

ANALYSING THE IMPACT OF THE REGULATION ON THE NATIONAL APPROVAL SYSTEM FOR PRODUCTS IN CONTACT WITH WATER INTENDED FOR HUMAN CONSUMPTION

Water intended for human consumption is an essential commodity marketed under a monopoly regime, so regulation and ensuring its quality are of particular importance, as users do not have freedom of choice.

In a supply system, from abstraction to the consumer's tap, the quality of water can be influenced by several factors, namely the nature and quality of the raw water source, the treatment processes and respective products used, the nature and conservation status of the materials used, either in the public network or in the building network, as well as operational practices and conditions.

Despite the importance of any of the aforementioned factors, the quality of products in contact with water is particularly important due to the possibility of organic substances and/or heavy metals migrating/leaching from their constituent materials into the water, which, despite occurring at very low levels, can be continuous and long-lasting.

Therefore, in order to ensure a high level of protection of human health, it is important to assess the influence of the products used on water quality. Furthermore, Article 10 of Council Directive 98/83/EC of 3 November 1998 has not had the desired effectiveness in removing existing obstacles in the European Union internal market for the free movement of products in contact with water.

In fact, by assigning to each Member State the responsibility of ensuring the suitability of these products to be in contact with water, the desired harmonisation has not been achieved, resulting in different producers having to deal with different approval mechanisms for the same product, which unnecessarily burdens the cost of production and administrative costs for obtaining marketing authorisation.

Given this background, it was necessary to find an alternative solution, which was enshrined in 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

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consumption, in particular by entrusting the European Commission with the adoption of implementing acts establishing specific minimum hygiene requirements for products that come into contact with water.

In this way, it is possible to ensure the uniform application of all the criteria in the various Member States of the European Union.

In order to comply with the requirement of the above-mentioned Directive, Article 33 of Decree-Law No 69/2023 of 21 August 2023 establishes the obligation for the ERSAR, as the competent authority for the coordination and monitoring of the implementation of the above-mentioned Decree-Law, to establish in the form of a regulation a national approval system for products in contact with water.

To this end, ERSAR draws up this Regulation, based on Commission Delegated Regulations 2024/369, 2024/370 and 2024/371 of 23 January, and Commission Implementing Decisions 2024/365, 2024/367 and 2024/368 of 23 January, adopted by the European Commission in accordance with Article 11(2) of Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December.

The impact of this regulatory act on the sector of products in contact with water intended for human consumption, taking into account the criteria of simplification, efficiency and effectiveness, is to simplify the processes of product supply and purchase by management organisations, making them simpler and quicker.

In effect, the process of acquiring a product will become simpler and less costly for suppliers and users of the product (management entities or private individuals), since the supply and acquisition process will require less documentation and technical knowledge related to assessing the conformity of the product's quality, given the establishment of harmonised specifications within the European Union market, the conformity of which is verified through a specific marking enshrined in Commission Delegated Regulation (EU) 2024/371 of 23 January.

In this way, potential users of these products only have to ensure that they buy products with the appropriate marking, since this is only awarded to products that fulfil the technical specifications laid down in European regulations and transposed into this regulation. It should also be noted that product assessment is carried out by a conformity assessment body accredited by the national accreditation body and notified to the European Commission by the Portuguese Quality Institute.

The reduction or even elimination of these obstacles to the internal market may, according to the impact study carried out by the European Commission on the revision of Council Directive 98/83/EC of 3 November 1998, result in annual savings within the European Union of EUR 669 million, although there may be some damage to national conformity assessment bodies, since the same product only needs to be assessed by one of these bodies in order to be used throughout the European Union market.

These savings result, for example, from reduced costs in the approval and certification processes, with a particular impact on the small and medium-sized enterprises that are the majority in this sector.

This same study identifies for the baseline situation calculated for the year 2015 that harmonising the approval process for products in contact with water can contribute to the reduction of 900,000 European inhabitants potentially exposed to a situation of risk to health, as well as a reduction of €3.20 per year in the costs incurred by consumers in paying the bill.

Removing these obstacles is also an incentive for innovation, since the lack of standardisation in the approval processes did not help companies to invest in new products. With the standardisation of the rules, the approval process is clearer and catalyses a commitment to new products which, once approved in one Member State, can be freely used in others.

These savings are justified by the fact that suppliers no longer have to deal with different national approval systems and different brands. With this regulation an equal approval system is created in the European area and only with one mark.

Regarding the impact of this regulatory act on the environment, it is considered that by fixing the type and maximum quantity of substances in the manufacture of the product in contact with water, in addition to ensuring better protection of human health, the emission of chemical substances into the environment is also being reduced, whether in wastewater, soil or in the workplace, in other words, also generating positive impacts on the environment.

It is also worth noting that the provisions of this regulation will also facilitate the role of public authorities, since there is no longer a need for each member state to have its own approval criteria.

In summary, the economic impact of the harmonised regulation of products in contact with water is expected to be positive for



producers, with cost reductions in the approval and certification processes, positive for potential

buyers because they see the purchasing process facilitated by the use of a uniform trademark in the European Union, positive for consumers with increased protection of human health and positive for the environment, in particular for the water cycle, with the minimisation or even elimination of the deposition of some chemical substances in the environment.