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Support to the implementation and further development of the Drinking Water Directive (98/83/EC): Study on materials in contact with drinking water.

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1 INTRODUCTION

1.1 Background

When products such as pipes or valves manufactured from inappropriate materials are in contact with drinking water, impurities can leach into the drinking water or the materials may encourage microbial growth. As a result, these materials may pose a significant risk to human health, may cause taste and odour (organoleptic) issues and may even affect the aquatic environment if their residues are not removed in wastewater treatment.

The Drinking Water Directive (98/83/EC) (DWD) recognises the need to govern the use of materials in contact with drinking water. Article 10 (see box) requires Member States (MSs) to ensure that no such substances remain in drinking water at concentrations harmful to human health. However, it does not stipulate how this is to be achieved.

Many MSs have developed their own requirements and approval schemes for demonstrating compliance with Article 10. There is currently little harmonisation or mutual recognition of these between MSs, and industry cites this as causing barriers to trade. The consequence for manufacturers and suppliers of materials/products in contact with drinking water is that they need to separately demonstrate compliance with national requirements for each MS in which they want to market their product(s). It is currently not possible to use a CE mark for this purpose, due to the lack of harmonisation. Addressing the issue of the application of Article 10 has been highlighted by stakeholders in the current review of the DWD being undertaken by the European Commission.

The European Commission assigned this study: “Support to the Implementation and Further Development of the Drinking Water Directive (98/83/EC): Study on Materials in contact with Drinking Water” to assess the problem of materials and products affecting the quality of drinking water.

DWD Article 10 - Quality assurance of treatment, equipment and materials
Member States shall take all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in water intended for human consumption in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive; the interpretative document and technical specifications pursuant to Article 3 and Article 4 of Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products shall respect the requirements of this Directive.

1.2 Objectives

The overall objectives of this study are to:

1. Assess the problem of materials and products affecting the quality of drinking water (Task 1),
2. To summarise consolidated information on appropriate materials/products and test methods in a Guidance for users including householders, plumbers and manufacturers (Task 2). This Guidance is delivered as a separate Document.
3. To support the preparation of a draft Inception Impact Assessment (Task 3) with initial policy recommendations on whether, how and at which level the material/product requirements and test procedures should be regulated, allowing the Commission to consult on the Inception Impact Assessment and to decide on further action. The draft Inception Impact Assessment is delivered in the Chapter Conclusions.

This Summary Report presents the main findings for Task 1. A supporting Technical Report covering the information collected for Task 1, the Guidance document (Task 2) and the draft Inception Impact Assessment are issued separately.

Specific objectives for Task 1 - assessment of the situation

The study was required to examine the current situation, but specifically not to cover the history of previous attempts to harmonise requirements or create an EU-wide acceptance scheme. Task 1 comprised four sub-tasks with the following objectives:

- Task 1.1 Legislation, Standards, Scope: to examine EU legislation, National legislation, available test methods and standards, and substances regulated under other legislation and from this to provide the scope of products and materials for inclusion, clarification of terminology and definitions and, an assessment of approaches to materials safety in different legislative areas (Chapters 1 and 2).
- Task 1.2 Market, Use, Mutual recognition: to identify major industry players and bodies competent for approval of materials/products; very rough approximations of: installed material/product base, investments/expenditures, annual sales, intra-EU trade; and assessment of barriers to trade and application of mutual recognition. (Chapter 3)
- Task 1.3 Drinking water contamination: literature review of drinking water contamination caused by materials and collection of information on test failures of materials (Chapter 4)
- Task 1.4 Appropriate materials/products and test methods: to describe which materials/products are commonly used without hesitation, and which are the common test methods used and their costs. Assess whether it could be feasible to set minimum EU requirements or performance classes for materials/products that are currently in use, and what test methods and approval systems would therefore be suitable (Chapter 5).

1.3 Methodology

Task 1 was undertaken using a combination of: literature searches of publicly available research, information and data; sourcing relevant unpublished information; and communication with some 80 stakeholder organisations in government, regulation and industry. Requests for data and information to support the tasks were made directly to organisations, or though presentations about the project at workshops and meetings held by stakeholders [Annex A].

The subjects covered by Task 1 are wide ranging. It was agreed with the Commission that, within the available resources, this task would indicatively assess the scale of the problem.

Task 1.1 Legislation, Standards and Scope

EU Directives and Regulations concerning materials in contact with drinking water and other relevant supporting and sectoral legislation were reviewed. National legislation and approaches, including approval systems for materials/products in contact with drinking water were examined, focusing on selected MS (Germany, France, Netherlands, UK, Portugal and Denmark) and the USA. Advantages and disadvantages of different approaches were considered. Testing standards and methods used at international (ISO), European (EN) and national level for materials in contact with drinking water were examined. Addressing the application of art. 10 of DWD, issues are not dependent on product types but on specific types of different materials (metallic, organic, cementitious). A product type can be made from different materials and compositions thereof. For a given product the assessment of the actual composition of the materials it contains in contact with drinking water is essential to analyse and assess their potential effect on health and water quality. Therefore, the approach of this study is based on materials rather than on products and thus deviates from the foreseen methodology. The Ecodesign Methodology MEErP has been used as reference (as agreed upon at the inception meeting) to identify the scope of the project. The overall approach to the tasks of this study was, however, partly inspired by the MEErP approach.

Treatment chemicals were not included in the project's scope and consequently the focus of the study is on materials and products used in the containment and conveyance of water, not treatment. Definitions for terminology were also examined and clarified to encourage consistent use.

Task 1.2 Market, use and mutual recognition

The primary source used for identifying major players was publicly available information from trade association and direct contact with stakeholders. This was limited to a practicable scale covering major material and product types used in water distribution systems and plumbing. However, with several thousand companies involved the sector it was not practicable provide listings of companies.

For the assessment of installed material/products it was expected that most data would be available at the national level and be used to extrapolate EU figures. Relatively little information was found in the public domain, whilst purchase of commercial market reports were out with the resources of the study. A number of EurEau's members (drinking water network operators) were particularly helpful in providing information on pipe materials and lengths in national public distribution systems.

For the assessment of new sales and market trends, and intra-EU Trade the primary source was Eurostat data, supported where available by relevant research reports and market information. However, there are limitations to Eurostat data for production, import and export since it is based on product categories that are not sector specific (e.g. 'pipe' categories include products for water, wastewater, drainage, gas and industrial uses). Some 150 product categories were identified as likely to include products used for drinking water. Of these 12 were selected for closer examination as being most representative of the sector including plastic, cementitious and metallic pipes, pumps and taps (Section 3.2). The proportion of each category that comprised drinking water contact products could not be accurately assessed so the data was taken as being indicative of scale of economic activity.

The assessment of barriers and mutual recognition was undertaken by reviewing information provided by national competent bodies, trade associations, and companies, and examining the requirements of selected national approval schemes.

Task 1.3 Drinking water contamination

This task examined the extent to which substances and materials have been linked with drinking water contamination, and the extent to which materials have been found to fail compliance testing. A systematic review was undertaken to source information on incidents where materials were linked to chemical, organoleptic and microbiological contamination drinking water and adverse health effects. Grey literature was sourced from competent authorities and laboratories in MSs. Information was also sought concerning experience of which materials fail test procedures. Although responses were limited, mainly because of confidentiality, detailed information was provided for testing undertaken on materials in the UK.

Task 1.4 Appropriate materials/products and test methods

Existing information was reviewed and relevant bodies in selected MS (Germany, France, UK, Netherlands, Portugal, Denmark and Poland) were contacted for information concerning appropriate and reliable materials/products that are in current use, commonly used tests and how results are used for a product/material approval, and a rough assessment of costs of testing. The extent to which EN test method standards are applicable and/or need to be developed and/or amended was examined.

Appropriate materials are considered to be those that have passed assessment but, as no single EU wide common assessment exists appropriate materials remain listed on a country by country basis. There is extensive information in the public domain on substances that have been approved for use in National Positive Lists (organic and cementitious) and product brands that have been assessed under the various national schemes.

1.4 Material types and product types in the scope of this study

1.4.1 Introduction

This section sets out the scope for the material types to be addressed in this study and the scope of the types of product used in new installations that contain these materials in contact with drinking water. It was been developed and refined following review of legislation, particularly DWD and the Construction Products Regulation (EC No 305/2011) (CPR), harmonised standards and supporting standards, MSs' requirements and approvals schemes, and findings from Tasks 1.3 and 1.4.

Products manufactured and sold for contact with drinking water comprise: products with defined shape (e.g. pipes and tanks) whose inner surfaces form the water pathway for conveying, storing and controlling water; malleable products without a defined shape that incidentally mix with water (e.g. lubricants used for moving parts or to aid installation); and treatment chemicals that are deliberately mixed with water. Though as highlighted above treatment chemicals are outside the scope of this project.

Products are either factory produced (e.g. a pipe) or site applied (e.g. a waterproof coating). Assembled products (e.g. a pump, meter, valve, pipe joint) usually comprise a number of separately manufactured components in contact with water (e.g. the body, sealing rings, gaskets, connectors, adhesives and lubricants). These components are often sourced from specialist suppliers and are in effect 'products' placed on the market in their own right and submitted for assessment for their safety in contact with drinking water. There are also repair products for fixing damage or extending the life of products (e.g. linings for pipes and storage systems) and replacement parts for worn components (e.g. seals and gaskets). Relatively few substances or materials are sold directly to water network operators and building owners, except in their manufactured finished form (e.g. in manufactured assembled products, lubricant products and chemical products).

1.4.2 New installations and products in scope

The review initially needed to identify which new installations and therefore which products contain substances and materials that Article 10 applies to.

The title of Article 10 includes 'equipment' (see box above), but this is not defined other than the Article applying only to new installations covering the 'preparation or the distribution of water'. The DWD itself applies to the quality of water intended for 'human consumption' from the point of its collection (e.g. in a groundwater borehole), through treatment, storage, distribution in the public network and building plumbing systems as far as the DWD's points of compliance, which are:

- taps that are normally used for 'human consumption' in buildings at the end of a distribution network;
- from the point of emerging from a tanker (if so supplied for human consumption);
- the point at which water is put into bottles or containers (if so supplied); and
- the point where water is used in a food production undertaking.

The distribution systems before these points comprises both the publicly owned water treatment, distribution system and service pipes connecting to buildings, and the plumbing systems within domestic, commercial and industrial buildings. The majority of the public distribution and building plumbing comprises pipe. Sections are joined directly together or by using separate connectors/couplings (e.g. elbow, tee) referred to as pipe fittings. Throughout the system valves, sensors, pumps, meters and other products are used in-line for the control of water. These are collectively referred to as accessories or ancillaries. At certain points water is stored in order to ensure a constant supply, in reservoirs in public distribution or tanks in treatment works and building plumbing. At the point of delivery for human consumption, buildings contain, in addition to taps, a range of appliances that are connected to the drinking water plumbing.

DWD does not describe the products that comprise the systems, other than a clarification that the ‘domestic distribution system’ comprises privately owned ‘pipework, fittings, and appliances’ between the taps normally used for human consumption and the distribution network. Although not explicitly stated in DWD, Article 10 is interpreted in European materials testing standards and National requirements as applying to both hot and cold water systems within buildings.

The application of Article 10 at EU and MS level has particularly focused on the CPR (which replaced Council Directive 89/106/EEC referenced in the text of the Article) and its associated development of harmonised supporting standards for materials testing under Mandate 136 (Section 2.1.3). However, the CPR covers only to construction products used in permanent civil engineering works and is applied to water distribution systems after the point of treatment. Within buildings its scope includes pipes, tanks, protection and safety devices, valves and taps, pumps, water meters and water conditioning equipment, and their components (including membranes, resins, adhesives, joint sealings and gaskets, coatings, linings, lubricants and greases) but does not include non-permanent fixed items such as appliances (e.g. washing machines, dishwashers) connected to the plumbing system.

‘Human consumption’ is defined in DWD as drinking, cooking, food preparation and ‘other domestic purposes’. The latter are not specifically defined, but, having reviewed interpretations in national legislation, for the purposes of this report these are considered to include: the use of water for washing (bathing and showering); washing of clothes and dishes (in sinks and using appliances e.g. dishwashers and washing machines); and, flushing of WCs and bidets. In non-domestic buildings the public water supply is connected to a wider range of appliances (e.g. steam ovens, vending machines and medical equipment). Appliances are usually fitted with a backflow prevention device near the point that drinking water enters the appliance to stop contaminated water from within the appliance being drawn back into the system and contaminating the drinking water supply. For the purposes of this study we consider that plumbing equipment used up to the ‘point of delivery’ in the backflow preventer in appliances should be included within scope (i.e. flexible hoses, pipe, connectors, valves, backflow prevention devices that are continuous with the plumbing supplies to taps and other points of compliance).

A clear definition of the scope of ‘new installations’ would assist in the interpretation and application of Article 10 for harmonisation legislation and its interpretation at national level. We consider new installations within the scope of this study to comprise:

- Pipes, fittings and ancillaries used for hot and cold water plumbing in building installations from the water supply system to the four DWD points of compliance (including tankers) and to the point of delivery in backflow prevention devices within other appliances;
- Pipes, fittings and ancillaries in water supply systems from point of capture, including service pipes connecting to buildings; and water treatment works installations;
- Water storage system installations in water supply systems and buildings.

Any product used within these systems was considered potentially within the scope of this study.

It was conceived in the project’s terms of reference that it might be feasible to identify products of particular importance (e.g. greatest contact area or greatest risk) and to be able to exclude some products (e.g. with small surface area) as having little potential for deteriorating the drinking water quality; so narrowing the scope of the study and the focus for the guidance and options going forward. However, following the review, it is our opinion that, although product type may be taken into consideration in some aspects of the assessment of the materials it contains, no product types could be excluded from requiring assessment, so no specific product types should be excluded from the scope of the study, as explained further under materials scope below.

1.4.3 Materials in scope

Products are made from one or more material. The significance of a particular product in the context of Article 10 concerns the potential for the substances and materials it is made from to reduce the protection of human health provided for in the DWD.

Essentially, the materials used in contact with drinking water divide into three main types: metallic, organic and cementitious (see box for categories and uses) the latter two being collectively referred to a non-metallic. Because of different characteristics these material types vary in their potential effects on water quality (Chapter 4) and require different approaches for evaluation and testing in EN harmonised supporting standards and national test standards (Section 2.3).

For an assembled product, any hygienic assessment requires examination of its components list and the formulation of the materials from which these are made. A chrome plated brass tap, for example, contains both metallic and non-metallic materials comprising different grades of brass, rubber seals, ceramic (if used in the cartridge), a plastic or metal flow straightener/aerator at the end of the spout and rubber lined flexible connections are provided with some models to connect with plumbing. Within the water pathway there will be areas where nickel and chromium surface areas overlay the brass, when deposited as a result of the chrome plating process.

Depending on their formulation these materials have the potential to leach metals and organic substances causing toxicological or carcinogenic risk, to enhancing the growth of micro-organisms or affecting taste, odour or appearance of water (Chapter 4).

Different models of a product vary uniquely in their design, use of components, material compositions and surface areas in contact with drinking water. This means that each model has a unique potential to affect water quality and public health. Even a small component, such as rubber O-ring used to seal a joint in a plumbing fitting, has potential to impact on water quality (Chapter 4).

A substance may be a minor constituent in one material, but a major constituent in another. Similarly a specific material may comprise a very small surface area within one model of a product or a major surface area in another. Thus the potential risk depends on the actual composition of each material and relative surface area. For example the pipes have different internal diameters which determine respective surface area to volume ratio (S/V). Typical internal diameters (ID) of pipes are: domestic installations and buildings < 80mm, service pipe 80 < ID < 300mm and mains piping in the public distribution system ID > 300mm. Material composition and relative surface area are key factors used by competent authorities in MSs to assess risk to human health and to determine the extent of testing required and analysis of results for a material or product (Sections 2.2 and 2.3). The usual approach taken is to assess the composition of materials used in products on a case by case basis.

Substances are chemical elements and their compounds, natural or manufactured, including additives or impurities.

Materials are prepared from one or more substance in a form suitable for use in a manufacturing process.

Organic materials include plastics, rubbers, silicones, coatings and lubricants. Their composition may comprise a wide range of substances including by-products of manufacture, aids to polymerisation, additives, dyes and pigments; and intermediate products which arise during manufacture, or decomposition products of the substances used. Products made with organics include pipes and their linings, fittings and ancillaries and components thereof, storage systems, and repair products.

Cementitious materials are those which include cement in their composition (e.g. mortar, concrete, cement and cement-based composite materials such as asbestos cement). Materials used in these include aggregates, mixing water, admixtures, fibres, polymer modifiers, formwork release agents and curing compounds. Cementitious products include pipes, pipe linings (e.g. cement lined ductile iron pipe) and tanks.

Metallic materials comprise metals (e.g. copper, nickel, chromium and iron), metallic alloys (e.g. brasses) and plating. These are used in products in supply systems and building network, such as piping and fittings, valves, flow meters, pumps and tanks and components thereof (e.g. pump bodies, valve bodies and water meter bodies).

There are substances or materials that are considered by the competent authorities in MSs to be safe to use and are listed in national 'Positive Lists' for metallic, organic and cementitious materials, based on testing, evaluation and practical experience (Section 2.2.2). However, there are no common Positive Lists for use EU wide. Where Positive List are used, materials and products are assessed by checking the actual compositions of the materials present within a product against the national list, in order to determine whether the product is considered safe or requires further evaluation.

As previously mentioned, product type is taken into consideration in some aspects of the assessment of the risk from substances and materials. Risk assessment based on material composition and product use is used by some MS (e.g. Netherlands and Draft Portuguese Regulation) to determine if a product is high risk or low risk, with reduced requirements for testing for the latter (Section 2.2.2). Rules concerning the level of specification of composition used in assessment may take product type into account depending on the surface area, with substances present in very low concentrations not required to be declared (Section 2.3). Generic product type (e.g. pipe according to diameter) is taken into account in certain test protocols where S/V has to be considered for converting test results into actual the concentrations that would be found in drinking water, for comparison with acceptance criteria (e.g. chemical migration test results for organic and cementitious materials, under EN and national test standards). However, although taking product type into consideration these approaches, do not exempt any types of product from requiring assessment.

