be harmonised.

HYGIENIC REQUIREMENTS

- a) A **list of substances** approved for the production of materials in contact with drinking water. Since all materials (plastics, silicones, rubber, cement, metals, etc.) are made from substances, harmonisation can only happen if the same set of substances is approved all over Europe. This list of substances should also include – where applicable – specific migration limits or special conditions of use for certain substances.
- b) **Requirements** on organoleptic characteristics, microbial growth and other relevant characteristics that can have an impact on the hygienic safety of materials and products in contact with drinking water.

TEST METHODS

Test methods are the procedure to assess whether the hygienic requirements are complied with.

PROCEDURES FOR CONFORMITY ASSESSMENT

Procedures to be followed by companies to demonstrate that they are compliant with the defined hygienic requirements.

16. Which are the benefits arising from harmonisation?

EDW believes that harmonisation will:

- Ensure that all EU citizens enjoy the **same high degree of human health protection**.
- Deepen the **EU internal market** and, therefore, incentivise companies to invest in the development of innovative technologies (e.g. in products having a longer lifetime) to be placed on the whole European market.
- Stimulate the **competitiveness** of the EU industry and job creation by reducing unnecessary administrative and financial burden.

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- Contribute to turn the EU into a **global reference point** regarding the legislation on materials and products in contact with drinking water.

17. How can harmonisation occur under the Drinking Water Directive?

EDW supports the introduction of a provision under the Drinking Water Directive enabling EU institutions to adopt legally binding measures (delegated or implementing acts) establishing hygienic requirements, common test methods and procedures for the conformity assessment of materials and products in contact with drinking water.

18. Who would be in charge of assisting the European Commission in the development of harmonised requirements?

EDW believes that an EU risk assessment agency (such as EFSA) would be the most suitable organization to perform a scientific assessment of the hygienic safety of materials and products in contact with drinking water. The European Commission could then base its draft delegated/implementing acts on EFSA assessments. A possible alternative to this approach is the establishment of a Member States Committee – including national experts from Health Ministries or national health authorities – which would assist the Commission in the development of the draft delegated/implementing acts harmonising hygienic requirements on materials and products in contact with drinking water.

19. How long would harmonisation take?

Harmonisation would not happen overnight, but it would be a gradual and progressive process.

For instance, the development of a list of approved substances could follow the approach already taken by the four Member States Initiative:

- For substances that have already been scientifically assessed by either EFSA or the Member States Committee, the Commission may propose that they are placed on the list of approved substances.
- For all other substances that still need to be assessed, either EFSA or the Member States Committee should establish a clear timeline for the scientific assessment. After that, the Commission may propose that the relevant substances are placed on the list of approved substances.

The list of substances, as well as all other generic hygienic requirements, should be kept under constant review, on the basis of a clear timescale, to take into account scientific and technical developments.

20. Are there already existing initiatives from which the harmonisation process can draw inspiration?

Yes. Several actors have worked towards a further harmonisation of the hygienic requirements on materials and products in contact with drinking water:

- [The 4 Member States Initiative \(4MS\)](#).
Starting their work in 2011, the 4 Member States Initiative - including France, Germany, Netherlands and UK, with Portugal and Italy as observers, intend to adopt common, or directly comparable, practices for:

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- The approval of substances approved for the production of materials and products in contact with drinking water.
- The setting of other hygienic requirements.
- The specification of test methods and procedures for conformity assessment.

- **The MAID Project.**

Denmark, Finland, Norway and Sweden initiated the MAID project (Material and product innovation through knowledge-based standardisation in drinking water sector) in 2014 with the objective to foster innovation and harmonisation in the drinking water sector. The final report has been published in 2018.¹⁵

- **Development of several European standards for testing materials and products in contact with drinking water.**

Standardisation bodies have developed several European testing methods for the hygienic safety of organic, metallic and cementitious materials. These tests do not specify the actual hygienic requirements (e.g. threshold levels for the release of specific substances) that materials and products in contact with drinking water need to satisfy.

- **Industry initiatives.**

The European Drinking Water Industrial Alliance (EDW) has developed a [Scheme for Assessment of Plastic and Silicone Products for Suitability for Contact with Drinking Water](#) and is currently developing more schemes.

21. If harmonisation is pursued under the DWD, what would happen to national legislation?

Member States will have to transpose EU requirements into their national legislation within a given deadline. To allow EFSA or the Member States Committee the needed time to perform the needed scientific assessments, national regulations should provisionally apply until the relevant EU measures have been adopted in accordance with a clear timescale.

