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Economic Effects of article 10 of the Drinking Water Directive

Final report

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Management summary

This management summary gives an overview of the background of the study and the main conclusions. In addition a number of recommendations from Panteia are included as suggestions for improvement and further research.

Important objectives of article 10 of the DWD

Products in drinking water systems, can affect the quality of drinking water by release of toxic substances, enhance microbial growth and have effects on odour (smell) and taste. Such effects are often described as hygienic aspects. Article 10 of the Drinking Water Directive (DWD) requires Member States (MS) to prevent negative effects on the drinking water quality caused by materials and chemicals used in the entire drinking water supply chain.

The hygienic requirements for products in contact with drinking water are not subject to European harmonisation. At this moment various national requirements and regulations are in place. A recurring element in the discussions with stakeholders in the Netherlands and Europe concerns the economic impact of the lack of European harmonisation of hygienic requirements for producers of materials and products used in the drinking water supply chain from source to tap.

National systems

In order to achieve the objectives drinking water standards are set on a high protection level with regard to hygienic aspects in some MS. Prevention policy is applied which means that products or materials in the drinking water chain from source to tap need to be approved before use. National approval processes may include both hygienic aspects and mechanical aspects (fitness for purpose) though article 10 only relates to the hygienic aspects. Approval processes may include: investigation, tests, consultation, certification and evaluation audits. This is important and essential from the point of view of public health and quality assurance, but not guaranteed in every MS, because there are no common mandatory and concrete provisions on EU level.

Number and turnover of enterprises related to article 10 of the DWD

The exact number and turnover of enterprises that are producing products to be used in contact with drinking water, and have to deal with national schemes implementing article 10 of the DWD in the EU is not known. To estimate the number of enterprises and turnover, data from Eurostat were collected and analysed. Based on the lists of drinking water products at first searched for the relevant NACE¹-codes and the available data from Eurostat. An important note is that products used for drinking water are in none of the NACE-codes distinguished as a separated code, so only a part is linked with drinking water products. This means that the number of enterprises that are affected by article 10 of DWD and the relevant turnover is probably much lower than in the figures presented. On the other hand there are more products known than covered by the NACE code. Based on our expert judgement and the experience with the interviews with enterprises from the 4MS the number of enterprises that are affected by national schemes implementing article 10 of DWD is estimated.

¹ NACE is the acronym for "Nomenclature statistique des activités économiques dans la Communauté européenne" or in English the "statistical classification of economic activities in the European Community" and is the subject of legislation at the European Union level, which imposes the use of the classification uniformly within all the Member States.



The estimated number of enterprises that have to deal with national schemes implementing article 10 of the DWD is about 7,200 and the turnover is round € 43 billion per year. For the reasons given above there is uncertainty in these estimates. Therefore we make the following recommendations²:

1. It is a recommendation for further research to collect precise numbers of enterprises dealing with products to be used in contact with drinking water, for example at the various national certifying bodies or the individual MS on requirements by national schemes implementing in relation to article 10 of the DWD.
2. It is a recommendation for further research to collect more precise data about the extent of turnover of enterprises affected by national schemes implementing article 10 of the DWD, which should be compiled by the industry.

Perceived hindrance by enterprises as a result of different national approval schemes to implement article 10 of the DWD

The perceived hindrance is based on the opinion of 46 enterprises interviewed with a headquarter in the 4MS. The enterprises do not trade with all other EU MS. The number of enterprises interviewed is more than sufficient to meet the requirements of the used method of the Standard Cost Model (SCM). See Appendix 1 for more explanation of the SCM. The outcome is valuable to have a feeling how the current situation is being experienced by enterprises with regard to requirements, transparency and trade. This means that this is a quick scan of the European situation.

Summarized findings are as follows:

- To comply with national regulations costs a lot of time and money. In terms of time the enterprises need staff to change the products and to find out all the differences and to make sure these processes go well. In terms of money also large sums are needed to be paid for the tests of the products and for the certification at the certification bodies and audits with the certification bodies.
- Similar procedures have to be repeated over and over again. The 4 MS (NL, DE, FR, UK) are working together towards harmonisation of their approval systems. DE and NL are implementing common approaches and substances lists. FR is planning to implement part by part. The UK is also working on it. As the harmonisation work is still under development enterprises do not experience the benefits of the 4MS-Initiative and EU in practice yet.
- The approval procedures take a lot of time delaying the marketing of products. This also creates loss in turnover. Enterprises do not know how long it will take to get an approval. Getting the raw material information throughout the supply chain is a huge challenge. This is often confidential information that suppliers earlier in the chain are not willing to give³.
- The current situation gives high threshold for market access. Some enterprises stay at the domestic market because exports mean high costs for additional testing requirements for products that have to be tested again for each additional country. This means export is quite difficult and some enterprises have chosen not to sell their products abroad.
- Products become more expensive, less turnover. Producers are obliged to search for materials that are already certified (positive list). So producers claim not to be free to choose the right material on the basis of technical properties, but have to

² Implementation of all the recommendations in this executive summary will lead to more precise results, but presumably will not much change the direction of the findings of the present study.

³ In the Netherlands plastics manufacturers and the Dutch Certification Body are cooperating by formulating plastics coming in contact with drinking water in Drinking Water Master Files (DWMFs). Manufacturers can refer to DWMFs to speed up the certification procedure.

choose material that is certified according to hygienic requirements or to have new substances approved. This creates higher costs.

- Uncertainty what is allowed per country. Enterprises cannot choose the best products sometimes, but have to choose the ones which have the necessary agreements. Proper technical documentation and practical guidance for each different market and country is lacking. The renewal of agreements sometimes stops because of re-approval and/or new requirements. One product can contain many parts that need to comply. It is tough to synchronise this in a way that each part complies at the same time. It is also difficult to be prepared for future developments in legislation.
 - The existence of different approval schemes generates different quality products depending on the requirements of the destination country. Producers do want to meet high standards under the condition that they are harmonised and valid for all EU MS.
 - Some enterprises state it as unfair that they have to comply the stringent regulations, but that the consumer can buy uncertificated products directly on the market and internet. There is too little control on this. Market surveillance is in general an important point for improvement.
3. It is a recommendation that final decisions need to be made to facilitate mutual recognition between the 4/5MS in practice and a common positive and composition list. Even better is European harmonisation of requirements and lists that are equal for all MS and available, actual and transparent on the website of the EU.
 4. Furthermore it is a recommendation for both industry associations, producers and governments of the MS to provide in corporation more information and specific regulatory assistance to diminish the familiarisation costs for enterprises, also to obtain better compliance and that enterprises are better informed.
 5. It is also a recommendation to enforce market surveillance and further research to study if the control on internet products for drinking water is lacking and what can be done to enlarge and intensify that. This to prevent unfair competition between producers from outside the EU and EU producers. This in accordance with EU Regulation 765 about the requirements for accreditation and market surveillance relating to the marketing of products.

Furthermore:

- Barriers for free trade for smaller firms. There is no difference in enterprise size, because all enterprises pay the same amount. For small enterprises this is a relatively high share of their turnover. This is experienced as a barrier for free trade.
6. It is a recommendation for further research to look for possible specific provisions in legislation avoiding disproportionate burden on Small and Medium Enterprises (SMEs) in accordance with the EU principle of Think Small First⁴.
- Obstacles for harmonisation. Enterprises are unanimous in their opinion that politicians, national governments and certifying bodies protect their own system and market too much which hampers competition. Enterprises experience that MS have a high degree of freedom to create and maintain their own approval and testing systems and that mutual recognition is obstructed. Although the objective of the DWD is improving water quality and not trade.

⁴ See: http://ec.europa.eu/growth/smes/business-friendly-environment/small-business-act/index_en.htm



7. It is a recommendation for further research to study if the obstacles mentioned by the enterprises are valid and what are possible solutions to diminish this effect.

- Advantages of a lack of harmonisation. Half of the respondents do not see benefits of the current system only see severe disadvantages. The most frequently cited benefits include market protection for enterprises active only on the domestic market and competitive barriers for enterprises established in other MS and outside the EU.

8. It is a recommendation that all approval systems of individual MS are notified to the Commission, contain provisions for mutual recognition and that governments have a transparent protocol in practise to recognise national schemes that provide an equivalent high level of protection.

Principles at the calculation of costs and cost savings

The costs and potential cost savings are measured and based on the methodology of the Standard Cost Model (SCM), a model originally developed by Panteia. It is nowadays the most widely applied proven methodology for measuring costs. The SCM is adopted by the European Commission, OECD and the World Bank as the tool identifying and measuring compliance costs as a result of legislation. See further explanation at Appendix 1.