The potential risk from substances and materials depends on material type, composition and relative surface area, which vary between product type and between different models of the same type of product. Therefore assessment of the risk from product types and models needs to be undertaken a case by case basis and the approach to their evaluation based in the actual materials each one contains in contact with drinking water.

Table 1.1 summarises the scope of materials for this study and their uses in products installed in the public distribution network and buildings.

Table 1.1 Summary of Scope showing major material categories, examples of metallic, organic and cementitious materials and product categories uses in contact with drinking water

Material Types in scope		
Metallic materials	Organic materials	Cementitious materials
Categories -Copper alloys -Coppers -Steel / iron -Platings	Categories -Plastics -Rubbers -Silicones -Coatings -Lubricants	Categories -Cement -Aggregates -Mixing water -Admixtures -Fibres -Polymer modifiers -Formwork release agents -Curing compounds
Product Types in scope Uses cover installations for capture, storage, treatment, distribution, building systems to points of compliance and delivery listed in Section 1.4.		
Types of product made with metals	Types of products made with Organic materials	Types of product made with cementitious materials
• Pipes in building installations • Uncoated pipelines in water supply systems (not internally lined with cementitious or organic materials) • Fittings and ancillaries in buildings installations • Fittings, ancillaries in water mains and water treatment works • Components of products of fittings and ancillaries (e.g. pump bodies, valve bodies, water meter bodies)	• Pipes • Organic lined pipes • Fittings and ancillaries in buildings installations • Fittings and ancillaries in water mains and water treatment works • Components of fittings and ancillaries • Storage systems • Repair products for storage and pipe systems	• Pipes • Pipe linings (e.g. cement lined ductile iron pipe) • Tanks • Cement • Grout • Repair materials

1.5 Definitions

Definitions of key terms used in this report.

Term	Definition
Additive	**Substance** which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the finished **material** or **product**. It is intended to be present in the finished **materials** or **products**.
Aggregate	Granular mineral **material** suitable for use in concrete. Aggregates may be natural, artificial or recycled from material previously used in construction.
Aids to Polymerization	**Substances** which initiate the polymerization reaction and control the macromolecular structure of the **polymer** (i.e. catalysts).
Ancillaries	Complete functional unit made up of one or more **components** or **materials**, parts of which are in contact with water, e.g. taps, valves, pipe connectors and flexible hose assemblies. Same definition as **Fittings**.
Assembled products	P**roducts** comprising two or more **components**, possibly of different **materials**.
Competent Authority	A regulatory body authorised by a MS government to monitor compliance with the national statutes and regulations, and carry out duties on behalf of the government in compliance with EU law.

Term	Definition
Component	A part manufactured out of a specific composition, brought to the market as a **product**, part of an assembled **product**, or as a spare part. For drinking water applications, components may be considered as **products** and be individually approved (e.g. o-ring, gasket) or they are tested in the finished **product** (e.g. in a valve).
Composite material	Material comprising different constituents which are mixed and bonded together but remain separately identifiable material categories e.g. glass reinforced plastic (GRP).
Composition	**Constituents** found within a **material** or **product**.
Compound	**Substance** formed from two or more elements chemically united in fixed proportions.
Constituent	**Ingredient** used to make a material or product.
Economic operator	The natural or legal person who submits the application for certification or approval of the **product**, which may be the manufacturer, importer, distributor or authorised representative.
Elastomer	A polymer with both viscosity and elasticity, and very weak inter-molecular forces, generally having a high failure strain compared with other materials. The term, which is derived from elastic polymer, is often used interchangeably with the term rubber.
Fittings	Complete functional unit made up of one or more **components** or **materials**, parts of which are in contact with water, e.g. taps, valves, pipe connectors and flexible hose assemblies. Same definition as **Ancillaries**.
Pipe fittings	Complete functional unit made up of one or more components or materials, parts of which are in contact with water and are used to connect lengths of pipe.
Formulation	**Constituents** and their concentrations used to make a **product** or **material**.
Hygienic	For the purposes of this report a collective term was needed to describe the range of assessments and tests used to determine the effect of substances and materials on drinking water, which include taste, odour and appearance, growth of microbiological organisms and migration of chemicals, and to distinguish them from the ‘mechanical’ testing of materials and products. The term selected and which is increasingly being used in this context is ‘hygienic’.
Inert	Chemically inactive. Having little or no ability to react.
Ingredient	**Substance** or **mixture** used to manufacture the product or material.
Material	Prepared from a substance or from a combination of substances, suitable for use in a manufacturing process.
Material category	Sub-types within a **material type**, e.g. plastics, coatings, rubbers, silicones, lubricants, within the organic material type.
Material type	Type of **materials** of similar physical/chemical characteristics (e.g. organic, metallic).
Monomer	Monomers and starting substances mean substances undergoing any type of polymerization process to manufacture polymers
Multi-layer products	**Products** comprise two or more layers bonded together to form a single item, e.g. barrier pipe.
Notifying authority	Authority designated by a Member State with the responsibility for setting up, and carrying out assessment and notification of the bodies to be authorised to carry out third-party tasks in the process of assessment and verification of constancy of performance of construction products for the CPR, and for the monitoring of these **notified bodies**.
Organoleptic characteristic	Ability of a **product**, or **constituent** to affect the odour, flavour, colour or turbidity of drinking water.
Notified body	Body notified to the Commission and other MSS by a national Notifying Authority for undertaking 3rd party tasks involved in the assessment

Term	Definition
	and verification of constancy of performance for products - Notified product certification body, notified factory production control certification body and notified testing laboratory
Positive list	List of **substances** that have been assessed with respect to their toxicological characteristics and can be used for the manufacture of a constituent.
Product	Clearly identified manufactured item, in its finished form, that comes into contact with water intended for human consumption, or a **component** part of a manufactured item. A product can be **homogeneous, non-homogeneous** or may also consist of multiple **components** made out of one single or different **compositions** (e.g. a valve). The types of product include **single material products, assembled products, multi-layered products, site applied products** and **other products.**
Product type	Products of similar characteristics and purposes (e.g. pipes or valves).
Safe	Not likely to cause or lead to harm or injury; not involving danger or risk.
Single material product	A **product** made from one **material** (e.g. a solid wall pipe). Similar to a **homogenous product**.
Site applied products	Products such as coatings and linings are placed on the market as ingredients that will be mixed and applied on site.
Substance	A chemical element and its **compounds** in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its **composition**.
Thermoplastic	A material, usually a plastic polymer, which becomes soft when heated and hard when cooled. When thermoplastics are heated, they melt to a liquid.
Thermoset	Synthetic **materials** (plastics) that strengthen during being heated, but cannot be successfully remoulded or reheated after their initial heat-forming. This is in contrast to **thermoplastics**, which soften when heated and harden and strengthen after cooling.
Traceability	The ability to trace and follow a material or article through all stages of manufacture, processing and distribution.

2 LEGISLATION & STANDARDS

2.1 Current EU legislation

2.1.1 EU Product policy

The EU has been developing product policy principles over several decades to ensure both the free circulation of products in the single market and a high level of protection of EU consumers and professional users. Collectively referred to as the New Legislative Framework[1] (NLF) these policies comprise rules covering the free movement of goods (e.g. Regulation (EC) No 764/2008 on the Free Movement of Goods, the General Product Safety Directive and CE Marking) and Union harmonisation legislation that is sector specific and based on the definition of 'essential requirements' for assessing the performance of products. Assessment against these essential requirements is supported by harmonised standards on technical specification and harmonised supporting standards for testing. Where established these form a basis for CE Marking. For a number of reasons, products in contact with drinking water pose difficulties for interpreting how EU legislation is applied.

Regulation (EC) No 764/2008 on the Free Movement of Goods states that "a Member State may not prohibit the sale on its territory of products which are lawfully marketed in another Member State, even where those products were manufactured in accordance with technical rules different from those to which domestic products are subject". However, exceptions to that principle are permitted (under Article 30 of the Treaty on the Functioning of the European Union) for issues justified on the basis of overriding reasons of public interest. These include 'the protection of health and life of humans', which provides potential justification for MSs maintaining their own requirements for materials and products in contact with drinking water. However, such prohibitions or restrictions cannot constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

In the absence of other EU legislation, national standards, Commission recommendations or codes of practice relating to safety of products the General Product Safety Directive (GPSD) 2001/95/EC applies. This is a core element of the NLF intended to ensure that only safe products are made available on the market. However, this directive applies only to the supply of new and second hand products for consumers for personal use and therefore does not fully cover the scope of products containing materials in contact with drinking water.

The NLF is being progressively applied as Union harmonisation legislation is developed for sectors and product groups. However, responsibility for implementation of Article 10 rests with MSs (Section 2.1.2) and is not covered by comprehensive harmonised legislation. Although the CPR is linked to Article 10 and contains an essential requirement for the safety of construction products in contact with drinking water and rules relating to the NLF, its scope does not extend to all products in contact with drinking water (Sections 2.1.3 and 1.4). Harmonised technical standards have been developed for the mechanical performance of some product types, but not their effect on drinking water. Although the CPR has resulted in the development of harmonised supporting test standards for materials in contact with drinking water, these do not include harmonised pass/fail criteria for interpreting the test results. Consequently, the CE Mark, which was established to enable a manufacturer to declare that a given product is in conformity with all essential safety requirements of applicable Union harmonisation, cannot be applied.

2.1.2 Drinking Water Directive

The DWD is the principal EU legislation concerning protection of human health from products in contact with drinking water, but pre-dates the current EU products rules and policies and addresses few of the NLF rules for products. Although it obliges MSs to protect human health concerning substances or materials used in contact with drinking water, it leaves the interpretation of this requirement to their discretion. The DWDs instructions in the respect are confined to one Article (10)

[1] The 'Blue Guide' on the implementation of EU products rules 2016

and it does not contain any related Annex setting out how compliance should be achieved or how MSs should co-ordinate implementation between themselves.

Consequently MSs that were EU members at the time of its drafting in the late 1990s have continued to develop their existing approaches or, in the case of newer MSs, are adapting existing or drafting new national legislation and regulations usually independently of each other. This includes the development of national approval schemes for demonstrating compliance with national requirements.

The DWD does require that Article 10 is taken into consideration in the Construction Products Regulation (CPR), and this better reflects the rules of the NLF. However, CPR has a more limited scope than DWD.

Although the DWD established an advisory committee to assist in the Commission on scientific and technical developments, its responsibility does not extend to directing harmonisation or applying he mutual recognition principle.

2.1.3 Construction Products Regulation

The CPR's scope extends to the safety of construction products used in permanent civil engineering works in distribution systems from point of treatment and in buildings and therefore does not cover products used in contact with drinking water (Section 1.4). Its essential requirements for the performance of products cover wide ranging safety and health hazards associated with construction products. To address the requirements of Article 10 it states that construction works must be designed and built in such a way that they prevent:

> *the release of dangerous substances into drinking water or substances which have an otherwise negative impact on drinking water*

However, whilst setting a framework, CPR does not specify the technical requirements for demonstrating compliance with each of the essential requirements. This has been partially addressed in relation to Article 10 through the issue of Mandate 136 to CEN for the development of harmonised test standards for metallic, organic and cementitious materials. However, as highlighted in Section 1.4, CPR does not cover products used in all types of new installation used in public water distribution and treatment or buildings.

CPR does set out rules covering the roles and responsibilities of stakeholders; product traceability, need for technical documentation, content of declarations of conformity, use of CE Mark, procedures for conformity assessment; competence of conformity assessment bodies, accreditation policy and market surveillance policy.

Under the CPR, MSs are required to designate Product Contact Points (a requirement of the Mutual Recognition Regulation (EC) No 764/2008) for enquiries by any interested party concerning construction products. The Regulation also sets out the roles for Notifying Authorities and Notified Bodies and third party laboratories in assessment and verification of consistency of performance, including options for levels of conformity such as inspection of manufacturing plant and production control and performance.

The CPR established an 'organisation of Technical Assessment Bodies (TABs), the national bodies designated by MSs to assess specific product areas, to provide oversight of requirements for construction products at the European level. However, in the absence of harmonised standards for drinking water products, the current list of TABs does not specifically include the national bodies responsible for assessing materials in contact with drinking water

On market surveillance, the CPR requires that the relevant market surveillance authorities in MSs, when considering cases of non-compliance, should consider if this affects other national territories and inform the Commission and the other MSs of their evaluation and of the actions which they have required the economic operator to take.

2.1.4 Food regulation

Regulation (EC) No 178/2002 sets out common principles and responsibilities concerning food and feed safety, and the means to provide a scientific basis, organisational arrangements and procedures to underpin decision-making in matters concerning these. Together, with the supporting regulations specifically for materials in contact with drinking water the food regulations offer insight into options for addressing the Article 10 issues.

To achieve the general objective of a high level of protection of human health and life, food law is based on risk assessment based on available scientific evidence and undertaken in an independent, objective and transparent manner. Since, the existing system of scientific and technical support was considered no longer able to respond to increasing demands, the Regulation established a European Food Safety Authority (EFSA) to reinforce the available expertise at the EU level. Although it does not approve materials it has a panel of independent experts to provide opinions on substances and has a co-ordination role between the relevant national bodies. There is not an equivalent EU level body to the EFSA able to take this role for materials in contact with drinking water.

There are some parallels between the requirements for materials in contact with drinking water and food contact materials (FCMs) since both concern risks to public health and the perceived quality of food/water. Regulation (EC) No 1935/2004 on **materials and articles intended to come into contact with food** requires manufacture in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health; or bring about an unacceptable change in the composition of the food; or bring about a deterioration in the organoleptic characteristics. It allows for specific measures for groups of materials and articles including adhesives, ceramics, rubbers, glass, Ion-exchange resins, metals and alloys, plastics and silicones, which are also used in contact with drinking water.

Measures used include:

- listing of substances authorised for use in the manufacturing of materials and articles;
- purity standards for substances;
- special conditions of use for substances and/or the materials and articles in which they are used;
- limits on the migration of certain constituents or groups of constituents into or on to food;
- basic rules for checking compliance; rules concerning the collection of samples and the methods of analysis to check compliance,
- provisions requiring the Commission to establish and maintain a publicly available Union Register of authorised substances, processes, or materials or articles;

In the absence of specific measures the Regulation does not prevent MSs from maintaining or adopting national provisions provided they comply with the rules of the Treaty.

A Union reference laboratory for materials and articles intended to come into contact with food together with national reference laboratories are available to assist MSs by contributing to a high quality and uniformity of analytical results.

The Regulation sets out how an applicant is able to obtain authorisation for a substance to be added to the Union Register from the EFSA. This is done via the competent authority of a MS (each MS has to designate one) using a technical dossier demonstrating that a substance satisfies requirements. Under these arrangements the competent authority passes the dossier to the EFSA which informs other MSs of the application. The EFSA must then provide an opinion (within six months) as to whether, under the intended conditions of use of the material or article in which it is used, the substance complies with the safety criteria laid down. Such a body does not exist for drinking water contact materials.

The FCM legislation is further advanced for some materials than others. Commission Regulation (EU) No 10/2011 specifically addresses the **manufacture and marketing of plastic materials** and articles intended to come into contact with food. For other materials there are currently no specific EU measures, e.g. glass and metal alloys, and for these materials MSs are able to maintain or adopt their own national provisions. The FCM requirements for plastic establishes that only the substances included in the Union list of authorised substances (similar to a Positive List) should be intentionally used in the manufacture of plastic layers in plastic materials and articles. This is an established list of authorised substances used in materials for food contact, primarily for plastic FCMs at present, and is under the control of the Commission and is applicable throughout the Union. There is no similar provision under DWD and the nearest equivalents are the current attempts by the regulators in Germany, France, the Netherlands and the UK (the 4MS, Section 2.2.4) to produce common positive lists. The regulation also sets out compliance testing requirements for these materials. Aspects of the harmonised test standards developed under Mandate 136 draw on the FCM regulations approach.

2.1.5 Other relevant legislation

The application of the DWD is supported by subsequent EU legislation that limits the use of certain substances or materials that potentially could come into contact with drinking water.

The **Biocidal Products Regulation** (BPR) (Regulation (EU) No 528/2012[2]) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms by the action of the active substances contained in the biocidal product. This regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment. In terms of drinking water, the Regulation ensures that biocidal products and residues in contact with drinking water (e.g. for disinfection of drinking water) do not cause adverse effects in humans or animals.

The **Registration, Evaluation, Authorisation & restriction of Chemicals regulation** (REACH) was adopted to improve the protection of human health and the environment from the risks that may arise from chemical exposure; to make manufacturers and importers responsible for understanding the risk associated with the chemical use; to enhance the competitiveness of the EU chemicals industry; to allow free movement of substances on the EU market and to promote the use of alternative methods for assessing the hazardous properties of substances.

A major part of REACH is that substances must be pre-registered and registered with the European Chemicals Agency (ECHA) by the manufacturer or importer. Registrations must be supported by a standard set of data that is proportionate to the amount of substance manufactured or supplied, without which the substance cannot be made or sold legally (‘no data, no market’). The Member States play a role in the evaluation of data submitted in the registration process.

REACH also covers the restriction and authorisation of substances. Under Annex XVII, Restrictions may be implemented for substances that pose a particular threat, and are deemed to require Community-wide action. A restriction may range from a total ban to restricting its use i.e. not supplying it to the general public. To date, there are 64 substances, groups of substances or substances in a mixture listed[3].

For those substances that are deemed to be of ‘very high concern’ based on their toxicity and persistence in the environment, they are placed on Annex XIV of REACH and require industry to apply to ECHA for an authorisation. Applicants need to demonstrate that the risks associated to the use of the substances are adequately controlled or socio-economic benefits of use outweigh the risks. Decisions on authorisation are made by the European Commission aided by ECHA and the Member States. The latter plays an essential role in seeking agreement for the list of ‘substances of very high concern’ (SVHC) for inclusion in the authorisation list (Annex XIV) and provides opinions on ECHA’s

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:en:PDF

[3] https://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach

draft recommendation on priority substances for inclusion in the authorisation list. To date 31 substances are included in Annex XIV Authorisation list[4].

