Key parts of the study "Support to the Implementation and Further Development of the Drinking Water Directive 98/83/EC (DWD): Study on Materials in contact with Drinking Water"

Published in end March 2017, the European study on materials in contact with drinking water recognises the issues of little harmonisation or mutual recognition in EU Member States' application of Article 10 of the Drinking Water Directive (98/83/EC) (DWD) that requires them to ensure substances / materials in contact with drinking water do not remain in drinking water at concentrations harmful to human health.

The first part (Task 1) of the "Study on materials in contact with drinking water" aims at identifying and assessing the issues affecting materials and products coming into contact with drinking water.

This first part will be followed by two other sections which are intended to summarise consolidated information on appropriate materials/products and test methods in a Guidance for users (householders, plumbers and manufacturers - Task 2) and support the preparation of a draft Inception Impact Assessment (Task 3).

Read the following pages for a summary of Task 1 of the study.

About EDW

European Drinking Water (EDW) is an alliance of European trade associations formed in 2015. EDW represents industries which are involved with supply products or materials that are used in drinking water applications and connected to municipal drinking water supplies within the European Union (EU). This includes, for example, pumps, pipes, valves, taps, fittings, water treatment, water heaters, catering equipment industry, seals, raw material producers, 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.

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Task 1 - Assessment of the situation

1. Main aspects

Task 1 of the "Study on materials in contact with drinking water" (hereafter, the Study) details the current regulatory framework as well as economic aspects of the market for materials and products coming into contact with drinking water. It focuses on the constraints limiting the free movement of goods and, in its conclusions, it provides for possible policy solutions.

2. Products, materials and installations in scope

The Study analyses the implications for products and materials in the context of the application of Article 10 of the Drinking Water Directive 98/83/EC (DWD) which provides for the quality assurance of treatment, equipment and materials in contact with drinking water. The Study states that requirements and obligations are related to the substances, and materials which products are made, of as well as on their potential adverse effects on human health.

In terms of scope, Art. 10 of the DWD covers installations for the "preparation or the distribution of water from the point of its collection (e.g. in a groundwater borehole), through treatment, storage, distribution in the public network and building plumbing systems".

3. Regulatory framework

a. EU policy for products in contact with drinking water

After clarifying the scope of its analysis, the study provides for a description of the current EU regulatory framework.In particular, the Study correctly points out that Article 10 does not set out how compliance with its obligations should be achieved or how MSs should co-ordinate implementation efforts. Through the years, this has resulted in an insufficient level of harmonisation across the EU.

It is important to recognize that the principle of mutual recognition, which ensures market access for products that are not subject to EU harmonization (such as drinking water products), does not guarantee the free movement of materials and products in contact with drinking water. Under this principle, any product lawfully sold in one MS can be sold in another. However, this principle does not lead to positive results as it is largely and legitimately disregarded on the basis of overriding reasons of public interest.

The Study also states that currently, at EU level, there are harmonised standards for the mechanical performance of some product types. However, there are no harmonized standards on their effect on drinking water. Also, there are neither EU common material (positive) lists nor other pass/fail criteria to be referred to in order to assess the results

of a given standard. The application of these EU standards remains devoid of harmonization benefits.

The Study also points out that the overlapping scope of the DWD with other regulatory acts (Construction Products Regulation EU/305/2011, the Food Contact Materials Regulation /EC/1935/2004, etc.) did not lead to a satisfactory level of harmonization concerning the marketing of products coming into contact with drinking water.

Such harmonisation cannot be achieved by mean of application these overlapping regulations because of scope differences and the lack of harmonised pass/fail criteria for the assessment of compliance with the DWD obligations which prevent the use of harmonised marking and compliance certifications.

b. National approaches to implementation of Article 10

At national level, in the 28 EU Member States several different approaches are used for the implementation of Art. 10 of the DWD find application.

First of all, there are major differences concerning the definition of "installations and products" covered by the national legislations in the different MSs. The scope of drinking water materials therefore varies from MS to MS.

Also, some MS have created their own positive lists of substances or materials that are considered safe based on testing, evaluation and practical experience. Lists mainly exist for metallic, organic and cementitious materials.

Where Positive Lists are used, materials and products are assessed by checking their actual compositions against the list in order to determine whether the product is considered safe or requires further evaluation.

Lastly, the DWD sets standards for the most essential chemical and microbiological parameters that can be found in drinking water. It lists 48 parameters that must be regularly monitored and tested. They do not cover the many chemicals that can possibly leach from materials that get in contact with drinking water. As a consequence, these parameters would not be scrutinised in the context of the routine monitoring programmes carried out by MSs.

c. 4 MS

The study also dedicates few paragraphs to the approach adopted by the Germany, France, the Netherlands and the United Kingdom (known as the 4 MS approach).