For a proper interpretation of the results it is important to take good notice of the following principles in relation to national schemes implementing article 10 DWD:

- The purpose of the SCM methodology is to produce estimates that allow an order of magnitude of the burdens in regulatory areas to be identified. Considering the level of detail and the number of parameters, it is not cost-efficient to seek statistically valid results rather than more general estimates.
- The number of enterprises is based on figures from Eurostat.
- The costs of enterprises are based on the results of the interviews of the 46 enterprises. We compared the results of the average turnover on related article 10 DWD products based on Eurostat figures with the average turnover on related article 10 DWD products of the 46 interviewed enterprises and they are roughly equal.
- We present the results over all 46 interviewed enterprises, because of the limited number of enterprises interviewed per MS. In general we can say that the German enterprises interviewed had the highest costs. Maybe the reason for this is that the German enterprises interviewed seemed to have more products related to drinking water in their assortment. France and the Netherlands had roughly similar lower costs compared with Germany, whereas the costs in the United Kingdom were much lower as in France and the Netherlands. A reason for this is that some enterprises interviewed in the UK acted more on the domestic market and had few imports and exports of related article 10 DWD products.
- We present the median costs in the rationale to come to estimates of cost per enterprise in practice excluding the outliers by standardising. Moreover the mean costs of the interviewed enterprises are almost the same as the median costs.

Costs as a result of different national schemes to implement article 10 DWD

The regulatory compliance managed in terms of internal business processes depends on the size of the enterprise in turnover and employment. Bigger enterprises do have specialised units in relation to the article 10 DWD requirements. Smaller enterprises do have employees that part time study and fulfill the requirements. Based on the questionnaire results enterprises in the 4MS spend € 135,000 per enterprise on yearly

internal wage costs associated with the approval processes. In addition enterprises spend € 165,000 per enterprise on yearly costs of evaluation, testing or certification of products.

We only measured the costs in the 4MS in accordance with the standards of reliability of the internationally proven method of the Standard Cost Model and did not measure the costs in the other 24MS. That is why we make a recommendation for further research to identify these costs in the 24MS. For the time being an assumption is made that costs of the other 24 Member States are two-thirds lower than in the 4MS. This assumption is based on interviews with respondents from the 4MS who could estimate that because they also work in the other 24MS. The interviews have shown that the 4MS do have systems which are more demanding than the other 24MS. Some MS don't have a system at all. Another factor is that there are MS that recognize certificates from the 4MS so the cost can be lower. Furthermore a much smaller range and diversity of products linked to Article 10 of the Drinking Water Directive is on the market in the other 24MS in comparison with the 4MS.

The national requirements for approval / certification of products are applicable for all products unregarded the country of residence of the enterprise. Cost estimations are based on data of enterprises located in the 4MS. Comparable costs are there for the other 24MS to have approval / certification in the 4MS. So the total costs are € 300,000 yearly per enterprise to have approval / certification in the 4MS and € 100,000 per enterprise to have approval / certification in the other 24MS. The total amount on wage costs and evaluation or certification costs is approximately € 728 million yearly to have approval / certification in the 4MS and € 480 million to have approval / certification in the other 24MS or in total € 1.208 billion. The total turnover is estimated on € 42.949 billion per year. So the total costs yearly are 2.8% of the turnover of related article 10 DWD products. These results are based on the assumptions made in Chapter 5 and the Standard Cost Model method as shown in Appendix 1.

9. It is a recommendation for further research to interview enterprises of the other 24 Member States on the costs for further substantiation of the data.

Potential cost savings as a result of the harmonisation of different national schemes implementing article 10 of the DWD

By means of mutual recognition enterprises estimate the cost savings on 55% of the total costs. Both for harmonisation throughout the 4MS and for all EU Member States. A reason for this could be that we only interviewed enterprises in the 4MS. These enterprises trade for a substantial part with each other. Moreover many certificates of the 4MS are more or less recognized in other MS outside the 4MS.

In total this would be a cost saving of € 664 million out of € 1.208 billion per year. Furthermore the reader has to be aware that still the main part of the outcome is not quantified. The following aspects are not included:

- the positive effects because the time to market can be shortened substantially
- measures to achieve a more equal economic playing field
- the effect of a more certain environment for investment and innovation
- about suppliers who stopped producing drinking water products, because it is too complex.



Enterprises were unable to quantify these effects, because it was uncertain in which way these improvements would be defined and to what extent it can be applied in the MS.

10. It is a recommendation for further research to define the assumptions the way the further improvements by means of mutual recognition can be achieved and to what extent it can be applied in the MS, so that it is possible to imagine what this means for their turnover. This fits in the EU new Single Market Strategy to deliver a deeper and fairer Single Market that will benefit both consumers and businesses and to take measures to modernise the standards system, to strengthen the single market for goods, to reduce barriers in key sectors, prevent discrimination against consumers based on nationality or place of residence, strengthen preventive enforcement by reforming the notification procedure and enable the balanced development of the collaborative economy.
11. It is a recommendation to achieve much more mutual recognition and harmonisation of national schemes implementing article 10 DWD, also with the help of the EC. This is urgently needed from point of view of transparency, free trade, equal economic playing field, certain environment for investment and innovation and time to market for new products. Care should be taken that the application of new and or higher standards in Member States could lead to higher compliance burdens. On the other hand one can also argue that these costs should have been made already.

1 Scope of the study

1.1 Background and research questions

Products in drinking water systems, can affect the quality of drinking water by release of toxic substances, enhance microbial growth and have effects on odour (smell) and taste. Such effects are often described as hygienic aspects. Article 10 of the Drinking Water Directive (DWD) requires Member States (MS) to prevent negative effects on the drinking water quality caused by materials and chemicals used in the entire drinking water supply chain.

The hygienic requirements for products in contact with drinking water are not subject to European harmonisation. At this moment various national requirements and regulations are in place. A recurring element in the discussions with stakeholders in the Netherlands and Europe concerns the economic impact of the lack of European harmonisation of hygienic requirements for producers of materials and products used in the drinking water supply chain from source to tap.

In the recent past the European Commission (EC) had worked on the development of a common European approach to the assessment and certification of products in contact with drinking water. This work resulted in the publication of the "EAS – The European Acceptance Scheme for construction products in contact with drinking water" in 2005. Approval systems for products were at that time already in place in several Member States. It was envisaged that this EAS would replace existing national regulatory schemes. Although the EAS proposal received broad support from various stakeholders (authorities, industry, drinking water service operators) the EAS was not put forward. In response to the absence of a European Scheme the 4MS (Netherlands, United Kingdom, Germany and France) started working together on a step-by-step harmonisation of their national systems. The cooperation is open for other Member States. Portugal has joined the cooperation (4/5MS) and also other member states have showed their interest. The common approach of the 4/5MS is based on the EAS approval system, including the use of positive lists. The positive list system relies on approval by a scientific independent assessment which is also applied within other areas where a high level of safety is needed (as in case of material in contact with food and drinking water).

The EC has given a mandate to the Comité Européen de Normalisation (CEN) in the past under the Construction Products Regulation (CPR) to elaborate a CE mark with regard to hygienic aspects, which would favour the internal market. Also to specify the procedure for attesting of conformity (1+) as set out in Annex II of Commission Decision 2002/359/EC. Under Mandate 136 CEN would develop harmonised products standards and harmonised test methods for products in contact with drinking water. Work has advanced well for test methods; however the development of harmonised product standards did not succeed. One of the reasons was the variety of national systems and therewith a lack of regulatory guidance. The EC recently announced to withdraw Mandate 136rev2 and work on a new plan for products in contact with drinking water.

Panteia is commissioned by the Dutch Ministry of Infrastructure and the Environment to assess the economic effects of national schemes implementing article 10 of the DWD for business. The main goal of the study is to obtain data on and verifiable



figures about enterprises in the Netherlands, 5 Member States (the Netherlands, Germany, France, UK and Portugal) and the European Union that are influenced in their business and in what way and to what extent (both financial and corporate). Also part of the study are qualitative assessments about adding up costs by national assessments and national certification, hindrance of free trade, lack of equal economic playing field, uncertain environment for investments and innovations and a weakened trade position relative to imports from outside Europe.

The study's research questions and objectives are to assess, related to national schemes implementing article 10 of the DWD:

- which and how many enterprises have to deal with it?
- which hindrance is encountered by the current implementation with national requirements?
- who bears the costs for testing, assessment and certification?
- what would be the potential cost savings and other benefits of (European) harmonisation?

By affected enterprises, we understand entities that:

- need to obtain a certification or other form of approval on their products that come into contact with drinking water (e.g. pipes, valves, fittings, pumps, meters, taps, etc.) as a result of the national legislation implementing article 10 of the Directive or other indirect obligations;
- are required to change or adjust their production or enterprise processes because of the national legislation implementing article 10 of the Directive;
- otherwise need to change or adjust their business activity on the basis of the national legislation implementing article 10 of the Directive.