The **Classification, Labelling and Packaging** (CLP) Regulation (EC) No 1272/2008[5] aligns previous EU legislation with the Globally Harmonised System of Classification and Labelling of Chemicals)(GHS). The Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through their classification and labelling. It also has links to the REACH legislation. Before placing chemicals on the market, the industry must establish the potential risks to human health and the environment of such substances and mixtures, classifying them in line with the identified hazards. In most of the cases, suppliers self-classify the substance or mixture, based on available information. However, in some cases, the decision regarding the classification is taken at Community level so that users are better informed about their potential hazardous effects and how best to make use of them safely. In such cases it is mandatory for the suppliers to apply the harmonised classification and labelling.

The **Water Framework Directive** 2000/60/EC (WFD) sets out a number of strategies to protect against the chemical pollution of water. One strategy set out in Article 16 is to select and regulate substances of EU-wide concern, namely priority substances, among which are those designated priority hazardous substances. The initial list of priority substances defined in the WFD was added to by amending Directive 2013/39/EU[6]. This Directive sets out environmental quality standards (EQS) concerning the presence in surface water of certain substances or groups of substances identified as priority pollutants on account of the substantial risk they pose to or via the aquatic environment. Of the 45 priority substances listed, some are also regulated as SVHC under the REACH legislation.

The **Ecodesign Directive 2009/125/EC[7]** establishes a framework for the setting of ecodesign requirements for energy-related products with a significant potential for the reduction of energy. Detailed studies, including market analysis, have been undertaken of specific product groups including taps showers and pumps which are key components of water distribution systems (see Section 3). Significantly, the ecological criteria for the award of the EU Ecolabel for sanitary tapware (Commission Decision C(2013) 2826) uses the 4MS approach for assessing metallic materials of construction (see Section 2.4.4), but refers to testing of organic materials in accordance with the respective requirements of the Member State where the product will be placed on the market.

Alongside the CPR there is EU harmonisation legislation developed for specific sectors that apply to some of the products used in contact with drinking water to which Article 10 is relevant. An example is the **Gas Appliances Directive** 2009/142/EC (GAD)[8], which intended to ensure that gas appliances and fittings do not compromise safety. GAD applies to some water heating equipment used in building hot water systems and it includes the following reference to drinking water among its essential requirements:

> *Without prejudice to the Community rules in this area, materials and components used in the construction of an appliance, which may come into contact with food or water used for sanitary purposes, must not impair their quality.*

[4] https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF

[6] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:226:0001:0017:EN:PDF

[7] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0125&from=EN

[8] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0142&from=EN

2.2 National approaches to implementation of Article 10

2.2.1 Introduction

This section considers national legislation for materials in contact with drinking water and approaches to the assessment of materials from a review of selected MSs: the Netherlands, France, Germany, UK, Denmark and Portugal. The approach used in the USA is contrasted in Section 2.2.5).

2.2.2 Legislation

The DWD has been given effect through its transposition into national legislation by MSs. The absence of an EU Regulation concerning the interpretation and application of Article 10 or rules in an Annex to the DWD, means that MSs have the discretion to develop their own legislation, regulation or other requirements and what level of market surveillance is used to monitor compliance. It is currently not possible to use a CE mark, due to the lack of harmonisation, and some MSs operate schemes for the approval of materials and products as means for a manufacturer to demonstrate compliance with national requirements (Section 2.2.3).

National requirements often quote verbatim the text of Article 10 and are generally based on the principals that materials should not affect human health and should not significantly modify the chemical, microbiological, physical or organoleptic properties of the water. The competent authorities in each MS are variously organised and tasked under national legislation and regulation to set requirements, consider issues, operate certification/approval schemes and enforce compliance. The scope of which new installations and products are covered in national legislation varies as MS have discretion to determine where it is applied from source to point of delivery within buildings including hot and cold water plumbing, together with water treatment chemicals for which some MS have separate requirements.

Article 10 does not stipulate what criteria must be met to demonstrate that a substance or material does not reduce the protection of human health. Although under the CPR, CEN working groups have been developing harmonised test methods, the setting of acceptance criteria (pass/fail) is not within the competence of CEN, leaving responsibility for determining acceptable pass/fail criteria to the MSs, where common criteria do not exist.

What has emerged since the DWD was introduced and with the recent expansion of the EU is a situation where MSs are developing their approaches to compliance at different speeds. Therefore, the level of detail varies from limited requirements to highly developed approaches developed over many decades covering technical performance specification, roles and responsibilities of stakeholders; documentation requirements, assessment of conformity, marking requirements, accreditation and market surveillance. The larger MSs and those that have been longer term EU members tend to have better established national approaches supported by test requirements and approval schemes (Table 2.1). The smaller and the newer EU members tend to have less well established approaches and not to operate approval schemes. As they become available, MS have been gradually adopting EN supporting standards to replace national standards.

The DWD sets standards for the most essential chemical and microbiological parameters that are found in drinking water with relevance for human health, listing a total of 48 parameters that must be monitored and tested regularly in drinking water supplies. These do not cover the many hundreds of chemicals that potentially leach from materials into drinking water and consequently these would not be picked up in routine monitoring programmes. Where microbiological or organoleptic parameter failures are detected, a detailed investigation is usually required to determine their cause. Regulators have difficulty in conclusively demonstrating links between a water quality issue in supply and a particular material/product (Section 4). Consequently, a precautionary approach is taken by MSs to the hygienic assessment and testing of products. They have determined that it is easier to detect potential problems with materials through testing and so prevent the use of materials that pose a potential risk before they are installed, than it is to detect impacts on water quality and public health once installed, and retrospectively address the removal of products made from inappropriate materials.

The competent authorities within MSs that have responsibility for Article 10 vary in their outlook on the issues and priorities, which affects how they apply different national procedures, sampling requirements, laboratory methods, pass/fail criteria and operate national approval schemes. In some MS, responsibility for delivery (e.g. of approval schemes) has been passed to private organisations, which have the capacity to deal with volume of materials/products submitted for assessment (e.g. UK WRAS Ltd and DVGW, Germany). Most competent authorities make use of an expert group for specialist advice and opinions, including setting of pass/fail criteria for the assessment and verification of compliance of substances and materials for which these do not already exist.

To support the assessment of materials and products several MS (Table 2.1) maintain national ‘Positive Lists’ of substances or materials (metallic, organic or cementitious) that have been previously evaluated and ‘approved’ for use in contact with drinking water, based on testing, evaluation and practical experience. Comparison of the substances in the composition of a candidate material or product with a positive list facilitates the evaluation stage of assessment. However, there are no common Positive Lists for use EU wide, though there is voluntary co-operation between some MS to combine their lists (Section 2.2.4). Where Positive List are used, materials and products are assessed by checking the actual compositions of the materials present within a product against the national list, in order to determine whether the substances are considered safe or requires further evaluation. Limits may be set In these cases limits are set for the % composition of a substances in a material below which it does not need to be considered (e.g. substances comprising <0.1% of a materials composition).

Risk assessment based on material composition and product use is used by some MS (e.g. Netherlands and Draft Portuguese Regulation) to determine if a product is high risk or low risk, with reduced requirements for testing for the latter. Based on risk assessment, some approaches focus on assessment of products with large surface areas in contact with drinking water (pipes and containments) and have more limited requirements for relatively small products with small contact areas (e.g. accessories in public distribution systems in UK requirements or metallic components with small contact areas in 4MS metals approach).

The issues identified above demonstrate the divergence of national requirements and highlight a number of the reasons why currently products are separately assessed by many MSs and why the outcome of the assessment of a material sometimes varies between MS.

2.2.3 Approvals

Some MSs operate established schemes for the approval of materials and products as means for a manufacturer to demonstrate compliance with national requirements (Table 2.1). Some of them use an associated ‘quality mark’. These schemes are either mandatory (e.g. Denmark and the Netherlands) or voluntary (e.g. France). In the UK, the approval system is mandatory for materials and products used at treatment works and in distribution but voluntary for domestic use.

Demonstrating compliance is a complex procedure that is usually beyond the expertise of manufacturers/suppliers. So the voluntary schemes operated by MSs are intended to be a more convenient means of proving compliance with national requirements, and alternative ways of proving compliance are permitted. However, it the latter case it is usually the responsibility of the manufacturer/supplier to prove compliance rather than for a national competent authority/body to disprove it. For this reason and because customers come to recognise the national voluntary approval, voluntary schemes such as DVGW or WRAS in the UK acquire a de facto status as if they were mandatory. As the certification/approval body may be a private entity, though appointed by the national competent authority, this can give the impression that the approval scheme is a private scheme.

The roles of regulation, and particularly certification/approval and testing/auditing are usually undertaken by separate organisations to ensure transparency and independence. Under the CPR, and other EU legislation, competent bodies that are governmental or non-governmental can be appointed by the competent authorities of MSs to undertake 3rd party tasks involved in the assessment and verification of constancy of performance for products, covering certification, testing and auditing. These become 'notified bodies' that are authorised and have their performance monitored. In several MSs the competent authority has found that it does not have the resources or expertise to develop requirements and run certification/approval schemes and has contracted this provision out to the private sector (for example Netherlands and UK for plumbing products, and this is also the case for the EPA in USA).

The evolution of national requirements, certification/approval schemes and testing requirements pre-dates the introduction of DWD and other EU legislation in some MSs and certain organisations hold these responsibilities for historical reasons. The status of certification/approval schemes operated by private entities within MSs is an important issue in relation to MSs' duties under EU product legislation.

In Germany, the private DVGW had responsibility for developing requirements for product performance for the water and gas sectors. It believed that EU legislation concerning mutual recognition applied to the state not to it as a private entity. A court case (Fra.bo Court Case C-171/11) was brought against it by an Italian manufacturer concerning mechanical testing. The product was approved for use in Italy but was being denied approval by DVGW which argued that as a private entity it was not subject to the same rules as if the scheme was run by the MS. The court's ruling was that the German DVGW certification requirement for this fitting was an unjustified technical barrier to trade. As a consequence, Germany recognised that DVGW cannot decide unilaterally upon the requirements for materials in contact with drinking water and made the German Umweltbundesamt (UBA) responsible for developing mandatory evaluation criteria. To date, legally binding evaluation criteria have been set for metallic materials and come into force by April 2017[9]. They are linked to the 4MS metallic requirements. UBA has also been developing guidelines and draft Evaluation Criteria for other material types. Germany also recognises relevant tests and assessments from other countries.

The requirements for assessing products for compliance with national requirements is determined by initial examination of the composition/formulation of the water contact materials they comprise, from which requirements for further evaluation are determined. This is compared with national Positive Lists of acceptable substances (where used) and lists of banned substances, consideration of their intended use and consideration of the relative surface area of material that is in contact with drinking water. These evaluations are not product specific (i.e. there are not separate materials tests specifically for pipes, taps or pumps) so the assessment is undertaken according to the material types from which they are made. Most MSs' competent authorities and notified bodies running approvals make use of an expert group for specialist advice and opinions on assessment and verification of compliance of materials.

Under the current arrangements involving diverse national approval schemes and in the absence of CE Marking (or any other pan-EU mark) it is difficult for both market surveillance authorities and customers to identify whether a material/product has been subject to hygienic assessment of its safety for drinking water contact.

2.2.4 Co-operation between MS

Differences in the way that MSs assess substances and materials have been highlighted above. However, there is voluntary co-operation between some MS to address these differences. Notably, there is a voluntary initiative of the competent authorities in Germany, the Netherlands, France and the UK to collaborate in the harmonization of tests for the hygienic suitability of products in contact with drinking-water through common practices (see box). This is known as the 4MS Initiative and has been in operation since 2007. The 4MS aim is to adopt between them common, or directly comparable, practices for:

[9] https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/guidelines-evaluation-criteria#textpart-1

- The acceptance of the constituents used in materials in contact with drinking water
- The testing of materials
- The use of common test methods and setting acceptance levels
- The specification of tests to be applied to products
- Reviewing factory production control and setting audit testing requirements
- Assessing the capabilities of certification and testing bodies

Table 2.1 Summary of MSs that use approval schemes and positive lists for materials in contact with drinking water

Approval scheme	Collaboration between MS	Comments
MS which have testing requirements or ‘approval scheme’ or positive list Austria, ‘OVGW’ voluntary scheme - Positive List, Belgium – BELGAQUA, Hydrocheck used by Belgaqua members - Positive List Czech Republic – ITC, Czech National Standards (CNS) Compulsory, - Positive List, Denmark, - ETA, ‘GDV’, mandatory-Positive List Finland, Ministry of Environment type approvals, VTT France, ‘ACS’, CLP, CAS mandatory, - Positive list Germany, - DVGW voluntary scheme - Positive List Hungary, NIEH - mandatory Italy, - Ministry of Health – mandatory – Positive list The Netherlands, mandatory - Positive list – Poland, PZH – mandatory Portugal, Epal scheme, INSA Proposed scheme Romania – National Institute for Public Health Slovakia – National Institute of Public Health Slovenia, NIPH, RS – voluntary Spain, MSC - voluntary - Positive List Sweden, Sitac and Swedcert UK, WRAS (plumbing) – voluntary; DWI Reg31 (distribution) - No Positive List *EEA Members* *Norway, NIPH* *Switzerland, SVGW*	**The 4MS** Scheme. Collaboration on common assessment procedures for metallic, cementitious and organic materials by: Germany, Netherlands, France, UK. With Portugal (and recently Italy) as observers	Ongoing development but no major implementation of 4MS common approaches or application of principle of mutual recognition. Portugal has issued draft regulations in 2016 for a national approvals scheme based on 4MS Italy is attending 4MS meetings
	Nordic countries (Denmark, Finland, Sweden, Norway) are collaborating in the MAID Project with the aim of recommending modified and harmonized testing of materials in the Nordic region meeting European regulations Material. Includes evaluating applicability of 4MS acceptance procedures.	Slovenia has issued draft regulations in 2016 for a national approvals scheme. There is recognition of some test results between Austria, Germany, Switzerland and The Netherlands.
Those without an approval scheme Bulgaria, Croatia, Republic of Cyprus, Estonia, Greece, Ireland, Latvia, Lithuania, Luxembourg, Malta.	Some users of products in these MS look to evidence of compliance/approval in another country when purchasing products.	The most commonly cited situation is acceptance of German approval in neighboring countries

4MS is based on the development of separate common approaches for the assessment of metallic, organic and cementitious materials. It is using harmonised test standards as they are developed by CEN, but crucially is developing acceptance levels (pass/fail criteria) that are agreed across all four competent authorities and their associated expert groups. The regulation of materials in contact with food, particularly of plastics, is often cited as being of relevance to products in contact with drinking water, and justification that a material/product should be accepted for drinking water contact. The 4MS approach to organics draws on the FCM regulations approach.

The 4MS has a work in progress on developing a common Positive List for organic materials and currently a ‘combined list’ of some 540 ‘approved’ substances, compiled from Positive Lists currently used in Germany, France and the Netherlands has been developed.

2.2.5 Approach used in USA

The Federal Safe Drinking Water Act (SDWA) protects the quality of drinking water in the United States and requires the US Environment Protection Agency (USEPA) to develop National Primary Drinking Water Regulations for contaminants that may have an adverse impact on public health. Under the SDWA the individual States and territories must implement rules that are at least as stringent as the EPA's, so ensuring common minimum standards across the USA.

Due to the volume of requests for its opinion on whether a product would contaminate drinking water, USEPA found it necessary to move responsibility to a non-governmental, non-profit consortium in 1984. It issued a contract for this 'competent authority' to produce voluntary, third-party consensus standards and an associated certification program for all substances directly and indirectly added to drinking water. Two standards for additives products were produced and adopted in 1988:

> NSF/ANSI Standard 61 – Drinking water system components — Health effects covering all indirect additives, products and materials.
>
> NSF/ANSI Standard 60 – Drinking water treatment chemicals — Health effects covering many of the water treatment chemicals, also known as direct additives.

Their application and on-going development continues to be overseen by a consensus-based Joint Committee on Drinking Water Additives comprising representatives from key stakeholders:

- Regulatory entities such as USEPA, Health Canada, and US State water programs,
- Manufacturers of product covered by the scope of the standard, and
- Product users such as water utilities and the armed services.

Testing and certification services against NSF 61 are offered by a number of private test laboratories, as is the case in many MSs that operate an approval scheme.

The scope of the installations covered by NSF/ANSI Standard 61 includes pipes, tanks, fittings, plumbing products, protective materials, process media, sand and gravel, joining and sealing materials.

The focus of the Standard is the evaluation of contaminants or impurities imparted indirectly to drinking water, and it is intended for use by certifying organizations, utilities, regulatory agencies, and/or manufacturers as a basis of providing assurances that adequate health protection exists for covered products.

It is a toxicological based assessment and does not include testing for microbiological growth or taste and odour, unlike the approaches used in EU harmonised supporting standards for materials. Although the US-EPA has standards for aesthetic parameters (e.g. maximum drinking water odour limit is a "threshold odour number" of 3) compliance is voluntary because these standards are based on aesthetic, not health considerations. Consequently, aesthetic parameters are not considered in NSF 61.

NSF/ANSI Standard 61 is concerned with the potential extraction of any chemical and considers the composition of all materials in a product that is submitted for certification. In this respect it applies to metallic, plastic and cementitious materials uses a common evaluation process for products following a risk-assessment approach:

- Identification of the substances contributed to drinking water by a product or material.
- Estimation of human exposure to the substance.
- Evaluation of the potential health safety concerns presented by the exposure.
- Estimation of the acceptable risk associated with the use of the product in drinking water.

The material formulations used in a product are subject to toxicological evaluation by a professional toxicologist to determine the potential extractants and so identify what determinants to test for on a case by case (product by product) basis. Unlike the approaches of some MSs, NSF 61 does not use a Positive List. It also does not test substances or materials individually. For the US toxicological test method the complete internal water pathway of a product (e.g. a tap or a pipe with a joint) is filled with water and following exposure protocols this analysed for the determinants, rather than testing separate of samples of the individual materials within the water pathway.