The 4MS approach is based on the common development of a specific assessment of metallic, organic and cementitious materials. It relies on the use of harmonised test standards developed by CEN, whose results are crucially measured against pass/fail criteria that are agreed upon by the four MSs' competent authorities together with their associated expert groups.

The 4MSs are currently developing a common Positive List for organic materials. So far they come up with a 'combined list' of some 540 'approved' substances, compiled from positive lists which they currently use.

4. Economic aspects

After reporting on the regulatory aspects, the study also presents some facts concerning the current market for products coming in contact with drinking water. The description of the relevant key figures includes the following:

- some 2.500 companies hold materials approvals in one or several MSs;
- more than 5.000 companies are involved in the manufacture of finished products used in contact with drinking water;
- over 100.000 workers are employed in the manufacture of products used in contact with drinking water;
- the sector generates sales of up to €40 billion/year.

After presenting these data, the Study focuses on the barriers to trade and market fragmentation caused by the different national regulatory approaches applying in the different MS.

Interestingly, the Study provides a series of case-studies showing how discrepancies among the different MSs have resulted in obstacles to trade (e.g. either because companies had to halt the marketing of a given product, or because they incurred increased expenditures in order to modify and reassess their products).

Among other issues, the Study states that the main hindrances causing economic losses are:

- compliance costs with fragmented local requirements, which are a significant factor in the business decision concerning where to market a new product;
- delay to market - this means that when submitting a product for approval, there is uncertainty on how long the process will take in the different MSs, which results in unplanned delay to market with consequential economic impact on the company and customers.

- companies that choose to invest in approvals can find themselves at a competitive disadvantage against unapproved products available on those markets, due to the voluntary status of certain national schemes and a perceived lack of market surveillance to ensure compliance with national requirements.

5. Conclusions - 4 policy options

The final segment of the study provides options for regulatory solutions to the above mentioned issues. The Study states that the EU should provide for a centralised and harmonised set of rules.

For this purpose, it puts forward and briefly describes 4 policy options:

Option A – EU Regulation

A new EU regulation covering all drinking water contact materials (e.g. CPR: European assessment and product standards, third-party verification ("notified bodies"), European Organisation for Technical Assessment route). This option would ensure the highest degree of harmonisation. However, it is the most time and energy consuming. For example, it will presumably be cumbersome and difficult to identify and agree on a positive list of substances and a risk assessor. Thus, this option could take several years (during which the current regulations will apply).

Option B – Development of performance standards under the Construction Product Regulation (CPR)

This option entails the development of performance standards under the CPR addressing products covered by a harmonised European product standard(s) whereby in addition, specific performance classes would need to be created. This option would not cover products that outside the definition of “construction products” under the CPR. Such an approach could improve but not resolve the current harmonization issues for product that are not within the CPR.

Option C – Promotion of an EU-wide process to harmonise certification criteria

This option foresees the promotion of an EU-wide process to harmonise certification criteria in order to ensure that MSs accept certifications granted in other MSs. Certification means conformity assessment (testing and certification) aimed at declaring compliance with EU regulatory requirements. This option should include harmonised material standards and the identification of pass/fail criteria (e.g. SML). Following these steps, a certification is granted and included with the product on the market.

Option D – Creation of (non-legislative) guidance for MSs on the testing of materials in contact with drinking water

Very likely, these types of measures would not be able to take precedence over overriding public health concern of MSs. This means that MSs could still hinder free trade (e.g. if they do not recognise the safety of a given material/substance) and disregard tests as carried out in other MSs on the basis of public health protection interests.

Notably, the study emphasizes how policy options A and B and C are those likely to have a more positive economic impact on the industry supplying materials and products in contact with drinking water.

Under options A, B and C there would be a reduction in the current delays to market (consequence of having to obtain multiple national approvals in order to launch products across the EU) and greater competitiveness for operators. Multiple versions of a product would no longer be required in order to meet different MS market requirements. With a faster approval process, there would be a greater degree of product innovation as the more money could be invested for this purpose.

More innovation would boost EU competitiveness and therefore limit further increases in non-EU imports. It should be added that better market surveillance of non-compliant imported products should be ensured in order to preserve manufacturers and consumers.

Realistically, the study states that under option C it is more likely that some MSs will gain a comparative advantage where their industry already has to meet stringent standards. Those MSs (especially smaller MSs) with no system currently in place may have to struggle with the creation of a new certification system.

Besides the above considerations, the policy analysis of the Study on the impact of an increased harmonization remains quite generic as it only evaluates generic benefits without carrying out an in depth analysis of each single option.