1.2 Approach of the study

The study consisted of the following three research steps:

1. Collecting information on relevant products/sectors/enterprises, determine target enterprises and gather contact information for the interviews.
2. Consulting enterprises about hindrance, costs and possible cost savings.
3. Analysis, extrapolation and reporting.

1.3 Specific exclusions and focus in the study

In the beginning of the study some choices are made by the advisory board and the Dutch ministry of Infrastructure and the Environment to make the research more manageable in view of available resources and time. For instance the study only focuses on products like tubes and pipes and not on chemicals. Because of the limited number of interviews per country and the argument that certification for chemicals is considered to play a smaller role (in relation to problems due to article 10 of the DWD) than certification of the other products.

Cementitious products are also left out of the study, because there is only a very limited number of enterprises and the products are mainly sold on the domestic market, so there are fewer exports and imports, An exemption might be near the borders of MS, raw materials and admixtures, coating of pipes and side applied products.

In the study we focus on organic, metallic and combined products (mix of materials). Moreover, the study does not take into account the trade via internet web shops direct to consumers.

1.4 Activities in time table

From the start the following activities are carried out:

- End July 2015: Kick-off meeting. Panteia with Dutch Ministry of Infrastructure and the Environment.
- August and September 2015:
 - Collecting relevant reports and documents.
 - Collecting information from Eurostat (relevant NACE-codes) on numbers of enterprises and turnover.
 - Identifying and contacting relevant organisations in the EU to collect relevant information on the subject, products, sectors, numbers of relevant enterprises and contact details of enterprises for the interviews:
 - A lot of European and national organisations and normalisation institutes and the EC are contacted (by email, telephone and face-to-face). See Appendix 2 for an overview of the contacted organisations.
 - The representatives in the advisory boards of the project from The Netherlands, Germany, UK, France and Portugal (5MS) and Dutch organisations are contacted. See Appendix 3.
- 15 September 2015: interim report discussed in the advisory board in the Netherlands and opportunity to comment on the interim report by the advisory board of the 5MS and the special advisory board of Dutch stakeholder organisations (consultation groups).
- September – November 2015: finalising the questionnaire, conducting the interviews and the preparation of the draft report.
- December 2015: The draft report is discussed in the advisory board in the Netherlands. The advisory board of the 5MS and the consultation group of Dutch stakeholder organisations had the opportunity to comment on the draft report by e-mail. The comments are incorporated into the final report.

1.5 Structure of this report

In this report we describe the results of the study. This includes the following chapters in relation to article 10 of the Drinking Water Directive following the objectives of this study:

- Chapter 2: Enterprises affected by article 10 DWD. This chapter focusses on the relevant products and sectors and classifies them in adequate and workable groups. It also gives information about the number of enterprises and the turnover, using especially Eurostat data.
- Chapter 3: Questionnaire and number of consulted enterprises. This chapter describes the questions to enterprises, the type of enterprises consulted and the response.
- Chapter 4: Perceived hindrance of a lack of harmonisation. This chapter summarizes the results of the qualitative questions of the questionnaire about hindrance.
- Chapter 5: Costs and potential cost savings. This chapter gives an impression in the roughly estimated costs of a lack of harmonisation and cost savings of harmonisation. The results are presented at the level of 4 Member States and the European Union.



2 Enterprises affected by national schemes implementing article 10 DWD

2.1 Affected products and sectors

For the study an overview of relevant products which are affected by article 10 of the Drinking Water Directive (DWD) in the chain from the source to the tap was made on basis of all information obtained via described organisations (Appendix 2). This overview is needed:

- to determine the relevant sectors/enterprises
- to determine in the focus of the study which products/sectors to select
- to identify enterprises which are affected by the article 10 of the DWD to approach for data collection.

The number of products which are affected by article 10 of the Drinking Water Directive (DWD) is enormous. Examples of products are water plants, reservoirs, pipes, tubes, pumps, pumping stations, water quality monitoring equipment, pressure measuring devices, filters, membranes, appendages, films, sensors, valves, fittings, couplings, welding equipment, water heaters / boilers, water meters, sanitary products, taps and so on. The products can consist of different kinds of material, such as plastics, elastomers, lubricants, cast iron, steel, copper, lead et cetera. For the further study it was needed to cluster the products. There were several options to classify the products.

After considering different options eventually is chosen to distinguish three categories classifying the products by the material from which the products are made:

- Products made of organics (like plastics, elastomers, coatings, lubricants).
- Products made of metal (like cast iron, steel, copper, lead)
- Products made of a mix of materials (combined products, like taps).

This classification is chosen because:

- preference for non-overlapping clusters of products/sectors and distribution over different kinds of products
- focus on product clusters that are expected to be most affected by national schemes implementing article 10 of the DWD, and which are expected to be relatively similar or homogeneous in the expected hindrance, costs and possible cost savings.
- it is expected that sectors and enterprises can be selected on this criterion and population data about enterprises and turnover for these products groups are available in Eurostat data.



2.2 Sector information

2.2.1 *Relevant sectors*

One of the research questions is: which and how many enterprises have to deal with article 10 of the DWD, with other words enterprises who are producing products to be used in contact with drinking water? To estimate the number of enterprises we collected and analysed data from Eurostat. Based on the lists of products which are affected by national schemes implementing article 10 of the Drinking Water Directive (DWD) we at first searched for the relevant NACE-codes⁵. This resulted in the following overview of NACE-codes:

Manufacture of products

- C2219 Manufacture of other rubber products
- C2221 Manufacture of plastic plates, sheets, tubes and profiles
- C2223 Manufacture of builders' ware of plastic
- C2420 Manufacture of tubes, pipes, hollow profiles and related fittings, of steel
- C2521 Manufacture of central heating radiators and boilers
- C2529 Manufacture of other tanks, reservoirs and containers of metal
- C2561 Treatment and coating of metals
- C2813 Manufacture of other pumps and compressors
- C2814 Manufacture of other taps and valves

In the next sections we present the most recent available data on numbers of enterprises and turnover by NACE-code for the 4MS the Netherlands, Germany, France and the UK, the other 24MS and the total for all 28MS.

⁵ NACE is the acronym for "Nomenclature statistique des activités économiques dans la Communauté européenne" or in English the "statistical classification of economic activities in the European Community" and is the subject of legislation at the European Union level, which imposes the use of the classification uniformly within all the Member States.

2.2.2 Number of enterprises

The number of enterprises in NACE-codes linked with products related to article 10 of the DWD for 2013 are mentioned in table 1.

Table 1 Number of enterprises in the EU in NACE-codes linked with products related to article 10 of the DWD, 2013 *

NACE codes	4MS	Other24MS	All 28MS
<u>Manufacture of products</u>			
C2219 Manufacture of other rubber products	1,486	4,026	5,512
C2221 Manufacture of plastic plates, sheets, tubes and profiles	2,231	4,337	6,568
C2223 Manufacture of builders' ware of plastic	4,057	7,859	11,916
C2420 Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	866	1,148	2,014
C2521 Manufacture of central heating radiators and boilers	276	1,545	1,821
C2529 Manufacture of other tanks, reservoirs and containers of metal	710	2,079	2,789
C2561 Treatment and coating of metals	7,417	14,243	21,660
C2813 Manufacture of other pumps and compressors	1,016	1,075	2,091
C2814 Manufacture of other taps and valves	811	1,860	2,671
TOTAL	18,870	38,172	57,042

* figures for Czech Republic, Ireland and Malta not included, because unknown.

Source: Eurostat

An important note is that products used for drinking water are in none of the NACE-codes distinguished as a separated code. In the above mentioned codes, only a part is linked with products affected by article 10 of DWD. This means that the number of enterprises that are affected by article 10 of DWD and the relevant turnover is much lower than in the figures presented. On the other hand it is questionable whether all products to be used in contact with drinking water are part of the NACE overview. For example membranes. Based on our expert judgement looking at the products that are linked with article 10 of the DWD and the experiences and results of the interviews with enterprises from the 4MS we estimated the number of enterprises that have products to be used in contact with drinking water affected by national schemes implementing article 10 of DWD. The estimated shares are specified in Table 2.



Table 2 Estimation share and number of enterprises in the EU potentially affected by article 10 DWD

<i>NACE codes</i>	<i>Share * in enterprises per NACE-code specific art.10 DWD</i>	<i>Number of enterprises specific art.10 DWD (4MS)</i>	<i>Number of enterprises specific art.10 DWD (Other24MS)</i>	<i>Number of enterprises specific art.10 DWD (All 28MS)</i>
Manufacture of products				
C2219 Manufacture of other rubber products	5%	74	201	276
C2221 Manufacture of plastic plates, sheets, tubes and profiles	20%	446	867	1,314
C2223 Manufacture of builders' ware of plastic	10%	406	786	1,192
C2420 Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	10%	87	115	201
C2521 Manufacture of central heating radiators and boilers	10%	28	155	182
C2529 Manufacture of other tanks, reservoirs and containers of metal	5%	36	104	139
C2561 Treatment and coating of metals	10%	742	1,424	2,166
C2813 Manufacture of pumps and compressors	20%	203	215	418
C2814 Manufacture of taps and valves	50%	406	930	1,336
Number of enterprises specific art.10 DWD				
TOTAL		2,426	4,797	7,223

* shares based on expert judgement and the experiences and results of interviews with enterprises from 4MS.