NSF 61 lists drinking water acceptance criteria for over 600 contaminants that are used to determine pass/fail of materials in testing. If a product is found to leach a substance for which a drinking water criterion has not been established, the establishment of a criterion for the substance is required prior to certification.

Advantages of the US approach are that a single body sets the minimum performance and testing standard for products in contact with drinking water for all US States and Territories and key stakeholders have a say its application and on-going development. There is a strong focus on setting acceptance criteria for substances to ensure that common pass/fail criteria are available. NSF 61 is applied to all products on a case by case basis and covers metallic, organic and cementitious products. However, the assessment is limited to toxicological evaluation of substances entering drinking water and does not assess growth of microorganisms or organoleptic impacts.

2.3 Test methods and standards

In undertaking a performance assessment on a material, three things need to be established:

- The performance that is required to be met (e.g. an essential requirement set out in EU harmonisation legislation or standard),
- Test method(s) that are appropriate for assessing performance against that performance requirement (e.g. an EU supporting standard or national or international test method), and
- Pass/fail criteria that can be applied to the test results to determine whether the performance requirement has been met (e.g. a numerical value set at International, EU or national level).

For substances and materials in contact with drinking water in the scope of this study these three criteria are variously met through a combination of: performance requirements set at EU and national level; test methods set at international (ISO), EU (EN) and national level; and pass/fail criteria set mainly at national level or determined on a case by case basis for specific substances by expert committee.

The CPR has set an essential requirement for construction products for drinking water safety, and Mandate 136 has led to the development of a range of supporting standards for testing of organic, metallic and cementitious materials. However, these EN test standards do not set pass/fail criteria and therefore they are open to interpretation at the national level by competent authorities and/or their expert groups. In the absence of associated harmonised standards that state these performance requirements, it is not possible to demonstrate compliance across the EU using the harmonised test standards. Although there are EN performance standards for some construction product categories these focus on their mechanical performance and do not include detailed requirements for their possible effects on drinking water and, so refer to existing national requirements.

MSs have developed their own standards and test methods for the hygienic assessment of materials and products to varying levels, over many decades in some cases, and continue to use them where harmonised standards or test standards are not available, or deemed appropriate (Table 2.2). Currently, for each MS, its legislators set the regulatory framework for competent authorities to apply within which standards are used. This framework will usually prescribe which standards (International, European or national) for performance are used for different materials, which test methods are applied and how the pass/fail is assessed (absolute values or determination by expert committee).

Table 2.2 Standards commonly used in selected MS for assessment of Metallic, Organic and Cementitious materials.

MS	Metallic	Organic	Cementitious
Germany	EN 15664-1 and EN 15664-2 for copper and copper alloys	Organoleptic: EN 1420 and EN 12873 series. odour and flavour EN 1420 EN 1622:2006 Water quality. Determination of the threshold odour number (TON) and threshold flavour number (TFN) colour and turbidity EN ISO 7887 EN ISO 7027, TOC* EN 1484 Enhancement of Microbial Growth (EMG) according to EN 16421 (test method 1 or 2)	DVGW W 347 for cementitious materials
France	Composition reviewed but no testing required	XP-41-250-1 rapid Analytic screening test XP-41-250-2 analytical screening test XP P 41-250-3 cytotoxicity test	Certificate of conformity to the positive lists (CLP) Issuance of CLP is not conditional on carrying out migration tests
UK	Composition reviewed but no testing	BS 6920 comprising five tests: -Odour and flavour test -Appearance and Colour test -Extraction of metals test -Cytotoxicity test -Growth of aquatic microorganism test For products used in public distribution systems in addition to BS6920 leaching tests in accordance with EN12873 part 1-4	BS 6920 (see organics)
Netherlands	NEN-EN 15664-1:2008 NEN-EN 15664-2:2008	Migration tests for organoleptic aspects: • Pipes, fittings etc.: NEN-EN 1420-1:1999 for taste and odour • Pipes, fittings etc.: NEN-EN 13052-1:2001 for colour and turbidity • Reservoirs: NEN-EN 14395-1:2004 for taste and odour, and colour and turbidity Migration tests for the migration of chemical substances: • NEN-EN 12873-1:2003 for factory-made products (e.g. pipes) • NEN-EN 12873-2:2005 for site-applied materials (e.g. coatings) • NEN-EN 12873-3:2006 for ion exchange and adsorbent resins • NEN-EN 12873-4:2006 for water treatment membranes Method of detection or analyses of the migration water: • NEN-EN 1622:2006 for taste and	Migration tests for organoleptic aspects: • NEN-EN 14944-1:2006 for factory-made products (e.g. pipes) • NEN-EN 14944-2 for site-applied materials Migration tests for the migration of chemical substances: • NEN-EN 14944-3:2005 for factory-made products (e.g. pipes) • NEN-EN 14944-4 for site-applied materials Method of detection or analyses of the migration water: • NEN-EN 1622:2006 for taste and odour • NEN-EN-ISO

		odour • NEN-EN-ISO 7887:1994 for colour • NEN-EN-ISO 7027:2000 for turbidity • NEN-EN 1484:1997 for TOC (VOC** + NVOC***) • Accredited methods for specific substances on the basis of a step by step assessment (e.g. VCM from PVC pipes) Enhancement of microbial growth NVN 1225:2004	7887:1994 for colour • NEN-EN-ISO 7027:2000 for turbidity • NEN-EN 1484:1997 for TOC (VOC + NVOC) Accredited methods for specific substances on the basis of a step by step assessment (e.g. heavy metals)
Denmark	NKB4 or other relevant NKB-test (copper alloys) Optionally DS/EN 16058	Colour and turbidity DS/EN 12873-1. Flavour and odour EN 1420 TOC (VOC + NVOC) DS/EN 12873-1.) Phenols: DS/EN 12873-1 Toxicological assessment DS/EN 12873-1? Enhancement of Microbiological Growth EMG DS/EN ISO 6222 (Bacterial count)	Yes
Portugal (draft regulation based on 4MS)	EN 15664-1:2008 EN 15664-2:2008 EN 16058 (nickel) EN 16056 (stainless steel alloys)	Colour and turbidity EN 13052-1 Odour and flavour EN 1420-1 TOC (VOC + NVOC): EN 1484 or other provided it is accredited for that purpose Enhancement of microbial growth EN 16421, method to be used according to the product to be approved is optional, and should be one of the three methods (BPP, W270, or MDOD****) Release of substances NEN-EN 12873-1:2003 NEN-EN 12873-2:2005 EN 15768 Non-suspect organic substances (GC-MS)	Organoleptic EN 14944-1:2006 Migration of substances EN 14944-3:2005
Poland	Only occasionally testing for galvanic zinc coating, Test method not described	The migration testing as per PN-EN 12873 and the PN-EN1622 or local method established by NIZP-PZH Testing of biofilm growth Laboratory of Sanitary Microbiology (NIZP-PZH) own test procedure	Migration tests PN-EN 14944-1 and PN-EN 14944-3

**TOC: Total Organic Carbon*
***VOC: Volatile organic compounds*
****NVOC: Non-Volatile Organic Carbon*
*****BPP: Biomass Production Potential test (the Netherlands), W270 microbial growth test (Germany) ,MDOD: Mean Dissolved Oxygen Difference test (UK)*

Whilst there are harmonised performance standards for the mechanical performance of specific product categories that are used in contact with drinking water, the approach to standardisation and testing for their impact on water quality that has been used under Mandate 136 focuses on material categories from which they are made. Although a substantial body of harmonised European testing methods and standards have been developed there are gaps that are in the process of being addressed or need to be addressed.

The consequence of the current arrangements is that suppliers of products cannot demonstrate compliance with harmonised standards for hygienic testing of the materials they contain and cannot use a CE Mark for drinking water contact even if the product complies with harmonised mechanical performance standards.

Organic materials

The assessment of the effects of an organic material, component or product on water quality in harmonised supporting standards and national standards comprises testing to assess three aspects:

- organoleptic characteristics (effects on odour, flavour, colour and turbidity of the water)
- the migration of chemical substances from it into water,
- its ability to enhance the growth of micro-organisms.

The use of organic material testing standards by MSs is preceded by an assessment of the chemical formulation the materials used in a component or product by a national competent authority/notified body against that MS's requirements. This is used to define the requirements for subsequent testing the effects of the given substance or material on water quality. Some MSs make use of a national Positive List of accepted organic substances which have already been proven safe to use in manufacture (for some substances restrictions are made on how it is used) and so do not require further evaluation. Banned substances, under REACH etc. are also identified at this stage.

The principal European Standards (ENs) for migration testing for organoleptic parameters from organic materials are:

EN 1420-1	*Determination of odour and flavour assessment of water in piping systems - Part 1: Test method*
EN 13052-1	*Influence of materials on water intended for human consumption. Organic materials. Determination of colour and turbidity of water in piping systems. Part 1 -Test method*
EN 14395-1	*Influence of organic materials on water intended for human consumption. Organoleptic assessment of water in storage systems. Part 1 - Test method*
EN 1622	*Water quality. Determination of the threshold odour number (TON) and threshold flavour number (TFN)*
EN ISO 7887	*Water quality -- Examination and determination of colour*
EN ISO 7027	*Water quality -- Determination of turbidity*

However, common acceptance criteria have not been set for Threshold Odour Number (TON) and Threshold Flavour Number (TFN) for organoleptic assessment.

The main European standards applying to the assessment of the migration of chemical substances from organic materials are:

EN 12873-1:2014	*Influence of materials on water intended for human consumption. Influence due to migration. Part 1- Test method for factory-made products made from or incorporating organic or glassy (porcelain/vitreous enamel) materials*
EN 12873-2: 2005	*Influence of materials on water intended for human consumption. Influence due to migration. Part 2 - Test method for non-metallic and non-cementitious site-applied materials*
EN 12873-3: 2006	*Influence of materials on water intended for human consumption. Influence due to migration. Test method for ion exchange and adsorbent resins*
EN 12873-4: 2006	*Influence of materials on water intended for human consumption. Influence due to migration. Test method for water treatment membranes*
EN 1484	*Water analysis. Guidelines for the determination of total organic carbon (TOC) and dissolved organic carbon (DOC).*
EN 15768:2015	*Influence of materials on water intended for human consumption. GC-MS identification of water leachable organic substances.*

The procedure for assessing a material for chemical migration usually comprises:

- A migration test in accordance with an applicable (European) standard (e.g. EN 12873-1);
- A method of analysis in accordance with a standard to determine presence of substance(s) and a ‘migration rate’ for a substance (in e.g. mg/dm2.day) as result;
- Application of a conversion factor to the migration test results taking into account the surface area/volume ratio of the product and residence or contact time of the water, to convert them into concentrations that are more representative of the real situation.
- Assessment of the results against a MTC (Maximum Tolerable Concentration) in e.g. mg/l as maximum concentration (pass/fail criteria).

However, common acceptance criteria have not been set for:

Total Organic Carbon

Guidance for the interpretation of the results of the GC-MS-Screening (especially toxicological evaluation of the commonly found substances)

The principal standard for assessing whether a material encourages (by providing substrate and/or nutrients) the growth of micro-organisms is:

EN 16421: 2014 *Influence of materials on water for human consumption enhancement of microbial growth (EMG)*

This standard offers options of three different test methods, reflecting differences in approach in some MS. This can be confusing for manufacturers and in the draft Portuguese regulation it is stated that the competent authority has to option to decide which method should be used for assessment a specific material.

Common assessment criteria have not been set for the acceptance level for EMG. Consequently, the assessment of pass/fail is a matter for interpretation by MSs.

The use to which a product is put, together with assessment of chemical formulations are used by competent authorities to determine the level of risk posed to the water intended for human consumption. In some cases a material/product considered to be low risk will not require testing or be subject to more limited testing. Since the compositions of materials vary, a given substance that is an insignificant constituent in the composition of one material and not require further assessment, does require assessment if it is a more significant component in another material. Table 2.3 shows that in the draft Portuguese Regulation there is a requirement for all substances comprising >0.1% of the composition of organic pipe materials (which have a large contact area with water) to be included in the toxicological assessment, but that for adhesives (low contact area) only substances comprising >1% of their compositions need be included in the evaluation.

Table 2.3 Level of specification in the chemical formulation of the product (% composition) below which a constituent of a material would not be included in a toxicological conformity assessment in the Draft Portuguese Regulations.

Material or Product	Specified level (% m/m)
Pipe systems/tanks (in PVC/PE/PP/PU/…)	0.1%
O-rings (rubber, etc.)	0.5%
Adhesives for fittings in pipe systems	1%

Cementitious materials

For the purposes of EN test standards cementitious products are divided into those that are factory-made (e.g. pipes) or coatings and materials for application *in situ* (e.g. cementitious repair products, mortars applied to internal surfaces of pipe joints during installation).

As for organic materials, cementitious products are initially assessed through an evaluation of chemical formulation. Where positive lists for cementitious materials are in use the formulation is checked against these. Where a competent authority determines a product to be low risk it may determine that it is not be necessary to undertake all testing requirements. Cementitious materials used to repair water retaining structures and pipeline products usually contain organic substances and are consequently potentially high risk materials.

A range of harmonised standards for the performance of constituent materials of cementitious products exist, but these relate to their general fitness for purpose and do not specifically cover effects on drinking water. Cementitious materials are subject to migration tests (TOC, metals and organics), growth of microorganism tests and organoleptic tests (as for organics). In determining and assessing the results of the organoleptic parameters for cementitious products the same ENs as for organic materials apply.

Migration testing of chemicals from cementitious materials and products are covered by EN 14944. It has two parts that are in force, covering factory produced products. A separate testing standard for site-applied materials was in preparation under Mandate 136.

EN 14944-1:2006	Influence of cementitious products on water intended for human consumption. Part 1 - Test methods. Influence of factory made cementitious products on organoleptic parameters.
EN 14944-3:2007	*Influence of cementitious products on water intended for human consumption. Test methods. Migration of substances from factory-made cementitious products.*

Metallic materials

The assessment of metallic materials has to take into consideration the corrosion characteristics which show two distinct phases: metal release due to short term surface characteristics of the material in contact with water, characterised by a gradual fall in the concentration of leached metal over a period of weeks or months in service followed by a lower stable rate of leaching once the surface has corroded and corrosion of the bulk material begins. Surface characteristics arise from the manufacturing process, for example the smearing of lead during milling of leaded brass or the deposition of metal within internal surfaces during plating processes. Leaching rates are also affected by the composition of drinking water and stagnation time.

A long term leaching test standard has been developed that involves testing of individual grades of metal alloy to determine their leaching characteristics and acceptability.

EN 15664-1: Influence of metals on water intended for human consumption - Dynamic Rig Test for assessment of metal leaching – Part 1: Design and operation.

EN 15664-2: Influence of metals on water intended for human consumption - Dynamic Rig Test for assessment of metal leaching – Part 2: Test water

The 4MS has developed a Common approach and a Common Composition list for metals and alloys that have been tested against this standard. As this approach is based on establishing the leaching characteristics of individual grades of metallic material it can be deemed safe to use for any situation or have limitations on its use applied if deemed to pose a risk depending on how or where it is used, so whilst some grades are determined to be safe for 100% contact with water in a distribution or plumbing system i.e. for use in pipes, others grades have conditions of use applied (e.g. only for use in fittings and ancillaries such as pump, valve and water meter bodies, which comprise a relatively smaller proportion of the surface area in contact with water than do pipes).

Germany and the Netherlands are in the process of implementing the standard and 4MS approach in their national requirements and Portugal references it in its proposed regulations.

A number of metal specific standards exist that are relevant to assessment of effects on water and are available to MSs. Stainless steel is generally passive and resistant to corrosion, but can be affected by rusting. A passivity test can be used to assess the potential for corrosion and is covered by:

> EN 16056 - Influence of metallic materials on water intended for human consumption - Method to evaluate the passive behaviour of stainless steels.

An EN for assessing nickel layers is not in common use:

> EN 16058:2012 Influence of metallic materials on water intended for human consumption. Dynamic rig test for assessment of surface coatings with nickel layers. Long-term test method

Development of supporting standards and acceptance criteria

The work of CEN under mandate 136 has produced a number of harmonised supporting standards for metallic, organic and cementitious materials testing that are being used in some MSs and in the 4MS common approaches for metallic, organic and cementitious material. However, there remain areas where supporting standards are in development (site applied cementitious materials), where optional choices of test methods need to be resolved (growth of micro-organisms) and where common acceptance criteria need to be set (Chapter 5). Going forward, organic materials pose a particular issue since their use is increasing (Chapter 3), they are replacing traditional pipe materials, and more innovation is being directed to their selection and uses. The toxicological/carcinogenic effects of many substances/materials are as yet unknown, so requiring expert opinion to determine risk and encouraging Competent Authorities to take a precautionary approach to their approval.

Therefore, the further development of supporting test standards, setting of acceptance criteria and rules for sharing of expert opinion where acceptance criteria are not available, could be addressed at the EU level with the assistance and co-ordination of Competent Authorities.

3 MARKET

3.1 Companies, trade associations and competent bodies

This section considers scale of the industry and bodies competent for approval of materials/products. It was undertaken by reviewing published literature, trade association activity and membership, discussion with stakeholders and a review of the numbers of companies holding approvals in the German, French, Dutch, British, Danish and Belgian approval schemes. The latter was included to provide a clearer understanding of the scale of industry's engagement with the formal process of demonstrating compliance with national requirements. Unfortunately, the product categories in Eurostat and PRODCOM (Section 3.2.4) databases include all product uses, not just products for use in drinking water systems and are therefore not suitable for calculating numbers of companies providing products for use in drinking water systems.

3.1.1 Companies and trade bodies

We roughly estimate that some 2 500 companies in the EU28 hold materials approvals in one or more MSs and that more than 5 000 companies within the EU are involved in producing finished products used in contact with drinking water. It appears that many more of these companies are involved in providing products used in plumbing systems than in the public distribution system. In the USA market, which has 2/3 the population size of the EU and a market for products of similar sophistication, 1 600 companies hold approvals for drinking water system components.

