German Environment Agency

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Scientific Opinion Paper

How do we achieve a harmonised European regulation of materials in contact with drinking water?

What is this initiative about?

On its way from the source to the tap, drinking water is exposed to myriad materials. Those can leach substances into the water which can alter its odour or taste, have human health relevance (e.g. bisphenol A, lead), or enhance microbial growth.
Most components used for the abstraction, treatment and distribution of drinking water are permanently installed and have a long service life. It is therefore essential that they satisfy a high level of safety in order to keep our most vital food item clean and pure and protect human health.

Which regulations are currently in place?

The current version of the EC Drinking Water Directive (98/83/EC) of 1998 requires the Member States to adopt national regulations covering the materials used. Over recent decades, however, these regulations have evolved in very different ways in some Member States, specifically where they relate to testing methods[1] and requirements[2]. Some Member States, moreover, have never put any detailed regulations in place.

What are the difficulties?

National regulations are seen as obstacles to the trade in products on the Internal Market and are therefore, repeatedly challenged by the European Commission and some manufacturers.

Nevertheless, the national regulations continue in force and, since they all spell out different requirements, mutual recognition is a problem.

In the absence of harmonisation, this leaves all of the parties involved with an unreasonable amount of cost and workload: Every EU Member State must develop and maintain its own product evaluation and testing system and the manufacturers have to conduct onerous multiple testing procedures to meet highly disparate requirements.

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What activities are in progress?

Products in contact with drinking water are, for the most part, construction products. This is why a harmonised regulation for materials in contact with drinking water set within the context of the European construction products law has, by now, been more than two decades in the making. So far, it has yet to materialise. A major sticking point here has been the harmonisation of requirements.
Now, it so happens that the updating of the EC Drinking Water Directive is imminent. In this context, a study on materials in contact with drinking water[3] has identified various regulatory options.

How much regulation should be aimed for?

From the perspective of the Federal Ministry of Health and the German Environment Agency, the goal should be to have the fullest harmonisation possible, one that would cover all products in contact with drinking water. In the meantime, all relevant aspects are governed by CEN-standardised testing procedures that, however, have only been applied by a few Member States, so far. This is because, first, the testing standards themselves do not include any requirements and, second, application implies that a method is in place for the toxicological assessment of substances that are likely to migrate into drinking water. In a voluntary initiative to harmonise their requirements, the 4EU Member States France, Germany, the Netherlands and the United Kingdom (4MS Common Approach) have already drawn up regulatory proposals[4] (testing requirements and the management of common positive lists). These proposals from the 4MS Common Approach should be incorporated into drinking water legislation throughout Europe. This would enable the European product regulations (such as the EU Construction Products Regulation - R (EU) No. 305/2011) to invoke them as binding. This approach has the potential to reach a uniform EU-wide standard for products in contact with drinking water.

What is the benefit/added value of a Europe-wide regulation?

A European level regulation would substantially reduce the workload on the national bodies who currently do similar work independently of one another. Also, it would prevent diverging assessments (that are known to occur from time to time).
The manufacturers are likely to welcome the proposed regulation since they would need to have their products evaluated only once -- in any EU Member State -- to gain access to the entire European Single Market, which will substantially reduce the paperwork involved.
Consumer health protection should be paramount in the EU and be ensured at the same high level across the EU. Different levels of national requirements in the Member States should not, due to the obligation to grant mutual recognition, lead to a situation where the lowest of levels

would eventually prevail. This scenario can only be prevented by putting uniform standards in place that apply throughout Europe. The additional advantages and benefits this brings are obvious: In addition to cutting paperwork and advancing the EU Single Market as well as speeding up the market access of tested products, a uniform regulation would, first and foremost, serve to protect the health of all EU citizens.
The primary goal of the regulation is to protect drinking water from contamination. Therefore, the regulation of materials should be embodied in the EU's drinking water law. Once established, the provisions can be used as a reference by the specific product regulations (such as the EU Construction Products Regulation).
Thanks to this, the "packaging" of our drinking water - in other words the pipework, fittings and other components -- would be equally well regulated as the packaging of many other food items.

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[1]Testing is detailed in a standard and also specifies the sampling of water for analysis or, for instance, the determination of the odour threshold value. The requirements, however, have deliberately not been incorporated into a standard, because regulatory responsibility lies with the Member States. Requirements can be expressed as levels (such as the odour threshold value); however, they can also be quite elaborate, as in the case of substance migration, see footnote 2.

[2]The determination of requirements in respect of substance migration must be based on the toxicological assessment of the starting substances used. This then is the basis for imposing restrictions (on, for example, the starting substance or its reaction products). Likewise, it must be determined which substances should be subject to testing and how to convert the concentrations measured to levels expected at the tap. Therefore, the requirement documentation is extensive.

[3] https://circabc.europa.eu/w/browse/26398165-15d9-4eaf-8671-a6e8e6b6a32c

[4] https://www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen/anerkennung-harmonisierung-4ms-initiativ