Source: Panteia

Table 2 shows that the number of enterprises that have to deal with national schemes implementing article 10 of the DWD in the European Union is potentially 7,223. From which 2,426 in the 4MS and 4,797 in the other 24 MS.

2.2.3 Turnover

The turnover in NACE-codes linked with products related to article 10 of the DWD for 2013 are specified in table 3

Table 3 Turnover enterprises in the EU in NACE-codes linked with products related to article 10 DWD, 2013, in millions of € *

NACE-codes	4MS	Other24MS	All 28MS
<u>Manufacture of products</u>			
C2219 Manufacture of other rubber products	€ 18,831	€ 13,621	€ 32,452
C2221 Manufacture of plastic plates, sheets, tubes and profiles	€ 32,538	€ 24,452	€ 56,991
C2223 Manufacture of builders' ware of plastic	€ 20,140	€ 9,140	€ 29,280
C2420 Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	€ 14,894	€ 15,123	€ 30,017
C2521 Manufacture of central heating radiators and boilers	€ 6,227	€ 3,283	€ 9,510
C2529 Manufacture of other tanks, reservoirs and containers of metal	€ 3,850	€ 4,705	€ 8,555
C2561 Treatment and coating of metals	€ 15,046	€ 12,220	€ 27,266
C2813 Manufacture of other pumps and compressors	€ 19,595	€ 9,879	€ 29,474
C2814 Manufacture of other taps and valves	€ 16,146	€ 11,850	€ 27,997
TOTAL	€ 147,267	€ 104,273	€ 251,542

* figures for Czech Republic, Ireland and Malta not included, because unknown.

Source: Eurostat

As with the number of enterprises it also an important note by the figures of the turnover that products used for drinking water are in none of the NACE-codes distinguished as a separated code. In the above mentioned codes, only a part is linked with products used for drinking water. This means that the turnover for products in contact with drinking water is lower than in the figures presented. The turnover is estimated based on expert judgement and gathered information in interviews. The estimated shares are specified in Table 4.



Table 4 Estimation share turnover enterprises in the EU affected by products related to article 10 DWD

<i>NACE codes</i>	<i>Share in turnover per NACE-code specific art.10 DWD</i>	<i>Turnover specific art.10 DWD (4MS)</i>	<i>Turnover specific art.10 DWD (Other24MS)</i>	<i>Turnover specific art.10 DWD (All 28MS)</i>
Manufacture of products				
C2219 Manufacture of other rubber products	5%	€ 942	€ 681	€1,623
C2221 Manufacture of plastic plates, sheets, tubes and profiles	20%	€ 6,508	€ 4,890	€ 11,398
C2223 Manufacture of builders' ware of plastic	10%	€2,014	€ 914	€ 2,928
C2420 Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	10%	€ 1,489	€ 1,512	€ 3,002
C2521 Manufacture of central heating radiators and boilers	10%	€ 623	€ 328	€ 951
C2529 Manufacture of other tanks, reservoirs and containers of metal	5%	€ 193	€ 235	€ 428
C2561 Treatment and coating of metals	10%	€ 1,505	€ 1,222	€ 2,727
C2813 Manufacture of pumps and compressors	20%	€ 3,919	€ 1,976	€ 5,895
C2814 Manufacture of taps and valves	50%	€ 8,073	€ 5,925	€ 13,999
Total turnover specific art.10 DWD				
TOTAL		€ 25,264	€ 17,684	€ 42,949

* shares based on expert judgement and the experiences and results of interviews with enterprises from 4MS.

Source: Panteia

Table 4 shows that the total turnover products affected by national schemes implementing article 10 of the DWD in the European Union is € 42,949 million. From which € 25,264 million in the 4MS and € 17,684 million in the other 24 MS.

2.3 Recommendations Panteia

Recommendations Panteia:

1. Recommendation for further research to collect precise numbers of enterprises dealing with products to be used in contact with drinking water, for example at the various national approval and certifying bodies or the individual MS on requirements by national schemes implementing article 10 of the DWD.
2. Recommendation for further research to collect more precise data about the extent of turnover of enterprises affected by national schemes implementing article 10 of the DWD, which should be compiled by the industry.

3 Questionnaire and number of consulted enterprises

Questionnaire

The telephone interviews with enterprises were conducted using a questionnaire. The questionnaire is included in Appendix 4.

The questionnaire includes the following sections/steps:

- Information on the enterprise (products, turnover, exports).
- Questions on differences between Member States by national schemes implementing article 10 of the DWD and the perceived hindrance from these differences.
- Questions on the costs caused by national schemes implementing article 10 of the DWD and a lack of harmonisation
- Questions on possible cost savings of harmonization.

Selection of consulted enterprises to interview and results

For the five cooperating countries (the Netherlands, Germany, France, Portugal and the UK), the aim was to interview a selection of approximately ten enterprises per country, where we focused on the most important producers, distributors and importers of a selection of the most important organic, metallic and combined products. In the first research step an inventory of relevant enterprises in the countries was already made by interviewing several organisations.

A lot of European and national organisations and normalisation institutes were contacted for more specific information on the number of enterprises and turnover (by email, telephone and face-to-face). See appendix 2 for an overview of the contacted organisations and the state of affairs. Certainly by far not all organisations were able to support, because it was difficult for them to give a list of enterprises and then contact persons dealing with products in contact with drinking water and who were able to give required information. So it was a challenge to get the right enterprises and within the enterprises to find the right contact persons to speak to. This part of the study took considerable effort. Table 4 gives the number of enterprises approached per country, after the pre-research, and the number of interviews held.

Table 4 Number of approached enterprises, interviews completed

Status	NL	DE	FR	UK	PT	TOTAL
Total approached	23	23	24	27	33	130
Interviews completed	13	12	12	9	0 *)	46
No reaction / no art. 10 products / no cooperation	10	11	12	18	33	84

*) Despite Portugal has been participating in the 4MS meetings since 2012 as a candidate member and has notified to the EC their draft Regulation with the PAS this year, the Portuguese industry could not contribute to this report mostly because PAS still is not in order and so there is not yet sufficient experience to respond to the study of Panteia.



4 Perceived hindrance by enterprises

In this section, and chapter, the reader has to take into account that an important part of the interviewed enterprises does not trade with all other EU MS, but with some MS, and that only enterprises with a headquarter in the 4MS were interviewed. This means that this is a quick scan of the European situations which requires further research for more precise conclusions. Furthermore the reader has to be aware that still the main part of the outcome is not quantified and reflect the opinions and experiences of interviewed enterprises. The opinion of the enterprises are generic, unless it is specified that it is an opinion of a single enterprise or enterprises in a particular Member State. The outcome is valuable to have a feeling how the current situation is being experienced by enterprises with regard to requirements, transparency and trade.

4.1 Experiences of enterprises with current national legislation based on article 10 DWD

The 4/5 MS (NL, DE, FR, UK, PT) are working together towards harmonisation of their approval systems. Germany and the Netherlands are implementing common approaches for the approval of materials including substances lists (positive list, compositions list). France is currently planning to implement part by part. Portugal recently notified their regulation which is based on the common approaches. United Kingdom has not implemented the common approaches yet. Furthermore final decisions need to be made to facilitate mutual recognition in practice. As the harmonisation work is still under development enterprises do not experience the benefits of the 4MS-Initiative in practice yet.

It is notable that the enterprises in each of the 4MS consider the system of certification and approval of their own MS as the most stringent. Presumably this is because enterprises at first put a huge effort in obtaining a certificate or approval in their own MS and then they can use parts of these information and experiences obtaining certificates or approvals in other MS.

In some cases there is no difference in the law, but the practices are different. The information that is requested, the use of the positive list and combined list is different and the requested tests are different. There is still no mutual recognition of the tests between the 4MS. According to the interviewed enterprises in some MS like for instance the Southern European countries recognition of certificates and approvals of other MS is more common. For instance the eastern European MS mostly accept the German certificate as proof. According to the interviewed enterprises, in the Northern European MS there is mutual recognition of each others certificates and approvals. Furthermore the enterprises replied that many MS do not require extra tests, or some additional tests, if products have certificates from one of the 4MS. MS, mentioned in the interviews by some enterprises, who are applying this policy are Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, Greece, Hungary, Italy, Norway, Poland, Spain, Sweden and Switzerland.