The majority of companies that have materials approvals in EU national approval schemes hold only one or two approvals (67% (705 companies) of companies holding ACS, France; 87% (905 companies) for WRAS Material Approval, UK), relatively small number of companies hold large numbers of approvals for extensive product ranges. This indicates a predominance of SMEs, though some large companies will only be supplying a small number of their products to the drinking water sector.

It is estimated that over 100 000 staff are employed in the EU in producing products used in contact with drinking water and the project estimates the combined sector as generating sales up to €40 billion per annum, which is similar to estimates from a study by the Dutch Ministry of Infrastructure and Environment[10] and data presented by the EDW[11].

Because of the many thousands of companies involved in the manufacture and supply of materials and products in contact with drinking water, confidentiality issues concerning data and difficulties in identifying what proportion of production is specifically for drinking water contact, it proved impracticable within the available resources to compile and list the companies and their turnover and employment.

3.1.2 Competent Bodies

In Section 2.2.2 the roles of competent authorities within MS to perform regulation and their use of notified bodies to undertake approval/certification and testing/auditing roles on their behalf have been explained. The Notified Bodies that undertake these 3rd party tasks may be publicly or privately owned. Examples of public bodies are national health and/or environmental agencies, whereas private bodies are for example drinking water associations like the German DVGW or the UK's WRAS Ltd, to which competent authorities have passed responsibility for approvals.

Approvals bodies employ teams to administer the process and may draw on experts for judgements/opinions to address issues and determine outcomes. We estimate that the number of staff involved full time in the administration of certification/approval schemes to be around 100.

[10] Economic Effects of article 10 of the Drinking Water Directive. Report to Dutch Ministry of Infrastructure and the Environment. Panteia, 2016

[11] EDW (ICPCDW) presentation to GD Grow conference - Single Market for products: Fresh ideas to unleash the full potential, 2016.

Laboratories undertaking testing of materials in contact with drinking water are usually specifically accredited as notified bodies with the competence to do so by the relevant national authorities. Providing such services represents a serious and on-going commitment of resources and laboratories usually also much wider suites of testing that may cover other business sectors and may include mechanical testing of water related products. Some laboratories are part of international groups with activities in more than one MS or have relationships with laboratories in other MSs to provide services to mutual customers.

Because of the specific requirements in the CPR and other legislation for third party activity to be undertaken by Notified Bodies the laboratories that undertake testing of substances and materials in contact with drinking water are appointed and monitored by MSs. If a manufacturer or supplier wishes to use test data from a laboratory that is not a Notified Body evidence to prove its competence is required by the certification/approval scheme.

There are relatively few laboratories that provide these services, but there is a competitive market in many MSs (e.g. in UK, which has the WRAS Material and Products schemes, the largest approval schemes in the EU, there is a choice of four accredited laboratories, in France there are two laboratories, in the Netherlands one).

Laboratories are not organised either nationally or internationally into a trade body specifically dealing with drinking water materials. They employ a range of staff covering sample stock control, analysis, maintenance, data handling, quality assurance, project management, marketing and sales. However, the number of staff directly employed on testing materials in contact with drinking water in a European laboratory is relatively small, often less than 10 per laboratory. It is our estimate that the number of staff involved full time in the testing of materials in contact with drinking water is around 200-300 across the EU. There are in addition consultants with specialist knowledge of national schemes who assist applicants in undertaking the approval/certification processes.

Certification/Approvals bodies employ small teams to administer the process and may draw on experts for judgements/opinions to address issues and determine outcomes. We estimate that the number of staff involved full time in the administration of certification/approval schemes to be around 100.

3.2 The market

3.2.1 Installed material/products

This section provides an approximate estimation of elements of the substantial installed base of materials/products in contact with drinking water across the EU.

Methodology

Publicly available information on installed materials/products was sought and discussions undertaken with selected industry trade associations and the water industry to source relevant information. The assistance of the water industry was obtained through its EU trade body EurEau in estimating the lengths and types of pipe used in public distribution networks. National data was provided for six MS (Denmark, Finland, Germany, Hungary, Netherlands and UK) together with Switzerland, and partial information for a further 8 MS. The data is summarised in Annex B and was extrapolated to provide estimates for the EU. However, it was found that industry trade associations do not generally hold comprehensive information on installed products for their sectors. Although, some specialist market reports for products are commercially available, their purchase was beyond the resources of the project.

Installed base

The estimated 27 billion cubic meters of water delivered per day to the EU's 508 million people is supplied through some 5 million km of pipe in the public distribution system. It comprises pipes of varying diameter (from 300 mm to >4,000mm diameter) made from a range of metallic (cast iron, ductile iron, steel), cementitious (asbestos cement, concrete) and plastic (PE, PEHD, PVC) materials. Estimates of the proportions of different pipe materials show substantial variations between MSs reflecting of historical availability of materials, development of the network and investment in replacement. Overall the available data indicates that currently some 44% (by length) are plastic, 43% metal and 12% are made of cement. The joints used to connect lengths of pipe usually contain seals made from organic materials.

The public system supplies the majority of the 250 million dwellings and non-residential buildings across the EU's 4 million km² through roughly 2 million km of service pipe (connecting the public supply in the road to buildings) and, we estimate, some 25 million km of hot and cold water building plumbing. Service pipes are smaller diameter than the pipes used in the distribution network but usually larger than much of building plumbing. Our estimates based on data from EurEau indicate a total of some 129 million service pipes (one service pipe can serve multiple dwellings) each usually fitted with a stop tap for isolating the supply. The majority are now plastic (80% in UK and Germany, 95% parts of France), replacing traditional metal service pipe.

Within buildings copper and plastic pipe are used for cold and hot water plumbing systems. Industry estimates indicate that plastic pipe is becoming the material of choice for new installations of cold and hot water systems replacing copper pipe.

An estimated 1.2 billion taps are installed in buildings[12], 406 million showers and 14 million water pumps[13], demonstrate a very substantial installed base for assembled products associated with the pipework.

3.2.2 Estimates of investments/expenditures

Based on information received from EurEau members it is estimated that across the EU28 the annual investment in pipes for the renewal of the public water distribution system is €10 to 12 billion. Of this total, Germany, for example is investing €1.5 billion and the UK €0.75 billion per annum. The UK contributor estimates that materials (product) costs are 12.5% of the total. On that basis the annual EU28 expenditure on materials for pipe replacement in the public distribution systems is estimated at between €1.3 and 1.4 billion.

Estimates of life in service of pipes provided by EurEau members range from 50 to 100+ years for different pipe materials. EurEau members reported replacement rates ranging from 0.5% to 1% per annum indicating a current replacement rate of between 100 and 200 years. The actual rate of replacement in each MS vary and will reflect the condition of the pipe (age and serviceability), maintenance philosophies (proactive vs reactive maintenance) and financial/investment resourcing.

The European Plastic Pipes and Fittings Association (Teppfa) estimates that European production of plastic pipe is valued at €12 billion, but this is split between water, gas, sewerage and other uses. Teppfa was not able to apportion a split between these, but our upper estimate would be between 33% and 50% for water i.e. 4 to 6 billion and that this would include both public distribution pipes and building plumbing systems so perhaps a 50% spend on each. These rough figures for water company investment and pipe sales seem reasonably aligned in the low billions of Euros.

[12] MEErP Preparatory Study on Taps and Showers Preliminary Report for Tasks 1 to 5 2013.

[13] Ecodesign Pump Review Study of Commission Regulation (EU) No. 547/2012 incorporating the preparatory studies on 'Lot 28' and 'Lot 29' (Pumps) Final Progress report

The fixed out of sight plumbing system components are rarely replaced and are installed either when the property is built, in which case the cost is covered in the purchase price, or due to renovation or extensions in which the cost of plumbing will be a small part of an overall investment by the property owner. For the domestic plumbing system the most likely purchase will be the kitchen and bathroom taps, which receive the most mechanical wear, but are also the most prominent plumbing items and are increasingly regarded as fashion items. The MEErP study on taps and showers also estimated annual expenditure for taps at €4.7 billion (2012), based on Eurostat production and import/export data for the EU.

Published market information indicates total sales of plumbers' merchants in UK, at €5.1 billion for all purposes, of which perhaps 60% or up to €3.1 billion is for water systems and rest on wastewater, drainage and other building systems. A further €250 million of general plumbing is estimated to be sold via the internet in the UK, some through plumbers merchants, indicating a total around €3 billion per annum. The UK is both a relatively expensive and affluent market in the EU and extrapolating this investment by the UK population to the 508 million population in the EU would indicate a maximum annual investment of around €25 billion on hot and cold water plumbing in buildings. Therefore, we conclude that the private investment in products for building plumbing systems exceeds the investment in the public distribution network. The public distribution system market and the private building plumbing markets are dominated by products using metallic and organic materials, with cementitious materials occupying a more niche market in public distribution system.

It appears from the example sector estimates described above, that recent estimates by the study for the Dutch Ministry and the EDW of a total market of €40 billion or more per annum of products in contact with drinking water should be considered to be an upper estimate of the annual investment made in products in contact with drinking water across the EU.

3.2.3 New sales and market trends

The EU market for new drinking water installations comprises three elements:

- new extensions to the existing public water distribution network to connect existing and new properties, to improve inter-convertibility or to connect new sources of water.
- plumbing in new buildings and in extensions to existing buildings
- replacement of the existing stock of pipes, fittings and accessories in the public distribution network and building plumbing:
    - as the end of service life is reached, and
    - for upgrading equipment before end of service life.

The current scale of these markets and forecasts to 2030/50 are considered in this section, together with trends in the use of material types.

New networks and buildings

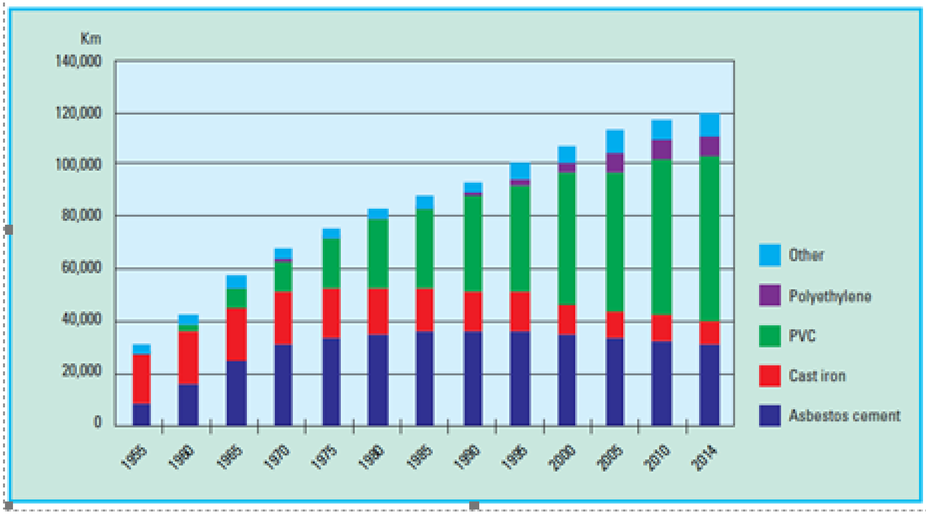
During this century the population of the EU will stabilise. It is projected to peak around 2050 at 526 million, following modest growth of 18.7 million (3.7%) from 2014[14], and is then projected to fall to a low of 519.8 million by 2075. This will eventually affect both the demand for new buildings and consequently the need for extensions to the public network, probably during the second half of the century. In the meantime new developments will need to be connected to the network and in some MSs existing properties still on private supplies will be added to networks. The proportion of population connected to the public network varies across MSs, from 57% in Romania to 100% in the Netherlands and is generally lower in eastern European countries where growth of the network through the connection of existing buildings to public supplies will be more significant.

Public water distribution systems have been a relatively recent development and the past century has seen substantial expansion of the network to cover geographical areas and cope with population

[14] http://ec.europa.eu/eurostat/statistics-explained/index.php/People_in_the_EU_%E2%80%93_population_projections

growth. This is illustrated in Figure 3.1 showing four-fold growth in the size (length km) of the Dutch water distribution network since 1955. The rate of growth is slowing; Figure 3.1 indicates average growth of around 0.7% per annum in the past decade (possibly reflecting the period of worldwide economic recession). The UK contributor to the EurEau members' data provided for this project reported a similar growth of 0.5% per annum for the UK network. Extrapolating these rates indicates growth of the network of between 7.2% and 10.3% by 2030.

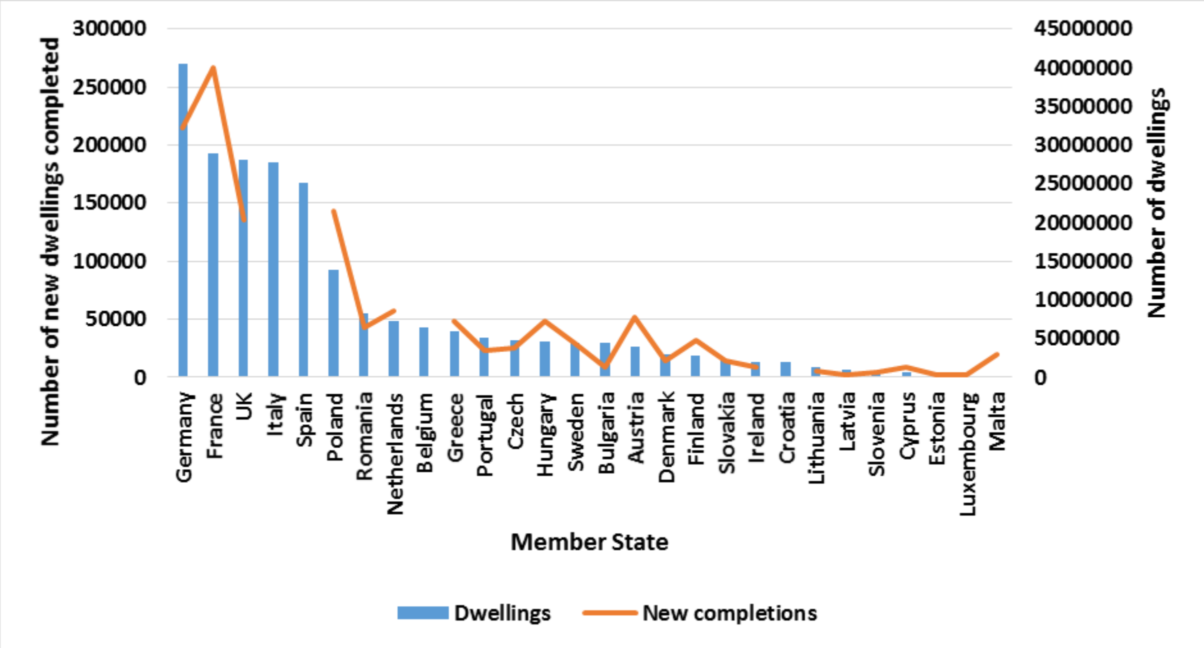
Figure 3.1 Trends in the development of the Dutch distribution network and trends in the use of pipe materials 1955 to 2014. Source: Dutch Drinking Water Statistics 2015, Vewin.



The market for new domestic buildings (dwellings) is illustrated in Figure 3.2 which shows the distribution of the 236 million existing dwellings across the MSs and the number of new dwellings completed per MS in 2012[15]. These 1.6 million new dwelling represented growth of 0.65% of the stock, albeit at a time of slow recovery following the economic downturn. Projecting that figure forward provides a forecast of growth in the stock of dwellings, and plumbing systems they contain, of some 9.5% between now and 2030 and 26% to 2050. Growth in plumbing systems through the extension or re-modelling of existing buildings (adding or extending bathrooms/utility rooms/kitchens) has not been estimated and is not included. The market for new service pipes will expand in line with the development of new housing across the EU and the transfer of existing stock not yet connected to the network.

[15] Estimated from The State of Housing in the EU, 2015 http://www.housingeurope.eu/resource-468/the-state-of-housing-in-the-eu-2015

Figure 3.2 Dwellings per Member State and number of new dwellings completed per annum (2012): Source: The State of Housing in the EU 2015 (see reference in footnote).



In 2012 annual sales of taps in the EU were estimated to be 83.4 million units and growth of +11% has been forecast to 2030 to 92.6 million (Ecodesign study on taps and showers). The same study estimated annual sales of showers to be 44.1 million units with growth of + 11% to 49 million over that period. The separate Ecodesign study of water pumps forecasts that total annual sales of new and replacement pumps will increase by 60% from an estimated 1.5 million clean water pumps sold in 2014 to 2.5 million by 2030.

Replacement of existing stock

The market for replacement of installed equipment is driven by both the past expansion of the distribution network and the building stock, and by the lifecycle of the products used. The latter varies considerably with pipes now expected to last for 100 years, whilst fittings with a mechanical action such as taps, pumps and meters have lifecycles of 10 -15 years due to wear (i.e. replacement rates are >6% of stock per annum). A further issue is the early replacement of products through upgrades as technology improves and user requirements change.

Data provided by EurEau members indicates that the annual rate of replacement of existing pipe in the public distribution network is currently between 0.5 to 1.2% of the estimated 5 million km in the network, totalling some 25 000 to 50 000 km per annum. The replacement rate of the service pipes connecting buildings to the public network was reported to be around 1% per annum and our rough estimate is therefore that some 20,000 km of replacement plastic service pipe is installed per year. This is predominantly PE plastic pipe which is replacing the use of metal and PVC.

Annual replacement rates of plumbing pipe are difficult to assess since they are in private ownership and not collectively monitored or managed like public networks. Plumbing pipe tends to continue to be used with minor repair or replacement during the lifetime of a building and is rarely completely replaced within a building. New pipework in existing buildings is most likely to be installed during extensions or internal modification to bathrooms and kitchens. With pipe product lifetimes of 50 to 100 years a replacement rate of around 1% per annum is assumed.

At the point of compliance, the tap has been evolving from a simple brass bodied valve, with an elementary mechanism to control flow, into an increasingly complex item whose design and use of materials is now driven by fashion (appearance, colour, use of materials, feel), functionality and performance, which encourages replacement before the end of product life. With an average in service life of up to 15 years, the current stock of taps (estimated to be 1.29 billion), will potentially be replaced twice between now and 2050, as will other mechanical devices subject to wear such as pumps and meters.