22. Can an environmental legislation, such as the Drinking Water Directive¹⁶, lead to harmonisation?

Yes, environmental legislation can lead to more harmonised hygienic requirements. There are no provisions in the EU Treaties preventing environmental legislations from harmonising hygienic and safety requirements. For instance, the Waste Framework Directive – another environmental legislation – provided for the establishment, *via* an implementing act, of a harmonised list of properties rendering waste hazardous. At the same time, EU Treaties entitle Member States to adopt or maintain national measures that are more stringent than

¹⁵ MAID Project (2018), “Final Report– Material and product innovation through knowledge based standardisation in drinking water sector “,

<http://www.nordicinnovation.org/Global/Publications/Reports/2018/MaiD%20Final%20Report.pdf>

¹⁶ The Drinking Water Directive falls under the Environmental Chapter of the Treaty on the Functioning of the European Union ([Art. 191 TFUE](#)) of which the objective is to guarantee a high level of health and environmental safety.

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EU rules.¹⁷ In spite of this, EDW believes that harmonisation under the Drinking Water Directive would be a significant progress compared to Commission proposal for the following reasons:

- 1) It would cover all materials and products in contact with drinking water.
- 2) It would allow the establishment of EU-wide hygienic requirements.

To sum up, harmonisation under the DWD would create minimum European hygienic requirements. Even though Member States would still be able to introduce national measures, this would not be the norm – as it is today – but would be only a possibility.

23. What would be the relationship between the Drinking Water and product legislation?

Standards developed under the Construction Products Regulation as well as other pieces of legislation covering the marketing of products in contact with drinking water (e.g. Gas Appliances Regulation) shall refer, wherever applicable, to the hygienic requirements developed under the Drinking Water Directive. This cross-reference would ensure coherence between different pieces of EU legislation.

24. Which are the alternatives to harmonisation under the Drinking Water Directive?

EDW believes that an alternative solution could be the establishment of a specific new regulation on materials and products in contact with drinking water - as it already exists for food contact materials¹⁸ - under [Article 114 of the Treaty on the Functioning of the EU \(common market chapter\)](#). This option could bring an even higher level of harmonisation:

- A regulation would be directly applicable in all Member States, without the need to be transposed into national legislation.
- Under the common market chapter, Member States would be able to introduce national measures in contrast with EU provisions only when duly justified by environmental and health reasons.¹⁹

Even though a new regulation would be the ideal solution, its adoption is rather unlikely in the coming years - due to the long preparation period needed for the drafting of a new regulation. For this reason, the EDW believes that a harmonisation under the DWD is the most realistic solution in the medium term and may also lay the ground for a future specific legislation on materials and products in contact with drinking water.

¹⁷ Article 193 of the Treaty on the Functioning of the European Union (TFEU), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12012E193>

¹⁸ [Food Contact Materials Framework Regulation](#) (Regulation (EC) No 1935/2004).

¹⁹ Article 191 TFEU, <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E191:EN:HTML>

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European Drinking Water – Member associations



ANIMA
Federation of Association of
Mechanical and Engineering
Industry



APPLIA
Home
Appliance
Europe



AQUA
European Association of
Water Meters and Heat
Meters Manufacturers



AQUA EUROPA



BMA
Bathroom Manufacturers
Association



Branchehuset



British Water



CEIR
European Association for
the Taps and Valves
Industry



CES
Silicones Europe



CESA
Catering Equipment
Suppliers Association



DKI
Copper Alliance



EADIPS
European Association for
Ductile Iron Pipe Systems



EFCEM
European Federation of
Catering Equipment



EHI
European Heating Industry



ELISANA
European Light Stabilisers
and Antioxidants



ESA
European Sealing
Association



ETRMA
European Tyre & Rubber
Manufacturers' Association



Europump
The European Pump
Manufacturers Association













EVA
European Vending
Association



EWTA
European Water
Treatment Association

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<p>FCA Food Contact Additives (a Cefic Sector Group)</p>	<p>Figawa Association of Companies for Gas and Water Technologies</p>	<p>KRV Fachverband der Kunststoffrohrindustrie</p>	<p>PlasticsEurope</p>
			
<p>SOIA Synthetic Organic Ion Exchangers and Adsorbents</p>	<p>TEPPFA The European Plastic Pipes and Fittings Association</p>	<p>VDDW Association of German water- and heat meters industry</p>	<p>VRH Association for Piping Systems Inside Buildings</p>
			
<p>WQA Water Quality Association</p>	<p>ZVEI German Electrical and Electronic Manufacturers' Association</p>		

About us

The European Drinking Water (EDW) is an alliance of currently 30 European trade associations representing industries involved with the supply of products or materials that are used in drinking water applications and connected to municipal drinking water supplies within the European Union (EU). This ranges, from raw materials suppliers to producers of pumps, water meters, pipes, valves, taps, fittings, water treatment, water heaters, catering equipment industry, seals, etc. and all types of materials, such as elastomers, metals, plastics, etc. The alliance is open to any industry association relevant to drinking water contact applications.