One of the problems for mutual recognition between MS is that some MS still apply national standards for testing. Procedures and time frames are not always clear to the enterprises. Another mentioned experienced problem is that there are no guidelines and that every country has a different approach for product testing. In general,



enterprises find it is easier to trade with enterprises from MS that do not have specific national requirements. It is difficult to understand what the differences are between the systems of the MS and how one should adapt. Enterprises have to modify their products in order to sell them in certain countries. Also some larger foreign enterprises only want to adapt their products for the big markets, such as Germany and the USA, because they do not have enough sales in the smaller markets. They do not adapt their products for the smaller markets.

Awaiting a European acceptance scheme the 4 MS co-operate concerning the convergence of their national acceptance schemes for products in contact with drinking water. The national implementation of the procedure for the acceptance of metallic materials allows the compilation of a common composition list for metallic materials that are accepted in all 4 MS. In that case a small number of enterprises say that there is still uncertainty about dezincification-resistance brass materials (DZR). A material used for fittings in potable water supply systems. Use of these materials could have a so-called dezincification effect. This might arise in soft, chloride-containing water at high temperatures. Following a 2-year transitional period, which ends on 10.04.2017, only those materials which appear in the positive list may be used in drinking water installations in Germany. For other countries like for instance the Netherlands it is unclear whether these materials are permitted. The approach of some MS based on the use of positive lists is mentioned by some enterprises to constitute a constraint, to the technological development and to research and use of new materials. The development time of new products cannot be planned or forecasted due to the need to make long term tests in ways often not reproducible or clear to the enterprises. The costs related to the inclusion in the positive lists of a new material are experienced as high and cannot easily be sustained by small or medium-sized enterprises.

Another obstacle mentioned by a small number of enterprises is that plastics have to be explained including all ingredients by the original manufacturers. It is often difficult to get this information. The information is sometimes no longer valid at the time the enterprise gets the certification.

4.2 Extent differences with negative consequences for enterprises

Almost all enterprises interviewed experience negative consequences of national implementation of article 10 of the DWD. Some experiences are closely related to each other. The experiences are summarised hereunder and explained further after that:

- Costs a lot of time and money
- Similar tests over and over again
- Time to market for approval is long
- High threshold for accession to the market
- Products become more expensive
- Uncertainty what is allowed per country
- Barriers for free trade for smaller firms.

Costs a lot of time and money

The enterprises need staff to change the products and to find out all the differences and to make sure these processes go well. Also large sums are needed to be paid for the tests of the products and for the certification at the certification bodies and dealing with the certification bodies. Training of sales staff is "mandatory" due to the different requirements of each country.

It takes time to deal with different authorities and testing and enterprises have to pay a fee. Some enterprises do have a separate department dealing with approvals. It also costs money to register products. Research of different parts to fit the different requirements costs a lot of time. Some enterprises have problems with products like plastics and rubbers to be explained including all ingredients by the original manufacturers. It is often difficult to get this information and not all suppliers are willing to do so. Enterprises also have to make sure suppliers have the right approvals/certificates.

Similar tests over and over again

The burden on the industry is that even if a raw product has already been tested (initial type testing), it has to be tested again in the manufactured form. This means the same product is tested multiple times.

In many cases, the same product needs different parts and approvals to be sold in a national market and another country despite almost similar testing procedures. The main problem are the hygienic requirements that have to be repeated in hygienic testing in each country. This is experienced as a barrier to trade.

For industry, the high level of requirements seems no problem, but the differences between countries are experienced as a problem with regard to costs and time to market.

Time to market for approval is long

It takes a lot of time delaying the marketing of products. For instance to get approval from the authorities in one country costs one year. After that one has to deal with authorities in another country, which costs another year and so on. It creates a huge delay in the time-to-market for a product. This also creates loss in turnover.

A negative consequence is the elapse of time. Enterprises do not know how long it will take to get an approval. In addition, prior to applying for the approval, the whole product has to be finished/designed. This causes a further delay. Getting the raw material information throughout the supply chain is a huge challenge. This is often confidential information that suppliers are not willing to give.

High threshold for market access

Some enterprises do not try hard to sell in countries where they have no feeling for the national requirements and certification. Sometimes they look for a supplier in the foreign MS that has the right certification to sell their products. In that case, it is the responsibility for the supplier to fulfill the requirements and certifications. To sell one product within the EU is hardly possible mentioned by a substantial number of enterprises, because of variants of the products do create a lot of costs. It is also difficult to find suppliers of materials that match the requirements for all the countries.

A small number of enterprises stay at the domestic market because exports means high costs for additional testing requirements for products that have to be tested again for each additional country. This means export is quite difficult and some enterprises have chosen not to sell their products abroad.



Products become more expensive, less turnover

Some enterprises do have the opinion that the design of products related to article 10 DWD requires the use of new materials. There are higher costs for raw materials, because the price is higher due to certification.

Less turnover for some individual enterprises, because it is too expensive for them to get certification in all countries. Some enterprises choose not to sell in certain countries. Enterprises are obliged to search for material that are already certified (positive and composition list). So enterprises claim not to be free to choose the right material on the basis of technical properties, but have to choose material that is certified according to hygienic requirements. It creates higher costs, as in some countries one can use the materials that have good technical quality but are also quite cheap, but if they are not on the positive list in one country they have to use a different material or to have the material approved for the positive list. The different positive lists in use are confusing. Overall enterprises miss an open and transparent common positive list for the 4MS and all other MS and a system at which they can follow easily the changes in the list, for example via a website.

Uncertainty what is allowed per country

Proper technical documentation and practical guidance for each different market and country is lacking. Some enterprises state that the renewal of agreements sometimes stops because of re-approval and/or new requirements. One product can contain many parts that needs to comply. It is tough to synchronise this in a way that each part complies at the same time.

It is also difficult to understand future developments in legislation. Enterprises want to adapt to upcoming legislation, however plans and procedures are not always clear, for example the development and agreements of positive lists and combined lists. When and how will legislation change? One enterprise stated that as Germany has the leadership for metal products, enterprises try to adapt to the list now adopted in Germany as they expect this will be the standard. However, there is no common solution yet and all MS have different interpretations. According to a small number of enterprises new legislation based on article 10 could create a huge barrier for using recycled materials, because not all types of materials can be used.

Barriers for free trade for smaller firms

The smaller enterprises stated that there is no difference in enterprise size, because all enterprises pay the same amount. For small enterprises this is a relatively high share of their turnover. This is experienced as a barrier for free trade. They have to deal with all those acceptance routes and this mostly creates huge costs and effort. Some smaller enterprises mention difficulties to interpret the legislations in different languages.

4.3 Degree of differences hampering free trade

To a large extent aspects about the degree of differences hampering free trade are partly the same as mentioned in section 4.2 about the negative consequences of differences. About 75% of the interviewed enterprises feel that differences between MS hamper free trade.

Some considerations. For enterprises it is difficult to monitor if all products and materials they produce and supply are certified in different countries and which period the certification expires. Enterprises think that without a certificate it is not possible

to sell anything. It could be an advantage if an enterprise is the only one with a certificate in a MS. This leads to market exclusion. It is experienced as a barrier.

There are huge labour costs, the time for approval is sometimes several years. This means loss in sale. Enterprises feel the differences as contradictory to the free movement of goods the EU advocates. From outside the European Union, most enterprises perceive it as one market, while on this subject in fact it is not. There are 28 different markets with their own rules. It is also difficult to do cross border business as there are so many different rules and adaptations one needs to make.

Even the constitution of positive lists and composition list and the experienced impossibility of including in such lists any innovative materials is a factor which, in itself, is experienced as a trade barrier by some enterprises.

Some small enterprises are unable to afford the tests, so they do not feel free to sell products in another country. In that way there is no access to some countries.

4.4 Economic playing field

About 75% of the interviewed enterprises have the opinion that there is no equal economic playing field. The rest of the enterprises do not see this as a problem or do not know.

A uniform economic space means to have the same set of rules that are shared by all the operators. The current situation forces each player to act in a different way as the current rules are different from country to country. This implies an enormous amount of resources for those wishing to operate on different markets than the national.

Most enterprises have the opinion that there is no equal economic playing field, although all enterprises have to follow the same rules, but smaller enterprises do have a further disadvantage if they follow the rules and want to sell in multiple countries. For the small enterprises it is difficult to adapt to all these different regulations. Smaller enterprises sometimes have no choice but to focus on one market. They do not have the resources that are needed to go to other countries as these costs are very high. So in most cases they only focus on the domestic market and are quite restricted. The bigger enterprises do have the resources to comply in multiple countries.

Some suppliers also stop producing drinking water products, because it is too complex, so the number of enterprises and the competition is declined. This creates some monopolies which is considered by enterprises as bad in the long run.