With the population of the EU set to stabilise the market for new products will become increasingly dominated by the replacement of existing assets as demand for new extension to networks or plumbing in new buildings slows. However, this replacement market is set to grow as the expanded networks and house building of the past century feeds through into requiring repair.

Trends in use of materials

EurEau members reported that when pipe replacement is required they have been replacing their traditional iron and cement water pipes with plastic. This has mainly been with PVC, and polyethylene pipe is emerging as a new alternative. These reported trends are well illustrated in Figure 3.1, which highlights how the relative proportions of different pipe material are changing. Of particular note is the reduction in the length of cast iron and asbestos cement pipe by 23% since 1995 in the Dutch network, and the downward trend. Plastic pipe has a particular advantage as due to its flexibility it can be used in various replacement techniques that avoid the need for the ground to be excavated to replace pipe.

The ‘other’ category in the figure includes use of novel in situ repair and renovation materials and pipe, for which material type is not recorded. Rehabilitation techniques to extend life of public network metal and concrete pipes and tanks by re-lining are being increasingly used by water companies, so greater use of site applied materials (e.g. spray on anti-corrosion linings and structural linings, which are mainly organic materials) is expected as assets age and reach the end of their lifetimes. This market will continue to grow as the pipes laid down in the rapid expansion of networks over the past century feed through into the replacement market.

For many assembled products used in plumbing and public networks there is a trend towards increasing sophistication in design to incorporate improvements to their function, mechanical performance, weight, ease of maintenance, water efficiency, energy efficiency and sustainability. This is driving innovation in the design and use of materials, particularly for stronger, lighter-weight, more wear and corrosion resistant, and cheaper materials (currently, 15mm plastic pipe is around 40% of the price of 15mm copper pipe). This has led to the increasing use of organic materials in place of metals for components, including the development of composite plastic bodies for water meters and valves.

Associated with this is an ongoing widening of the available choices of water delivery in the kitchen so that, in addition hot and cold water, customers are also being offered filtered, boiling, chilled and sparkling water delivered at the kitchen sink. The consequence is more complex designs and wider use of different materials, components and ancillary fittings within and before the tap including greater use of organic components (see also Section 1.4).

Looking forwards, in the next decades to 2030 and 2050 the predicted trends are for growth in the markets for pipes and fittings for both new sales and replacement sales, increasing technical sophistication and performance of the products installed, with consequent demand for innovation to improve material performance, increasing demand for repair products to extend the life of pipes and an ongoing shift from metal and cementitious materials to organics. Consequently, there will be an ongoing need for Competent Authorities to assess and evaluate new substances and materials and to ensure that material formulations used in products do not have the potential to affect human health.

Evidence for a trend to lower quality products

Concerns have been raised with the Commission by some reputable manufacturers and other stakeholders that there is a drive towards the use of cheaper products and that this, together with a lack of market surveillance, is be encouraging the use of lower quality products that are potentially less safe.

As already mentioned, the competent authorities in MSs mainly rely on unsafe materials being identified through testing for compliance with their national requirements rather than market surveillance once installed.

The primary source for information on such trends was considered to be testing laboratories and responses were received from one UK and one French laboratory.

The UK laboratory reported on feedback it had received from materials manufacturers, particularly for rubbers. They stated that rather than developing innovative materials that might cost more, their customers are most interested in sourcing materials that are cheaper than the materials they currently use. As mentioned in the previous section, the increasing cost of metal alloys and the weight of metallic/cementitious materials (therefore cost of transport/installation) has also been driving a shift towards use of plastic and other light weight composite organic materials. However, the laboratory was not aware of any obvious corresponding increase in the proportion of materials submitted to it for testing against BS6920 that were failing.

In France the system for approval of materials and products in contact with drinking water requires good traceability of the origins of materials. When a product is submitted for approval it is disassembled and for each component the applicant must provide details of which company and which facility produced the materials. The French laboratory commented that major companies regularly present for ACS approval cheaper products that offer them market advantage. However, they often cannot obtain approval for these products because one or more organic material being used is either from unknown origin or the cost of tracking back the origin of the materials and auditing their production facilities proved uneconomic. In these cases the materials are not subject to testing and so their safety is unknown.

Both these cases confirm that there is a trend towards the use of cheaper materials, but could not confirm if there was a trend towards lower quality and hence greater risk. However, it is our experience that manufacturers and suppliers do not put forward materials and products of poor quality for hygienic approval as it is not their interest to pay for testing that ends in failure. Thus, test laboratory data may not reflect the true situation in the market place. Because of the voluntary status of most approval schemes, materials and products are placed on the market that have not been subject to hygienic testing. As highlighted by the French laboratory, even their large, well established customers were unable to identify the sources of all materials they were intending to use.
There are untested and potentially harmful materials on the market, but proving a trend towards increasing use of lower quality, less safe materials would require a programme of random testing of materials in products obtained at the point of sale, over several years.

3.2.4 Intra-EU Trade

This section assesses very roughly intra-EU Trade, considering important transboundary sales, the biggest EU internal importers and exporters, the proportion of the EU production/EU sales and trade that is imported and exported, and imports from outside the EU.

Methodology

The primary source used for the assessment of intra-EU trade was Eurostat data on production, import and export by EU28, supported where available by relevant research reports and market information. Further insight was obtained by reviewing which countries the companies holding approvals in the major national approvals schemes were from, and use has also been made of recently published research by figawa[16] on the export behaviour of German companies.

However, there are limitations to Eurostat data since it is based on product categories that are not sector specific (e.g. ‘pipe’ categories include products for water, wastewater, drainage, gas and

[16] Study: Effects of Article 10 of the EU Drinking Water Directive on test and certification costs for products in contact with drinking water. Member survey Period: September 2015 to March 2016, Figawa

industrial uses). Among the 3839 categories of material and product listed in the Eurostat PRCCODE categories, we identified around 150 as likely to include products used for drinking water. However, it was beyond the resources of this study to examine the trade flows between MSs for all materials/products. Therefore, 12 were selected for closer examination in this section, which are representative of products used in new installations and cover all three of the main material types (Table 3.1). Although the proportion of each category that comprised drinking water contact products could not be accurately assessed, the data was taken as being indicative of the relative scale of production, import and export activity within and between MSs. The rationale for selecting the 12 product groups was:

- Products that cover the three major material types - organic, metal and cementitious
- Products with large surface areas in contact with drinking water systems.
- Examples of products with smaller surface areas
- The most extensively used products
- Products with high and low unit value
- Products with short and long in service life.

Pipes represent the largest surface areas of material in contact with water in each of these sections, and are consequently a focus for detailed assessment in national regulations and approval schemes. Associated with them are a wide range of fittings for joining lengths of pipe together, and fittings/accessories for controlling their operation (valves, pumps, etc.). Review of the major types of pipe used in water distributions has been undertaken within this project, with the assistance of EurEau (Section 3.4.1). This divides the pipe types into three types for the purpose of reporting the installed base in distribution systems: metallic (Cast iron, ductile iron, steel), plastic (PVC, PE) and cement (Asbestos cement, concrete). For service pipes connecting the water main in the street to the building plumbing metal (steel, iron, ductile iron and lead) is being increasingly replaced by PE pipe. Within buildings the use of copper and plastic pipe predominates and there is some use of steel. Also included were plastic fittings for pipes (including joints, elbows and flanges) and copper and copper alloy fittings for pipes.

For accessories, taps, cocks and valves for sinks wash basins bidets water cisterns and mixing valves for the same. As highlighted in Section 1.3 these products usually contain both metallic and organic components and are found in every property served. They are also most visible plumbing component have a relatively short service life because of mechanical action. Within distribution systems pumps are required to maintain water pressure and are the main energy-using component in water supply, apart from water heating in buildings and treatment processes. They comprise metallic and organic components and have a relatively short in service life (10 to 15 years) because of the wear and tear of their mechanical operation. There are multiple Eurostat categories for pumps and the Ecodesign Study on water pumps found that those destined for water use could not be identified using Eurostat pump categories, so compiled data from industry. Data from that report is used here as appropriate.

Table 3.1 Summary of Eurostat product categories selected for examination.

Material type			Use	Relative surface area	life in service* (years)
Metallic	Organic	Cement			
Plastic pipes					
PVC Rigid tubes, pipes and hoses of polymers of vinyl chloride PRCCODE 22212157					
-	PVC organic seals	-	Distribution	High	50+
PE Rigid tubes, pipes and hoses of polymers of ethylene PRCCODE 22212157					
-	PE organic seals	-	Distribution, service and plumbing systems	High	50+
plastic fittings for plastic tubes, pipes and hoses PRCCODE 23691930					
May include metal components	Organic components	-	Distribution, service and plumbing systems	Low	50+
Metal pipes					
Copper tubes and pipes **Copper tubes and pipes PRCCODE 24442630** **Copper and copper alloy tube/pipe fittings including couplings, elbows, sleeves, tees and joints PRCCODE 24442650 -**					
Yes	Some joints		Plumbing	High	50+
Tube or pipe fittings of malleable cast iron PRCCODE 24513050 **Tube or pipe fittings of non-malleable cast iron PRCCODE 24513030 -**					
Iron	For some joint seals		Distribution and service pipes	High	50+
Ductile Iron	For some joint seals	Internal corrosion resistance lining	Distribution and service pipes	High	50+
24523000 - Tube or pipe fittings of cast steel PRCCODE 24523000					
Yes	For some joint seals	Internal corrosion resistance lining	Distribution, service and plumbing	High	50+
Cement pipes					
Pipes made from cement, concrete or artificial stone PRCCODE 23691930					
To strengthen some joints	For some joint seals	Yes	Distribution	High	50+
Plumbing and distribution fitting					
Taps **Taps, cocks and valves for sinks, wash basins, bidets, water cisterns etc. 28141235 -** **- Mixing valves for sinks, wash basins, bidets, water cisterns etc 28141233**					
Bodies and some components	Components e.g. flexible tails, o-rings, flow straighteners		Plumbing	Medium / low	10 – 15
Pumps					
Bodies and some components	Components e.g. seals and lubricants		Distribution and Plumbing	Medium / low	10 - 15

**see Section 3.4*

Production and intra-EU trade

Table 3.2 identifies which MSs produce the selected product categories across the EU28, though in many cases production is indicated but data is not provided by MSs. Manufacture of plastic products and pipes of cement, concrete or artificial stone is widespread across the EU with only the exception of Cyprus, Malta and Luxembourg. A smaller number of MSs manufacture metal tube and pipe fittings and taps/valves.

Table 3.2 National production by weight (kg) of selected Eurostat product categories in the EU Member States, where countries are recorded as producing but do not declare their production figure this is indicated by 'Produced' in the table.

	Tube or pipe fittings of cast steel	Tube or pipe fittings of malleable cast iron	Tube or pipe fittings, of non-malleable cast iron	Copper tubes and pipes	Copper and copper alloy tube/pipe fitting	Pipes of cement, concrete or artificial stone	Rigid tubes, pipes and hoses of polymers of ethylene	Rigid tubes, pipes and hoses of polymers of vinyl chloride	Plastic fittings for plastic tubes, pipes and hoses	Taps, cocks and valves for sinks, bidets, water cisterns,etc.	Mixing valves for sinks, bidets, water cisterns etc
Austria	0	Produced	0	Produced	Produced	315,264,823	Produced	29,091,358	9,899,361	Produced	Produced
Belgium	0	0	0	Produced	Produced	303,807,807	18,653,361	24,932,114	2,204,589	Produced	0
Bulgaria	Produced	Produced	Produced	0	0	74,891,094	5,534,123	7,923,368	941,564	Produced	Produced
Croatia	0	0	3,000	0	1,317	34,034,000	7,675,000	2,819,000	1,094,000	64,000	0
Cyprus	0	0	0	0	0	0	0	0	0	0	0
Czech Repu	Produced	Produced	Produced	Produced	217,000	127,807,000	16,698,000	10,267,000	6,844,000	1,585,440	2,104,000
Denmark	33,788	0	17,498	168,871	191,100	Produced	98,632,956	13,695,168	14,294,444	1,989,616	933,689
Estonia	0	0	201,700	0	372,000	16,121,000	9,486,400	2,154,000	612,000	24,000	0
Finland	0	0	0	14,792,000	365,886	70,459,920	25,451,686	12,289,221	15,130,456	Produced	3,481,302
France	Produced	Produced	Produced	Produced	3,138,003	802,950,007	66,792,091	163,151,918	10,828,112	1,268,238	1,048,519
Germany	Produced	10,157,000	41,484,000	185,167,000	Produced	1,737,766,000	186,329,853	162,233,187	63,815,423	Produced	23,146,051
Greece	Produced	0	Produced	56,085,412	Produced	136,361,563	8,952,226	9,486,905	16,103,198	Produced	0
Hungary	0	0	0	0	Produced	333,855,000	17,776,000	29,167,000	5,292,000	496,000	Produced
Ireland	Produced	Produced	0	0	0	100,712,245	Produced	Produced	Produced	Produced	0
Italy	5,753,000	0	17,763,000	123,411,000	90,216,000	997,543,000	178,767,000	119,976,000	42,442,000	32,546,131	23,838,571
Latvia	0	0	0	Produced	Produced	5,734,928	Produced	Produced	Produced	0	0
Lituania	0	0	0	0	0	3,796,820	2,333,666	4,901,000	1,310	755,430	191,944
Luxemburg	0	0	0	0	0	0	0	0	0	0	0
Malta	0	0	0	0	0	0	0	0	0	0	0
Netherlands	0	Produced	Produced	Produced	Produced	233,670,000	12,583,000	110,045,000	49,479,000	Produced	Produced
Poland	0	Produced	22,861,000	6,678,236	3,530,685	203,777,000	107,401,000	137,089,000	32,050,000	2,414,000	2,517,000
Portugal	0	0	Produced	0	1,976,626	Produced	29,016,308	26,481,194	4,898,075	1,705,306	9,854,802
Romania	0	0	0	Produced	726,000	Produced	22,465,084	37,370,518	4,221,889	Produced	Produced
Slovakia	0	0	Produced	0	0	66,346,000	2,800,667	Produced	3,989,204	Produced	0
Slovenia	0	Produced	0	0	0	Produced	Produced	3,377,425	Produced	Produced	Produced
Spain	0	4,044,000	25,000	16,314,000	2,001,000	Produced	121,374,000	163,401,000	40,637,000	9,741,732	8,942,826
Sweden	0	0	Produced	Produced	3,737,100	456,431,000	44,282,900	22,348,600	7,036,500	0	2,299,200
United King	Produced	1,854,445	Produced	Produced	Produced	597,909,470	112,101,000	Produced	99,302,797	Produced	Produced
EU28TOTAL	10,000,476	71,978,696	91,122,641	468123601	148,563,605	7,108,873,872	1,128,115,513	1,253,152,379	437,620,437	240,000,000	88,205,984

Import and Export

Tables 3.3 and 3.4 show analysis of the Eurostat data for export and import of respectively for the selected product categories. This is split into total intra-EU and extra-EU exports and imports and shows which of the EU 28 are the main exporters and importers. The intra-EU trade for these products involves all EU28 and even the smaller MSs that do not produce these product types engage in import and export (Figure 3.3, although the qualities involved can be small. (fuller details are provided in the Technical Report). However, and not surprisingly, the data shows trade dominated by the larger MSs

The proportion of EU production that is exported varies between the product categories shown, with export representing a relatively small proportion of production for some (plastic pipe and taps, 15-30%), but much higher (60 - >100%) for the other categories (Table 3.3) and these also have correspondingly high imports (Table 3.4). Overall, Tables 3.3.and 3.4 highlight the largest exporters, across the range of product groups as Italy, Germany, Poland, Spain and the UK, and the largest importers as Germany, France, UK and Poland. Other MSs rank highly for certain products, which indicates that for certain sectors they have particular manufacturing or trading strengths.

Table 3.3 Total exports by weight (kg) and value (€) of selected product categories by the EU28 MS and the proportion exported by the main exporting MSs. Note: the Eurostat data cover all industry sectors not just products in contact with drinking water, though this will be a significant proportion.

Category	Total EU28 Exports		Intra-EU export		Exports outside EU		Major Exporters listed by % of the total EU 28 exports by weight that they export.
	Weight and value	As % of EU prod-uction by weight	Weight and value	As % of EU exports by weight	Weight and value	As % of EU export by weight	
PVC Pipe	276M kg €488M	22%	221M kg €361M	80%	55M kg €127	20%	All MS exported except Cyprus: Italy 22.3%, Netherlands 15.8%, Germany 11.7%, Spain 10%, Poland 9.1%.
PE Pipe	332M kg €886M	29%	252M kg €616M	76%	80 M kg €270	24%	All MS exported except Malta: Germany 26.5%, Italy 21.6%, Poland 6.7%, Spain 4.2, Sweden 4.2 and UK 4.2%.
Plastic pipe fittings	265M kg €2,261M	62%	175M kg €1385M	66%	90 M kg € 876M	34%	All MS exported: Germany 31.5%, Italy 15.5%, UK 8.5%, Poland 7.5%, Netherlands 5.6%. All MS exported
Copper pipe	294M kg € 2,044	63%	231 M kg €1590M	79%	63 M kg €454M	21%	All MS exported copper pipe except Cyprus. Germany 34.9, Greece 18.6%, Italy 15.8%, Austria 6.9%, UK 5.1%.
Copper and alloy fittings	116M kg €1,790M	78%	84M kg €1,262M	73%	32M kg €528M	27%	All MS exported: Italy 33.2%, Germany 25.4%, Poland 9.7%, Spain 5.9%, UK 5.3%.
Tube or pipe fittings of cast steel	35M kg €314M	-	22Mkg €198	64% of	13M kg, €116M	36%	All MS exported except Cyprus and Malta. Italy 27.7%, Belgium 16.3%, Germany 8.9%, UK 9.7%, Poland 7.0%.
Tube or pipe fittings of malleable cast iron	81M kg €306M	113%	62M kg €229	76%	19M kg, €77M	24%	All MS exported: Poland 21.3%, followed by Germany (20.2% by weight, 21.8% by value), Austria (17.7% by weight and 26.9% by value), Bulgaria (11.1% and 7.1%) and Spain (8.2% and 7.0%).
Taps, cocks and valves	36M kg €636M	15%	17M kg. €338	48%	19M kg €298M	52%	All MS exported: Italy 29.2%, Germany 22.7%, Spain 13.3%, Slovenia 4.0%, Czech Republic 3.4%.
Mixing valves	116M kg €2358M	131%	79M kg €1538	68%	37M kg €819M	32%	All MS exported: Germany 32.5%, Italy 23.4%, Portugal 10.2%, Spain 5.4% and Bulgaria 5.4%.

Export is dominated by trade within the EU 28, with extra-EU exports comprising between and quarter to a third of total export in almost all cases (Table 3.3). Imports are also dominated by intra-EU trade (Table 3.4), with the exception of mixing valves, where just over half of imports are from outside the EU. The recent economic downturn and the need to reduce production costs led EU companies to seek cheaper manufacturing options outside the EU, for complete products or components. As a result China, in particular, has emerged as the major source for plumbing products from outside the EU.

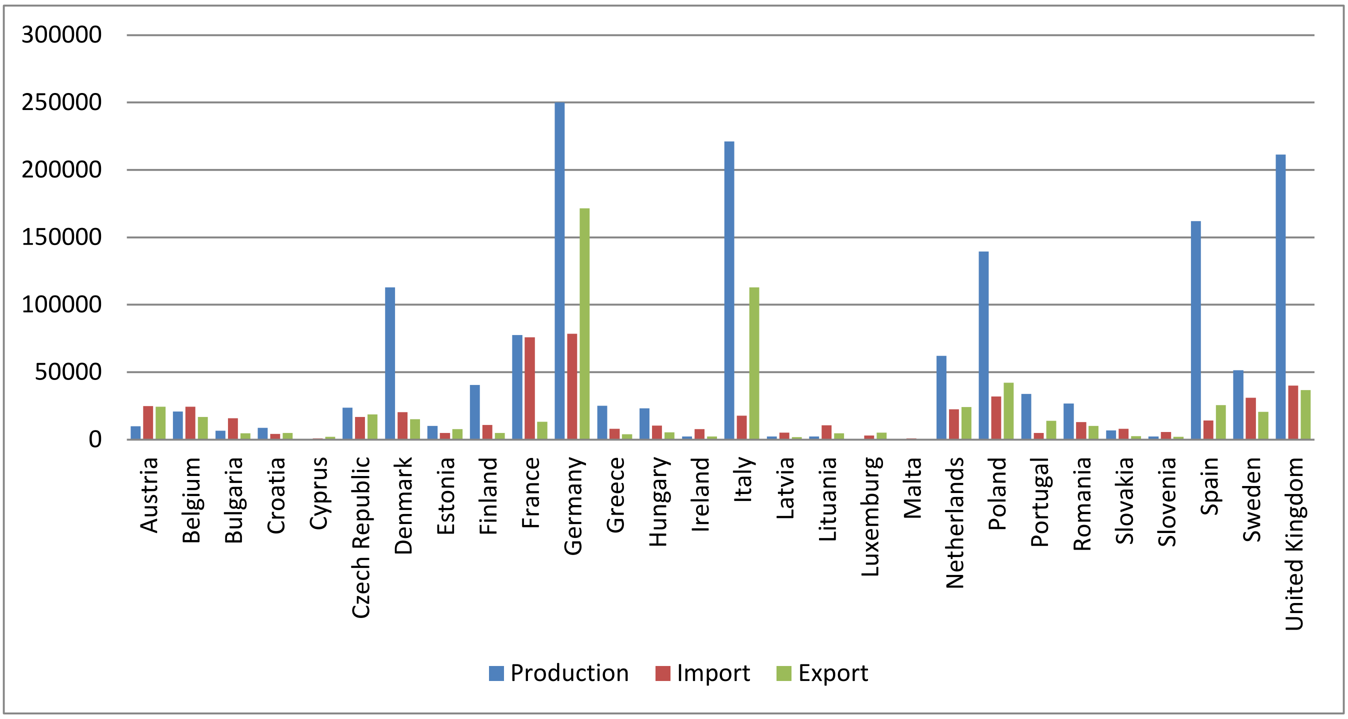
Companies from some 44 non-EU countries directly hold approvals in the major approval schemes operated by MSs and many companies from within the EU source products or components from outside the EU.

Table 3.4 Total imports by weight (kg) and value (€) of selected product categories by the EU28 MS and the proportion imports by the main importing MSs.

Category	Total EU28 Imports		Imports Intra EU		Imports from outside EU		Major Importers listed by % of the total EU 28 imports by weight that they import.
	Weight and value	As % of EU sales by weight	Weight and value	As % of EU imports by weight	Weight and value	As % of EU imports by weight	
PVC Pipe	211M kg €389m	23%	198M kg €359	94%	13M kg €30M	6%	All MS imported: France 35.8%, Belgium 9.9% Germany 8.5%, UK 6.8%' Czech Republic 4.5%
PE	257M kg €622M	24%	235M kg €563M	91%	22M kg €59M	9%	All MS imported: France 18.1%, Germany 11.7%, UK 9.5%, Poland 5.8%, Austria 5.0%.
Plastic fittings for pipe	255M kg €1959M	60%	209M kg €1503M	82%	45M kg €456M	18%	All MS imported: Germany 19.1%, France 11.5%, Sweden 7.3%, Poland 6.7%, UK 6.1%.
Copper tubes	276M kg €1,779M	63%	243M kg €1,533M	88% by weight	32M kg €246M	12%	All MS imported: Italy 15.4%, UK 12.5%, Germany 12%, France 11.2%, UK 12.5%, Poland 6.2%.
Copper and alloy fittings	132M kg €1,597M	84%	92M kg €1,203M	70%	40M kg €394M	30%	All MS imported: Germany 18.7%, France 13.9%, Poland 10.6, UK 8.4%, Belgium 6.2%.
Tube or pipe fittings of cast steel	46M kg 255M€	-	33M kg €202M	72%	13M kg €53 million	28%	All MS imported: Spain 12.9%, Belgium 11.5%, Germany 10.3%, UK 9.6%, Netherlands 8.6%.
Tube or pipe fittings of malleable cast iron	112M kg €316	108%	61M kg €211M	55%	51M kg €105M	45%	All MS imported: Germany 18.5%, Italy 9.8%, Poland 8.9, Spain 8.8%, Belgium 8.3%.
Taps, cocks and valves	54M kg €666M	22%	30M kg €423M	56%	24M kg €243M	44%	All MS imported: UK 20.4%, Germany 12.7%, France 10.5, Spain 9.5%, Italy 7.3%.
Mixing valves	147M kg €2,123M	117%	737M kg €1,357M	50%	74M kg €766M	50%	All MS imported: Germany 27.2%, France 17.9%, UK 8.9, Poland 5.1%, Italy 5.0%.

Production, import and export of two of these product categories, for which near complete data are available, PE plastic pipes and plastic pipe, are illustrated in Figure 3.3. This shows the substantial differences in production and trade between MSs and shows all engage in import and export of these products. Exports are clearly dominated by two MSs, Germany and Italy, which between them account for 47%. Between them they also account for 18% of imports.

Figure 3.3 Quantity (tonnes) of production, import and export by MS of rigid tubes, pipes and hoses of polymers of ethylene and of plastic fittings for plastic tubes, pipes and hoses (including joints, elbows and flanges), 2014



In order to gain a clearer understanding of intra-EU trade flows, data for each of the EU 28 MS would need to be obtained individually but again undertaking this level of analysis was not feasible within the resources of this project. Therefore a case study of UK trade in plastic fittings for plastic tubes and pipes using national trade data is presented as an illustration. The UK is one of the three largest producers and exporter by quantity of these products. The UK's exports of these products go to every MS, which includes those MS with approval schemes that do not. Table 3.5 highlights export levels to four MSs that operate approval schemes and four that do not. The largest export market for UK plastic fittings is Ireland; its close neighbour and trading partner, which does not operate an approval scheme. However, Italy is also a significant market. Therefore, there are a range of factors, such as geographical location, historic trade ties and market size, as well as hygienic testing requirements, which influence the level of exports between MSs.

Table 3.5 UK exports of plastic fittings to other MSs

Plastic fittings for plastic tubes/pipes/hoses				
	UK export destination	Value in millions of euros (2014)	Proportion of country imports of plastic fittings for plastic tubes	Proportion of country production of plastic fittings for plastic tubes
Countries requiring testing	Italy	6.429	5.84%	2.30%
	Netherlands	4.597	5.29%	3.20%
	France	4.221	2.24%	7.09%
	Denmark	1.168	2.18%	1.98%
Countries not requiring testing	Ireland	9.669	45.20%	-
	Malta	0.585	21.20%	-
	Lithuania	0.447	1.93%	-
	Cyprus	0.276	8.50%	-

An analysis of imports of these fittings (Table 3.6) shows the level of imports to the UK and the proportion of total plastic fittings imports originating from the various MSs. Imports to the UK are dominated by Germany, followed by the Netherlands and France. Other MSs have much lower levels of imports and 32% of UK imports of plastic fittings originate from outside of the EU. This could be due to materials test data being more readily available for UK WRAS accreditation from the MSs already undertaking testing, although it may also reflect the manufacturing capacity within the different MSs.

Table 3.6 UK imports of plastic fittings from other MSs

Plastic fittings for plastic tubes/pipes/hoses			
	UK import source	Value in millions of euros (2014)	Proportion of UK imports of plastic fittings for plastic tubes
Countries requiring testing	Germany	24.466	27.00%
	Netherlands	10.464	11.55%
	France	7.988	8.82%
	Italy	4.01	4.43%
Countries not requiring testing	Ireland	3.221	3.56%
	Lithuania	0.033	0.04%
	Greece	0.002	0.00%
	Latvia	0	0.00%

This analysis highlights the complexity of determining from production/import/export data whether the existing un-harmonised approach is adversely impacting intra-EA trade in materials in contact with drinking water. A more detailed modelling approach might be able to disentangle the various factors influencing imports and exports for different products, but this is by no means certain. A further approach could be to compare the overall level of trade in such products with other products traded within the EU that have a harmonised approach to testing or acceptance, though such an analysis is beyond the scope of this current study. In conclusion, other approaches to identifying the impact of the current situation on intra-EU are required. This includes collecting views from relevant industry stakeholders on their experiences of exporting (or attempting to export) products to other MSs.

Companies engaging with approval schemes

Further insight into intra-EU trade activity and import to the EU from the rest of the world is provided by analysis of the countries of origin of companies that hold approvals with national approval schemes. Table 3.7 summarises the countries where they are based and the numbers companies holding approvals operated by France (ACS), Germany (DVGW), the Netherlands (KTW), UK (WRAS Material Approval, WRAS Product Approval and DWI Regulation 31), Belgium (Hydrocheck) and Denmark. This shows the numbers of approvals held by companies from different EU countries and the rest of the world. Companies based in 24 of the EU28 MSs hold one or more of these approvals in one or more of these schemes (the exceptions being Croatia, Latvia, Lithuania and Romania). Companies from are held by companies from 24 of the EU28 and, as already mentioned, a further 44 non-EU countries hold approvals in in the rest of the world (fuller details are provided in the Technical Report)). Care has to be taken when interpreting the data in Table 3.7 since a number of factors account for differences in the take-up of approvals in the schemes, such as their administrative requirements, complexity, language and trading arrangements. Among the top five exporting MSs identified from the Eurostat data, companies from Italy and Germany appear particularly active in dealing directly with approval schemes in other MSs, whilst companies from the other three, Poland, Spain and UK, hold relatively few, possibly because their exports to other MSs are handled by local companies, or because of a willingness to market products without seeking approvals.

Table 3.7 Summary of numbers of companies holding approvals (Com) and total number of approvals held (App), where available, from each of the EU28 MSs in the approval schemes of France, Germany, the Netherlands, UK, Belgium and Denmark. Summary data for other EU countries and the rest of the world are included.

EU28	France		UK		UK		UK		Netherlands		Germany		Belgium		Denmark		All
	ACS Accessories		WRAS Material A		WRAS Product Ap		DWI Regulation 31		KTW		dvgw		Hydrocheck				total
	Com	App	Com	App	Com	App	Com	App	Com	App	Com	App	Com	App	Com	App	Com
Austria	4	10	6	25	3	3			4		19		4				40
Belgium	12	35	16	29	6	8	1		7		19*		43		1	2	105
Bulgaria	1	5			3	6											4
Cyprus			1	4					1								2
Czech Rep	1	1	3	6	4	10	1										9
Denmark	7	63	9	38	19	136	1		1		16**		3		39	112	95
Estonia			1	2													1
Finland			2	2	1	2	1				**						4+
France	267	1312	27	68	34	109	6		5		16		16		2	3	373
Germany	64	508	131	300	78	649	7		48		353		17		1	4	699
Greece	2	2	9	24	2	2			2								15
Hungary	1	2	1	1	4	16	1										7
Ireland			11	19	7	10	2		2				2				24
Italy	185	670	92	249	178	604	4		26		127		4		2	2	618
Luxembourg	3	11			1	1					*						4+
Malta					1	1											1
Netherlands	13	23	29	68	22	46	7		54		*		13		1	1	139+
Poland			7	11	8	9			2								17
Portugal	8	19	1	1	9	21			2								20
Romania																	0
Slovakia					3	4											3
Slovenia	1	5	2	7	3	3											6
Spain	40	121	28	42	26	72	2		2						2	2	100
Sweden	2	2	5	8	24	70			1		**						32+
UK	8	19	261	692	612	3303	145		14		15		3				1058
Total EU	619	2808	642	1596	1048	5085	178	-	171	-	614	-	105	-	48	126	3425
Other Europe	32	333	47	95	35	76	4		4		50		3		4	4	129
Rest of World	395	1128	472	824	395	1562	18		35		72		10		1	1	1330
World Total	1046	4269	1161	2515	1478	6723	200	400	210	550	736	2421	118		53	131	4884

*19 approvals from Benelux (Belgium, Netherlands and Luxembourg, **16 includes approvals from 'Scandinavia'

Regarding imports to the EU, for the French ACS scheme and the UK WRAS Material Approval and WRAS Product Approval roughly 30-44% of companies holding approvals are from non-EU28 countries. However, for the other five schemes, including UK Regulation 31, less than only 9-18% are from non-EU28 countries indicating that the former either have approval schemes that are easier for non-EU based companies to engage with directly or have stronger trade links outside the EU, possibly because of weaker domestic production. However, in the case of Regulation 31, which is approval for use in the public water supply (not buildings) in the UK, the materials requirements are more complex than for the WRAS Approvals. The fact that 75% of the holders of Regulation 31 approval are UK based, compared with around 25% UK based companies holding the WRAS Approvals, suggests that either UK based companies are better able to serve the public water supply customer or that they are better placed to engage with the scheme.

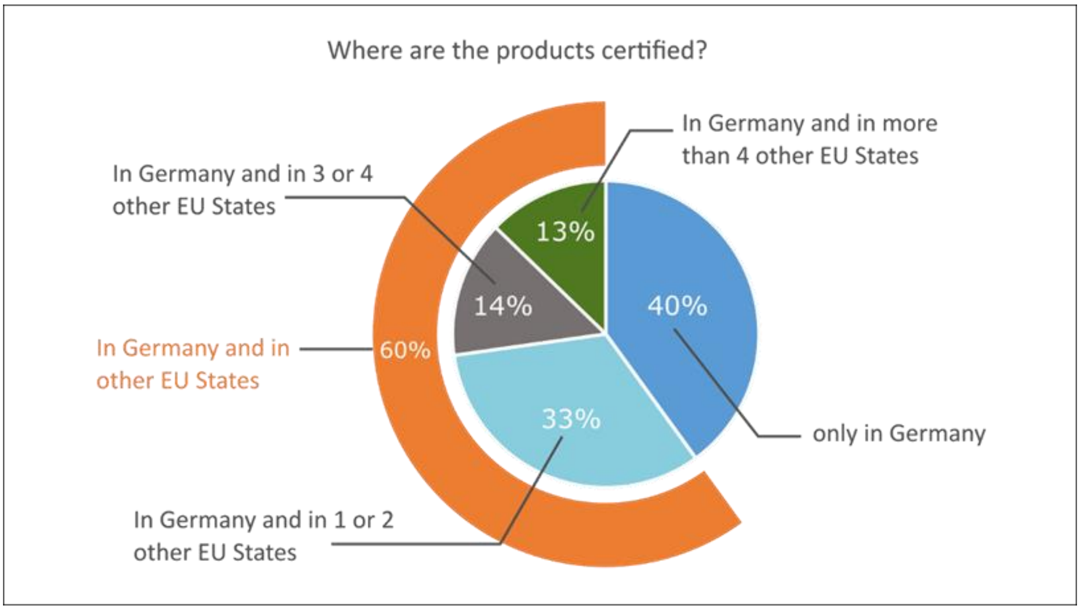
Indications from the UK Water Regulations Advisory Scheme (WRAS scheme[17]), the largest in terms of number of companies holding materials and product approvals, are that numbers of products submitted annually for approval are increasing.

[17] www.wras.co.uk/downloads/public_area/publications/annual_reports/annual_report_2014-15_final_10.11.15.pdf/

Export behaviour of companies

A final insight into Intra-EU trade has been provided through a study undertaken by figawa of its members among German manufacturers. The study asked companies what proportion of their products were sold only in Germany and how many were sold in other MSs (Figure 3.3). The companies surveyed covered production of five main product groups: safety and protection valves; water treatment; taps; pipes and fittings; tanks and pumps, for drinking water contact, all of which are covered by national approvals schemes. The findings show that 40% of products (study was by numbers of product types marketed not production/export volumes) were sold only in Germany, but these German producers export to at least 23 of the other 27 MSs (incurring costs for hygienic testing in 15 of these). However, 33% are exported to only one or two other MS and just 13% were sold in more than four other MSs. This suggests that only a small proportion of products from the EU's largest exporting MS are currently marketed pan-EU. The implication from the report is that national requirements and their costs for hygienic testing of materials and for mechanical testing of products act as burdens on industry and that export to other MS would be higher otherwise.