4.5 Extent uncertain environment investment and innovation caused by lack of harmonisation

Approximately 70% of the interviewed enterprises have the opinion that there is an uncertain environment for investment and innovation caused by a lack of harmonisation.

Because of the lack of harmonisation each country has its own market, which creates many small markets. Because products need so many adaptations and approvals, it is not interesting to innovate, as one needs to adapt the innovation to all these different regulations as well. One enterprise mentioned that if an enterprise has a big domestic



market, such as Germany, one could sell enough in the own country, but innovation is limited.

The drinking water sector does not have the newest materials, simply because it is too costly to sell a new innovation all across Europe. Investments are mentioned to be a problem. Many costs per country in a row. Some substances are certified in a MS, but not in another MS. Based on a bad business case enterprises stop with products, because of high costs.

At the moment a small number of enterprises do not know what will happen about the transitional standard and are very uncertain about DZR brass materials as mentioned before. Disclosure of the recipes of materials is also a problem, because some enterprises do not disclose information to other enterprises and this makes it more difficult to do the tests.

Some enterprises state that there is uncertainty if products satisfy the requirements. It is unsure if the different materials are going to be accepted and, this makes the sales uncertain and can restrict innovation. This means there is a risk that projects have to be stopped. Also the return on investments differ a lot between countries because of all these tests and requirements. Opportunities are drastically reduced because of the fragmented markets. Enterprises cannot choose the best products sometimes, but have to choose the ones which has the necessary agreements. For smaller enterprises R&D is rather impossible because the market is too small. It might be a problem that the quantity they can sell in a market is too low to invest in it.

4.6 Trade position weakened in relation to imports from outside Europe caused by lack of harmonisation

Approximately 75% of the interviewed enterprises have the opinion that their trade position is not weakened in relation to imports from outside Europe caused by a lack of harmonisation. The enterprises from outside the EU have to follow the same regulations and same approvals. Maybe it is even more impossible for the enterprises from outside of Europe to understand the complex EU system in the EU languages.

On the other hand a small number of enterprises say it depends on the honesty of the non EU enterprises. If they have only one product approval, but they market it as if they have approval for all products, because there is very little control, then there is a weakened position in relation to imports.

4.7 Main obstacles that make it difficult to achieve harmonisation

About 80% of the interviewed enterprises have an opinion over the main obstacles that make it difficult to achieve harmonisation.

Enterprises are unanimous in their opinion that politicians, national governments and certifying bodies protect their own system. As the MS have a high degree of freedom they are able to create their own approval and testing systems. Most of those testing institutes are without business as one test is enough for the EU. Revenues are important maintaining these organisations. Market protection also prevents competition.

Some enterprises see a lack of real will of the EC. They are not enough aware of the problem the industry is confronted with. There is a lack of communication between the EC regulation office and those who are in charge of technical requirements. The

economics of free trade for the industry are not taken into account by the policy makers.

Furthermore policy reasons play an important role, because according to the enterprises every MS wants to keep control over their own protection level for health. Experts are disagreeing on certain effects and so on, so there is not a clear idea what to do. According to the enterprises the quality of water is already good, so there is no urgency to change it.

4.8 Time to market for new products due to lack of harmonisation

70% of all enterprises encounter problems to bring new products to the market due to the national differences in implementation of article 10 of the DWD. 25% had no idea and 5% had no problems with the time to market.

From the 70% of all enterprises that encounter problems, the time to market due to the procedures is half till one year (46%), one year till two years (27%) and two till three years (27%).

A small number of enterprises indicate a step by step approach were they expand slowly into different countries and in that case they have to do it 3,4,5,6 times subsequently.

4.9 Advantages due to the current lack of harmonisation

50% of all enterprises do not see any advantages due to the current lack of harmonisation. 36% mention advantages and 14% don't have an opinion on that.

Half of the respondents who do not see the benefits of a lack of harmonisation only see severe disadvantages.

The group that mention advantages cannot quantify that in monetary terms. The most frequently cited benefits include market protection for enterprises active only on the domestic market and competitive barriers for enterprises established outside the EU. Sometimes monopolies exist in niche markets because enterprises can be the only one with a certificate for a special product in a MS. It can have the advantage that it discourages other enterprises from entering the domestic market because of the high costs and special requirements. Some enterprises say they are more forced to cooperate with local agents instead of just import their products. Some enterprises state it as unfair that they have to comply the stringent regulations, but that the consumer does not always care or is unaware about the effects of uncertified products that can contaminate drinking water, buying these products directly on the market or internet from for example Chinese suppliers. Some enterprises state there is too little control on this.



4.10 Recommendations Panteia

Recommendations Panteia:

3. Recommendation that final decisions need to be made to facilitate mutual recognition between the 4/5MS in practice and a common positive and composition list. Even better is European harmonisation of requirements and lists that are equal for all MS and available, actual and transparent on the website of the EU.
4. Recommendation for both industry associations, producers and governments of the MS to provide in corporation more information and specific regulatory assistance to diminish the familiarisation costs for enterprises, also to obtain better compliance and that enterprises are better informed.
5. Recommendation to enforce market surveillance and further research to study if the control on internet products for drinking water is lacking and what can be done to enlarge and intensify that. This to prevent unfair competition between producers from outside the EU and EU producers. This in accordance with EU Regulation 765 about the requirements for accreditation and market surveillance relating to the marketing of products.
6. Recommendation for further research to look for possible specific provisions in legislation avoiding disproportionate burden on Small and Medium Enterprises (SMEs) in accordance with the EU principle of Think Small First⁶.
7. Recommendation for further research to study if the obstacles mentioned by the enterprises are valid and what are possible solutions to diminish this effect.
8. Recommendation that all approval systems of individual MS are notified to the Commission, contain provisions for mutual recognition and that governments have a transparent protocol in practise to recognise national schemes that provide an equivalent high level of protection.

⁶ See: http://ec.europa.eu/growth/smes/business-friendly-environment/small-business-act/index_en.htm

5 Costs and potential cost savings

In this section the compliance costs of the requirements for enterprises arising from national schemes implementing article 10 of the DWD are discussed. In the questionnaire there were several questions about this issue. The questions about the costs and potential cost savings are based on the methodology of the Standard Cost Model (SCM), a model originally developed by Panteia. It is nowadays the most widely applied proven methodology for measuring costs. The SCM is adopted by the European Commission, OECD and the World Bank as the tool identifying and measuring compliance costs as a result of legislation. See further explanation at Appendix 1.

For a proper interpretation of the results it is important to take good notice of the following principles in relation to national schemes implementing article 10 DWD:

- The purpose of the SCM methodology is to produce estimates that allow an order of magnitude of the burdens in regulatory areas to be identified. Considering the level of detail and the number of parameters, it is not cost-efficient to seek statistically valid results rather than more general estimates.
- The number of enterprises is based on figures from Eurostat as specified in Table 2 of this report.
- The costs of enterprises are based on the results of the interviews of the 46 enterprises. We compared the results of the average turnover on article 10 DWD products based on Eurostat figures (Tables 2 and 4) with the average turnover on article 10 DWD products of the 46 interviewed enterprises and they are roughly equal.
- We present the results over all 46 interviewed enterprises, because of the limited number of enterprises interviewed per MS. In general we can say that the German enterprises interviewed had the highest costs. Maybe the reason for this is that the German enterprises interviewed seemed to have more products related to drinking water in their assortment. France and the Netherlands had roughly similar lower costs compared with Germany, whereas the costs in the United Kingdom were much lower as in France and the Netherlands. A reason for this is that some enterprises interviewed in the UK acted more on the domestic market and had few imports and exports of related article 10 DWD products.
- We present the median costs in the rationale to come to estimates of cost per enterprise in practice excluding the outliers by standardising. Moreover the mean costs of the interviewed enterprises are almost the same as the median costs.

In the remainder of this section we subsequently answer the questions.

5.1 Current costs

How is regulatory compliance managed in terms of your internal business processes, e.g. specialised unit, legal database, manuals? If relevant, how do you incorporate international aspects (e.g. certificates in other countries)? What amount of resources does your business allocate to regulatory compliance relating to the products in question per year at EU level? What percentage of total turnover does this represent?

The regulatory compliance managed in terms of internal business processes depends on the size of the enterprise in turnover and employment. Bigger enterprises do have specialised units in relation to the article 10 DWD requirements. Smaller enterprises do have employees that part time study and fulfill the requirements. Both bigger and



small enterprises use legal databases and manuals. Based on the questionnaire results enterprises in the 4MS spend € 135,000 per enterprise on yearly internal wage costs in relation to the article 10 DWD requirements. The costs ranged from several thousands euros for smaller enterprises to several hundred thousand euros for bigger enterprises.

Using the figures from table 3 and table 4 the total amount on wage costs is approximately € 328 million yearly in the 4MS.

We only measured the costs in the 4MS in accordance with the standards of reliability of the internationally proven method of the Standard Cost Model and did not measure the costs in the other 24MS. That is why we make a recommendation for further research to identify these costs in the 24MS. For the time being an assumption is made that costs of the other 24 Member States are two-thirds lower than in the 4MS. This assumption is based on interviews with respondents from the 4MS who could estimate that because they also work in the other 24MS. The interviews have shown that the 4MS do have systems which are more demanding than the other 24MS. Some MS don't have a system at all. Another factor is that there are MS that recognize certificates from the 4MS so the cost can be lower. Furthermore a much smaller range and diversity of products linked to Article 10 of the Drinking Water Directive is on the market in the other 24MS in comparison with the 4MS. So for now we made the assumption that the costs per enterprise in these 24 Member States are two-thirds lower than in the 4MS, which means € 45,000. According to this and using the figures from table 3 and table 4 the total amount on wage costs is approximately € 216 million yearly in the 24MS.

The total costs of the 4MS and the other 24MS are € 543 million. The total turnover is estimated on € 42.949 billion per year, so the costs for regulatory compliance manpower are 1.3% of the turnover of the enterprises.

What are the costs (yearly average) you encounter in your headquarters' country for complying to the national legislation based on article 10 of the DWD, such as evaluation or certification of these products. What are the extra costs (yearly average) encountered by your business in its headquarters' country for complying to the national legislation in other EU Member States you export to?

Enterprises could not distinguish the costs in costs complying the national legislation and legislation of other Member States, but only as a total estimate. Based on the questionnaire results enterprises in the 4MS spend € 165,000 per enterprise on yearly costs in relation to the article 10 DWD requirements on costs of evaluation, audits or certification of products. The costs ranged from ten thousand euros for smaller enterprises to several substantial hundreds of thousands euros for bigger enterprises. Using the figures from table 3 and table 4 the total amount on evaluation or certification costs is about € 400 million yearly in the 4MS.

As before stated we only conducted interviews with enterprises in the 4MS, so we do not know the evaluation or certification costs per enterprise of the other 24 Member States. It is a recommendation for further research to interview enterprises of the other 24 Member States on this topic. For now we made the assumption that these costs per enterprise in these 24 Member States are two-thirds lower than in the 4MS, which means € 55,000. Using the figures from table 3 and table 4 the total amount on costs of evaluation, audits or certification is approximately € 264 million yearly in the 24MS. The total costs of the 4MS and the other 24MS are € 664 million. The total

turnover is estimated on € 42.949 billion per year, so the costs are 1.5% of the turnover of the enterprises.

Summarised the total costs are € 135,000 wage costs and € 165,000 on evaluation audits and certification costs in total € 300,000 yearly per enterprise in the 4MS. These are median costs. The average, median, minimum and maximum costs per enterprise in the 4MS based on the SCM and requirements in national schemes implementing article 10 of the DWD are specified in the following table.

Table 5 Average, median, minimum and maximum costs per enterprise in the 4MS

4MS	average costs	median costs	minimum costs	maximum costs
NL	€ 230.000	€ 160.000	€ 20.000	€ 700.000
DE	€ 650.000	€ 550.000	€ 300.000	€ 1.400.000
FR	€ 180.000	€ 162.500	€ 40.000	€ 400.000
UK	€ 140.000	€ 40.286	€ 10.000	€ 360.000
TOTAL	€ 330.000	€ 300.000	€ 10.000	€ 1.400.000

Source: Panteia

The median costs in Germany are much higher. Probably because the interviewed German enterprises seemed to have more products related to drinking water in their assortment and as a result more certificates. The enterprises interviewed in the UK were more focused on the domestic market.

The national requirements for approval / certification of products are applicable for all products unregarded the country of residence of the enterprise. Cost estimations are based on data of enterprises located in the 4MS. Comparable costs are there for the other 24MS to have approval /certification in the 4MS. The median costs of € 300,000 yearly per enterprise to have approval / certification in the 4MS are made for an average of fifty certificates. In the other 24MS the median costs are estimated at € 100,000 per enterprise to have approval / certification. Using the figures from table 3 and table 4 and the earlier presented assumptions the total amount on wage costs and evaluation or certification costs is approximately € 728 million yearly in the 4MS and € 480 million in the other 24MS or in total € 1.208 billion. The total turnover is estimated on € 42.949 billion per year. So the total costs yearly are 2.8% of the turnover of article 10 DWD products.

What are the main types of administrative costs involved in meeting national regulatory requirements? Which product regulations are the most burdensome? Are there differences between the 4 Member States?

Most of the administrative costs are spent on conformity assessment procedures and testing (75%). Smaller parts are about product design and production processes (15%) and familiarisation (15%). This is the same for all countries.

How many certificates or approvals do you have in your headquarters' country for the products linked with products related to article 10 DWD?

Enterprises do have approximately 50 certificates or approvals for the products linked with article 10 DWD. This means the average compliance costs are about € 6,000 per certificate or approval (€ 300,000 divided by 50).

5.2 Possible cost savings from harmonisation

About the possible cost savings from harmonisation there were two questions in the questionnaire. These questions are:



- If harmonisation of article 10 would take place across all EU member states, what are the cost savings for you enterprise?
- When harmonisation takes place only between the cooperating five EU countries (the Netherlands, Germany, France, Portugal and the UK), what are the cost savings for you enterprise in your headquarters' country?

By means of mutual recognition enterprises estimate the cost savings on 55% of the total costs. Both for harmonisation throughout the 4MS and for all EU Member States. A reason for this could be that we only interviewed enterprises in the 4MS. These enterprises trade for a substantial part with each other. Moreover many certificates of the 4MS are more or less recognized in other MS outside the 4MS. This means per enterprise in the 4MS € 74,250 cost savings for wage costs and also € 90,750 cost savings for evaluation or certification costs for a total amount of € 165,000 out of € 300,000 per enterprise in the 4MS and € 24,750 for wage costs and € 30,250 on evaluation and certification costs for a total amount of € 55,000 out of € 100,000 per enterprise in the other 24MS. In total this would be a cost saving of about € 664 million out of € 1.208 billion per year.

In these figures the positive effects because the time to market can be shortened substantially or measures to achieve a more equal economic playing field or the effect of a more certain environment for investment and innovation or about suppliers who stopped producing drinking water products, because it is too complex are not included, because enterprises were unable to quantify this effects. This also because it is uncertain in which way these improvements would be defined and to what extent it can be applied in the MS. It is a recommendation for further research to define the improvements on this topics so enterprises can imagine what this means for their turnover.

5.3 Recommendations Panteia

Recommendations Panteia:

9. Recommendation for further research to interview enterprises of the other 24 Member States on the costs for further substantiation of the data.
10. Recommendation for further research to define the assumptions the way the further improvements by means of mutual recognition can be achieved and to what extent it can be applied in the MS, so that it is possible to imagine what this means for their turnover. This fits in the EU new Single Market Strategy to deliver a deeper and fairer Single Market that will benefit both consumers and businesses and to take measures to modernise the standards system, to strengthen the single market for goods, to reduce barriers in key sectors, prevent discrimination against consumers based on nationality or place of residence, strengthen preventive enforcement by reforming the notification procedure and enable the balanced development of the collaborative economy.
11. Recommendation to achieve much more mutual recognition and harmonisation of national schemes implementing article 10 DWD, also with the help of the EC. This is urgently needed from point of view of transparency, free trade, equal economic playing field, certain environment for investment and innovation and time to market for new products. Care should be taken that the application of new and or higher standards in Member States could lead to higher compliance burdens. On the other hand one can also argue that these costs should have been made already.

Appendices

Appendix 1 The Standard Cost Model methodology

The Standard Cost Model (SCM), originally developed by Panteia, is today the most widely applied methodology for measuring (administrative) costs⁷. The SCM methodology is an activity-based measurement of the businesses' (administrative) burdens. These are calculated on the basis of median costs of the required administrative activity (Price) multiplied by the total number of activities performed per year (Quantity). The cost is generally estimated by multiplying a tariff (based on average labour cost per hour including overheads) and the time required per action. External costs (outsourcing, equipment, certification costs, etc.) are taken into account as appropriate. The quantity is calculated as the frequency of required actions multiplied by the number of entities concerned.

The core equation of the SCM is $\Sigma P \times Q$, where P (for Price) = Tariff x Time and Q (for Quantity) = Number of businesses x Frequency)

The purpose of the SCM methodology is to produce estimates that allow an order of magnitude of the burdens in different regulatory areas to be identified. Considering the level of detail and the number of parameters, it is not cost-efficient to seek statistically valid results rather than more general estimates.

In the SCM, estimates for enterprises are based on the concepts 'typical firm', 'efficient processes' and 'standardisation'. The rationale is to come to estimates of cost per enterprise in practice excluding the outliers by standardising using the median of results. In a final step, the standardised median cost estimates per enterprise are globalised by multiplying them with the number of enterprises. To the extent possible, based on or derived from actual population figures of Eurostat.

⁷ See also: http://ec.europa.eu/smart-regulation/refit/admin_burden/scm_en.htm.



Appendix 2 **Contacted organisations**

European organisations

- Aqua Europe
- European Association for the Taps and Valves Industry
- European Copper Institute
- Plastics Europe
- TEPPFA

Dutch organisations

- Bureauleiding
- ENVAQUA - Dutch branch organisation for Aqua Europe
- FME Vedib VFK
- Kiwa
- VEWIN (CAD)
- VOBN

French organisations

- ANSES
- Centre d'Etudes et de Recherches dans l'Industrie des Bétons (CERIB)
- Fédération des Industriels du Béton (FIB),
- Fédération des minerais, minéraux industriels et métaux non ferreux (FEDEM)
- Fédération Professionnelle des Entreprises de l'Eau
- Industriels du Transport de l'Eau et de l'Assainissement
- Profluid
- Syndicat des Tubes et Raccords en PVC
- Union des Industries et Entreprises de l'Eau et de l'Environnement (UIE)

British organisations

- British Water
- DWI, DEFRA
- Future Water Association
- Water UK
- WRAS

German organisations

- Bundesvereinigung der Firmen im Gas- und Wasserfach e.V. (FIGAWA) (DE)
- DVGW
- German Association of Energy and Water Industries (Bundesverband der Energie- und Wasserwirtschaft - BDEW)

Portuguese organisations

- AICCOPN - Assoc. Industriais da Construção Civil e Obras Públicas
- APIP (Portuguese Association of Plastic Industry)
- APTA (Association of Producers of Pipes and Accessories)
- ATIC (Technical Association of the Cement Industry)
- CERTIF (certification body)
- EPAL (Laboratory and water supplier)
- ERSAR
- Portuguese Association of Water and Wastewater Services (Associação Portuguesa de Distribuição e Drenagem de Aguas)



Normalisation institutes

- AT: Austrian Standards Institute and Austrian Association for Gas and Water (Österreichische Vereinigung für das Gas- und Wasserfach)
- BE: Bureau de Normalisation/Bureau voor Normalisatie
- BG: Bulgarian Institute for Standardization
- CY: Cyprus Organization for Standardisation
- CZ: Czech Office for Standards, Metrology and Testing
- DE: Deutsches Institut für Normung
- DK: Dansk Standard
- EE: Estonian Centre for Standardisation
- ES: Asociación Española de Normalización y Certificación
- FI: Suomen Standardisoimisliitto r.y.
- FR: Association Française de Normalisation
- GR: National Quality Infrastructure System
- HR: Croatian Standards Institute
- HU: Hungarian Standards Institution
- IE: Normalisatie-instituten IE: National Standards Authority of Ireland
- IT: Ente Nazionale Italiano di Unificazione
- LT: Lithuanian Standards Board
- LU: Organisme Luxembourgeois de Normalisation
- LV: Latvian Standard Ltd.
- MT: The Malta Competition and Consumer Affairs Authority
- NL: NEN
- PL: Polish Committee for Standardization
- PT: Instituto Português da Qualidade
- SE: Swedish Standards Institute
- SI: Slovenian Institute for Standardization
- SK: Slovak Standards Institute
- RO: Romanian Standards Association
- UK: British Standards Institution (BSI)



Advisory boards and consultation groups

Dutch ministerial advisory board

The committee consisted of:

- Mrs. J. Appelman, Ministry of Infrastructure and the Environment
- Mr. E. Ronteltap, Ministry of Economic Affairs
- Mr. E. Ruwiel, Ministry of Infrastructure and the Environment.

Advisory board of the 4/5MS

The committee consisted of members of the 4/5 MS group:

- Mr. P. Goncalves, ERSAR, Portugal
- Mr. P. Marsden, DEFRA, United Kingdom
- Ms. J. Hunt (Defra, United Kingdom)
- Mrs. B. Mendel, BMG, Germany
- Mr. T. Rapp, UBA, Germany
- Mr. P. van Syngel, Ministère chargé de la santé, France.

Consultation groups

Within the consultation groups all stakeholders groups were represented consisting of the Commission of Experts of the Dutch Approval Scheme, the College of Experts of Kiwa and the umbrella organisations of the various material groups (and assembled products) with connection to the European umbrella organisations. The first is the advisory board of the Ministry with regard to the Dutch regulation on materials and chemicals in contact with tap- and warm water in the public domain. The latter is the advisory committee of Kiwa, a Dutch notified body, with regard to product standards and certification of products in contact with drinking water, in the private domain.



Questionnaire art. 10 Drinking Water Directive

Enterprise information

Panteia is carrying out a study for the Dutch Ministry of Infrastructure and the Environment to assess the Economic Effects of article 10 of the Drinking Water Directive (DWD) for businesses. Article 10 of the DWD requires Member States to prevent negative effects on the drinking water quality caused by materials and chemicals used in the entire drinking water supply chain. The hygienic requirements for products in contact with drinking water are not subject to European harmonization. At this moment various national requirements and regulations are in place. Mutual recognition of test results and certificates also varies much. One of the objectives of the study and of this interview is to make an inventory of hindrances and costs because of lacking harmonization and possible cost savings of harmonization.

Name of the firm:

Location:

- Headquarters:

- Subsidiaries:

The product range in this study is products from source to tap coming in contact with drinking water – the products relevant for Art 10 DWD. However, we exclude pure concrete products and chemicals.

Which (for this study relevant) product types do you produce/import/wholesale?
(yes/no in all boxes)

<i>Product</i>	<i>Production</i>	<i>Export</i>	<i>Import</i>	<i>Wholesale</i>
Organic (plastics, elastomers, coatings, lubricants)				
Metallic (e.g. cast iron, steel, copper, lead)				
Combined products (mix of materials)				

*note: pure concrete products and chemicals are excluded!

Could you describe to what kind of products this entails in a few lines?

- Organic (plastics, elastomers, coatings, lubricants)
- Metallic (e.g. cast iron, steel, copper, lead)
- Combined (mix of materials)

To which EU countries do you export these products from the country your headquarters is established in:



From which EU countries do you import to the country your headquarters is established in:

Turnover and shares?

<i>Turnover</i>	<i>Amount (euro?) (per year)</i>	<i>Share of total turnover</i>
Total turnover worldwide		
Total turnover EU		
Total turnover country head quarters		
Total Turnover relevant art.10 products (3 types) country head quarters		
Produced relevant art.10 products (3 types) country headquarters		
Imported relevant art.10 products (3 types) country headquarters		
Wholesale relevant art.10 products (3 types) country headquarters		
Relevant art.10 products (3 types) products exported to EU countries from country head quarters		
Investment in new relevant art.10 products (3 types) (not including certificates etc.)		

Perceived hindrance

What are the main differences between your headquarters' country and other (clusters of) EU Member States as regard to national legislation based on article 10 of the DWD?

In what way and to what extent do these differences in national implementation of article 10 (3 types of products) of the DWD have negative consequences for your enterprise?

To what extent do these differences hamper free trade for your enterprise?

To what extent is there no equal economic playing field as a result of differences in national legislation?

To what extent is there an uncertain environment for investment and innovation as a result of the lack of harmonization?

To what extent is the trade position of your enterprise weakened in relation to imports from outside Europe as a result of lack of EU harmonisation of Art 10 of the DWD being in place?

What are the main obstacles that make it difficult to achieve harmonization?



Costs

How is regulatory compliance managed in terms of your internal business processes, e.g. specialised unit, legal database, manuals? If relevant, how do you incorporate international aspects (e.g. certificates in other countries)?

What amount of resources does your business allocate to regulatory compliance relating to the products in question per year at EU level? What percentage of total turnover does this represent?

What are the main types of administrative costs involved in meeting national regulatory requirements? Which product regulations are the most burdensome? Are there differences between the 5 Member States?

How many certificates or approvals do you have in your headquarters' country for the 3 types of products (article 10 DWD)?

What are the costs (yearly average) you encounter in your headquarters' country for complying to the national legislation based on article 10 of the DWD, such as evaluation or certification of these products

What are the extra costs (yearly average) encountered by your business in its headquarters' country for complying to the national legislation in other EU Member States you export to (3 products, Art 10)?

How much extra time does it take to bring new products to the market due to the national differences in implementation of article 10 of DWD?

Possible cost savings from harmonisation

If harmonization of article 10 (3 product types) would take place across all EU member states, what are the cost savings for you enterprise? Please explain.

When harmonization takes place only between the cooperating five EU countries (the Netherlands, Germany, France, Portugal and the UK), what are the cost savings for you enterprise in your headquarters' country?

Are there any advantages for your enterprise due to the current lack of harmonisation? Can you quantify in monetary terms?