Figure 3.4 Estimates of the proportions of products in contact with drinking water produced in Germany that are sold exclusively into the German market and those also sold into one or more other MSs. Source Figawa[18]



Conclusions on intra-EU trade

The conclusions that we draw concerning intra-EU trade in materials and products in contact with drinking water are that it covers all the EU28 and even the smaller MSs that do not produce products engaged in both import and export. Export as a proportion production varies from 15% to >100% of total EU28 production across different product categories. The majority of EU production is exported intra-EU, with a quarter to a third to countries outside the EU (for the product categories examined), Imports which range from 22% to >100% of sales for different product categories are also dominated by intra-EU trade. Imports from outside the EU range from 6% to 50% for the different product categories examined, the highest being mixing valves, where just over half of imports are from outside the EU. The largest exporters are Italy, Germany, Poland, Spain and the UK; and the largest importers are Germany, France, UK and Poland, though other MSs are dominant for some product categories. However, the figawa study of German exports found that companies are selective about which markets they operate in and although 60% of products included in the study were exported half of

[18] As above footnote 15

these were to one or two other countries and only 13% of products were exported to more than four other MSs.

Further confirmation of the scale of trade was provided by analysis of companies engaged with national approval schemes showing that companies from 24 of the EU28 MSs hold approvals for other countries and that 44 non-EU countries hold approvals with the MSs schemes that were examined. Italian and German companies were highlighted as being particularly active in engaging directly with approvals schemes in other MSs.

3.3 Barriers to trade

3.3.1 Introduction

This Section examines the extent to which national regulations and approvals create barriers to intra-EU trade and to innovation, and the application of EU rules on mutual recognition applying to non-harmonised products.

The issues concerning the non-harmonisation of materials/products in contact with drinking water and the application of Article 10 by MSs that this concerns have been previously described. The separate national approaches to the regulation of materials in contact with drinking water used by MSs in relation to the application of Article 10 have evolved over several decades, pre-dating DWD in several cases. Where these involve the use of national testing requirements, voluntary or compulsory approval schemes have been developed to assist with demonstrating compliance. Competent authorities in those MSs regard the schemes as being part of their holistic approaches to water safety planning in preventing migration of unwanted substances and growth of unwanted micro-organisms from materials. For the Competent Authority and its Notified Bodies they set out a means of assessing material safety, for manufacturers and suppliers they are intended to be a convenient means of demonstrating compliance with national requirements and for end users they provide re-assurance of the safety of their purchases.

In the course of examining whether these present barriers to trade, it became apparent that there are two separate, though related issues to consider,

a) 'Barriers to trade' were an MS does not accept a substance/material because it does not comply with its own requirements, although it is accepted by another/other MSs.

b) 'burdens on industry' generated by companies complying with different national requirements such as additional costs, delays to market and competition with un-approved materials/products that can deter entry to national markets.

These are addressed separately below.

3.3.2 Methodology

The issue was addressed by: examining published information, in particular the findings of studies undertaken by the Dutch Ministry of Infrastructure and Environment[19] and Figawa[20]; communication with regulators, trade associations and companies; and issuing requests for case studies. Information was provided by several industry trade associations: (PlasticsEurope/FCA, CEIR, Europump, TEEPFA, EDW, EHI and the European Sealing Association), mainly in the form of position statements reflecting their members' collective experience. A relatively small number of individual case studies were provided, despite the various requests issued to trade associations and companies, which we

[19] Economic Effects of article 10 of the Drinking Water Directive. Report to Dutch Ministry of Infrastructure and the Environment. Panteia, 2016

[20] Effects of Article 10 of the EU Drinking Water Directive on test and certification costs for products in contact with drinking water. Figawa, 2016

believe was mainly due to companies being reluctant to make public what they consider to be commercially sensitive information.

3.3.3 Barriers to trade

Barriers to trade relating to Article 10 arise when a substance or material is submitted to the competent authorities/notified bodies of more than one MS for hygienic evaluation and testing against respective national requirements and fails to meet the requirements of one MS whilst being accepted as safe to use by at least one other. Illustrative Case Studies (A-D) are shown in boxes. The reasons for such failures include: a test failure against established pass/fail criteria, a decision by an expert group, or a substance not featuring in a national Positive List when it is accepted by another (Case study A). Cases also occur where a MS changes its requirements making a previously approved substance or material no-longer acceptable, whilst it remains compliant in other MSs (e.g. Case Study D).

Case Study A, experience of by PlasticsEurope member company concerning positive lists

A given substance used as desensitizing agent of organic peroxides is listed in the Warenwet (Netherlands) and several chapters of BfR (Germany), but not in the French positive list of substances authorized for the manufacture of drinking water materials. Consequently, polymers and articles containing this substance were not approved in France. Industry was required to run migration test studies in order to demonstrate that the migration into water is below 0.5µg/l. After four years of work and discussion with the French authorities a derogation was obtained recently with the obligation to verify that the migration is below <0.1µg/l. The applicant submitted then a risk assessment to the French Health Ministry (Direction Générale de la Santé), who after its evaluation requested industry to carry out a new in-vitro test. The new requested tests were carried out and ANSES published an opinion confirming the safety of that substance in the intended drinking water applications. Currently industry is still awaiting the modification of the French law. The entire process lasted 6 years and during that period materials containing that substance were put on the market on other EU countries without further objections.

Case Study B – provided by EHI concerning stainless steel

Even if a material is approved in one Member State, another Member State may not accept it, or require additional test studies and risk assessments to demonstrate compliance with local regulation or the DWD article 10. For example, corrosion resistant stainless steel grades are accepted in some countries (France, the Netherlands, the UK) but are not accepted in others (such as Italy). Manufacturers have to create variants made of low grade stainless steel or cast iron for stainless steel materials to be approved.

Case Study C – provided by CEIR concerning flexible hoses

CEIR commented that differences in the schemes are, commonly, forcing manufacturers to create multiple versions of the same product, for different national markets. This is typically the case for polymers and rubber materials with CEIR members stating that it is ‘almost impossible’ to use an inlet flexible hose for a tap that will pass France’s ACS, UK’S WRAS and Germany’s KTW testing requirements.

Case Study D, experience of by PlasticsEurope member company concerning a new test

The introduction of an additional specification by a Dutch certifying body, led a given product not passing the new criteria and losing its certification, which was obtained before the development of this additional test. This product remained authorized in other EU Member States. The tentative business damage was estimated at an order of magnitude of roughly millions of €s.

We were unable to establish the full extent of the numbers and types of material that have been affected impact of these barriers on trade. However, these case studies and other anecdotal information from stakeholders indicate that such barriers are encountered by many companies. Basically, any modification of product which is needed for placing it on the market of an EU member state presents a barrier for free trade. Quantitative statements like “business damage in the order of magnitude of millions of Euros (case study D)” or “four years of work and discussion (case study A)” let us conclude that these barriers are significant and can only be overcome by companies that can afford the costs and delays to market (affecting the principle of equality). The consequence of this risk of local non-compliance is that manufacturers and suppliers currently, reluctantly, seek to comply with the separate national requirements and approval schemes individually and in so doing incur financial and other burdens (see below), including the development of variants of some products for some specific national markets.

Recourse to legal challenge

In the course of this research no specific cases of companies using recourse to legal action to challenge hygienic compliance requirements by MSs were identified. In this respect the Fra.bo case (Section2.3.2), which related to mechanical performance compliance rather than hygienic issues, appears to be unique. Some companies do take issue with national approvals schemes on a case by case basis, without recourse to legal action, to argue that existing evidence they have should be accepted.

Some industry stakeholders commented that there is a reluctance to pursue a legal approach, due to concerns that such action could result in an overall lowering of the current high safety standards for materials/products of some MSs, which are recognised by industry as necessary to protect water quality and human health. In this respect we noted that the EDW’s draft proposal for a single EU-wide Scheme for Assessment of Plastic and Silicone Products, which is written by industry, includes strong provisions in its testing methods and attestation of conformity requirements for: initial type-testing of the product; initial inspection of factory and of factory production control (repeated biennially); continuous surveillance, assessment and approval of factory production control; and audit-testing of samples taken at the factory, on the market or on the construction site.

Burdens on industry

The current situation in which reputable companies engage with the Competent Authorities/Notified Bodies in their target national markets individually to demonstrate hygienic compliance generate burdens on industry in a complex manner that can affect companies’ investment and marketing decisions. These primarily concern the costs of obtaining separate approvals in different MSs and delays to market due to the time it takes to gain multiple approvals. These are summarised below.

Costs

With finite resources for new product development and an unproven sales potential in target markets the costs of demonstrating compliance with national requirements are a significant factor in the business decision concerning where to market a new product.

The costs comprise both external and internal costs:

- External
    - Payment of third parties for testing and approval which can include:
        - Application fee, pre-certification audit of manufacturing facilities, testing, assessment, certification/approval, periodic re-tests, periodic audits, renewals.
        - Companies find that they must undertake similar tests or repeat the same test for more than one MS where only locally approved test houses are accepted.
    - Sourcing appropriate materials and components that will comply for each market.

- Internal
    - Staff costs associated with obtaining and maintaining approvals,
        - Compilation of required evidence
        - Liaison with suppliers
        - Preparation of application
        - Provision of samples
        - Replacement of materials/components (if required)
        - On-going liaison with authorities
    - Modifying products to suit national requirements
        - manufacture/assembly of more than one version of the same product (if required)
    - Monitoring and reacting to changing national requirements.
        - Maintaining awareness of national regulations and approval requirements either internally or by commissioning outside assistance.

The costs of obtaining a national approval are the same for any size of company and thus the ability to absorb the cost as part of market entry will depend on available investment and may therefore favour larger companies.

Delay to market

When submitting a product for approval there is uncertainty over how long the process will take, which results in unplanned delay to market with consequential economic impact on the company and customers. Data submitted to Figawa by its members on time taken to gain approval in countries outside Germany show that the duration of the process lasts from a little as three months to up to two years. A common approach used is to apply for approval in the domestic market first and then follow this up with other national approvals in a staged process. Consequently, companies cannot launch locally compliant product simultaneously across the EU.

Loss of competitiveness

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 schemes and a perceived lack of market surveillance to ensure compliance with national requirements.

If compliance is not effectively enforced within an MS or if the requirements are not understood by customers then those suppliers that have invested in proving compliance suffer from competition from non-compliant product that may be cheaper or faster to market.

The lack of requirements for products in contact with drinking water in some MSs creates a competitive disadvantage for exporting companies against local suppliers, since it is not possible for them to reflect the cost of product tests and certification obtained elsewhere on prices in these countries.

Barriers to Innovation

Stakeholders commented that the cost and duration of approval of new materials/products can discourage companies from developing new concepts and bringing innovative solutions to the water cycle and building markets.

Materials vary in their properties and enterprises seek innovative materials to perform a particular task in a product based on their properties, such as strength, workability, durability and other aspects of mechanical performance. Companies reported finding their choice of materials can be limited if it contains substances that are not on Positive Lists, if the product is not already approved or if the supplier is unwilling to provide the necessary formulation/manufacturing information. With regard to sourcing materials from third parties, enterprises have to take the risk that the material will continue to be available to them for the duration of production. The cost of obtaining approvals and then maintaining them can prove uneconomic for a supplier particularly where small quantities are concerned. If they are not in a position to arrange for approval of a desired material they have to compromise by using approved materials with a less than desired performance.

3.3.4 Mutual recognition

The principle of mutual recognition set out in the Mutual Recognition Regulation (EC764/2008) applies, in theory, to products in contact with drinking water since these are currently un-harmonised. The regulation provides for a product in an un-harmonised sector that is lawfully sold in one MS being accepted by another even if it does not fully comply with the technical rules of the other country. Here again there are two separate but related issues to consider:

a) That mutual recognition applies to products if legally sold in one MS.

b) That mutual recognition of approval schemes between MSs is a separate issue, since under the Regulation a product need only comply with the requirements/scheme of one MS if required for its legal sale, to be legal in them all.

A recent review by the Commission of the application of the principle of mutual recognition (June 2015)[21] found significant barriers stemming from MSs' acceptance, application and knowledge of the principle, lack of trust between authorities, companies' lack of awareness of the principle and differences in MS's national standards and testing. It particularly identified non-harmonised construction products as a sector where action should be taken and used water taps as an example, citing lack of trust between authorities and requests for national testing.

With regard to mutual recognition of approval schemes, we did not find evidence of MSs with well-established schemes accepting equivalence of another MS's scheme. The focus is on seeking convergence of schemes, use of harmonised supporting standards as they are developed, development of common acceptance criteria and development of common Positive Lists as precursors to 'mutual recognition'. Although established schemes state that they will consider evidence and test results from other MSs and sources that can be demonstrated to be equivalent to their requirements, burden is on applicant to prove equivalence rather than the scheme provider to disprove it, which is usually outside the competence or resource of the applicant to do so.

There is an appearance of the application of principle where countries without approval schemes accept approval from another MS as evidence of the safety of substances and materials (e.g. of materials/products with UK WRAS Approval in Ireland and Latvia, Lithuania, Luxembourg, Croatia, and Romania cited as accepting DVGW approval for pipe systems in the figawa study). One company cited Danish Approval as a means of having its products accepted in other Nordic countries. However, these are cases of a one way recognition of a 'lawfully sold' product not mutual recognition.

The Commission's 2015 review of the principle of mutual recognition has made a series of recommendations for improving its application, each of which could be applied to this sector:

- Better monitoring of the implementation of the mutual recognition principle by Product Contact Points and Competent Authorities
- Setting up a mechanism for easier demonstration of "lawful marketing" for economic operators
- Ensuring better communication/dialogue between competent authorities by the Commission
- Harmonisation to limit use of technical rules by MSs
- Awareness raising campaigns by the Commission

The full application of the principle of mutual recognition to this sector would require that each MS has in place measures able to ensure that substances and materials lawfully sold in that country comply with Article 10, and that all MSs accepted that their markets were not exempted from applying the principle in this sector.

[21] http://ec.europa.eu/DocsRoom/documents/13381

4 DRINKING WATER CONTAMINATION

4.1 Introduction

Methodology

This section examines the extent to which inappropriate materials have been associated with adverse impacts on water quality and public health through chemical, organoleptic and microbiological contamination of drinking water. Information for this review was obtained from both published sources concerning water contamination caused or facilitated by materials and grey data contributed by regulators, laboratories and the water industry. A number of laboratories were contacted directly and a general call for information concerning laboratories experiences with test failures was issued at the 2016 Conference on Materials and Products in Contact with Drinking Water (Annex 1). Two French and one Dutch laboratory responded that they were unable to provide this information, whilst the WRAS Approvals scheme in the UK was able to provide data from exercises it has undertaken on pass/fail results from three UK test labs approved for testing materials against BS6920.

Historical context

During the last century it became established that organic, metallic and cementitious materials and products in contact with drinking water could adversely affect the quality of the water (Table 4.1) and this focused national regulators on the issue. One of the most widely publicised was the concern about levels of lead leaching from lead pipe and lead solder (used in welding water pipes), which led to a ban on the use of these in new installations since the 1970s.

Table 4.1 Historical examples of non-metallic materials and in-service water quality issues. Source WRAS.

Date	Material	Water quality issue(s)
1916	Leather tap washers	enhancement of microbial growth
1936	Coal tar coatings in ductile iron water mains	"naphthenic" off-flavours
1938	Residual organic solvents	development of visible thick slimes
1947	Joint sealants in storage tanks	fungi, including fruiting bodies at air/water interface and leakage due to bio deterioration of the seals
1947	Jute Yarn for seals	enhancement of microbial growth and bio deterioration
1955-6	Mineral oil lubricants for valves	enhancement of microbial growth
1957-8	Jointing compounds	enhancement of microbial growth
	Asphaltic linings	enhancement of microbial growth
1966	Flexible rubber hoses in hospital	enhancement of microbial growth, including growth of *Pseudomonas aeruginosa*
1974	"O" seal lubricants – soap based	enhancement of microbial growth
1977	Coal tar lining of pipes	off flavours and growth of *Pseudomonas aeruginosa*

In Table 4.2 details of more recent incidences of water quality deterioration in water distribution networks and building plumbing that were clearly attributable to the use of unsuitable materials caused by materials are shown, that were provided by the 4MS Joint Management Committee, WRAS and EurEau members.

Table 4.2 Examples of water quality issues observed in water distribution networks and building plumbing caused by materials, provided by 4MS Joint Management Committee, WRAS and EurEau members.

Product/material	Water quality issue(s)
Flexible hoses	Health symptoms (diarrhoea, distention), organoleptic problems (taste and odour). Very high TOC concentration in migration water, and organoleptic problems confirmed by testing.
Flexible hoses, shower heads	Microbial growth; risk of Legionella growth
EPDM rubber	Coliform bacteria growth on the rubber
Seams in a drinking water reservoir	Colonies of micro-organisms growing on the seams
Expansion vessel membrane	*Legionella*
Cellulose based products, e.g. hemp used to seal screw threads	Enhancement of microbial growth, including coliform organisms
Vegetable oils, e.g. linseed oil in screw thread sealants	Off-odours and flavours, enhancement of microbial growth, including coliform organisms
Industrial solvents, e.g. used in paints and coatings	Off-odours and flavours, bacterial slimes on water contact surfaces/fittings
Lubricant used for butterfly valves	Enhanced microbial growth, including coliforms
Lead pipes and lead based solders	Concentrations of lead above health based standards
Galvanized steel pipes	Leaching of lead from some types of galvanized steel pipes (from the Zn coating)
PE-tubes	Problems with odour and taste due to a changed (unreported) production process.
Brass fittings in new buildings	High concentrations of copper, zinc and some of lead caused by red brass connecting pieces between the PE tubes.
Brass taps	Leaching of metals (zinc, copper, lead, chromium)
Home water treatment units	The microbiological quality of treated water can be inadequate. After stagnation, the nitrite concentration can also increase. Leaching of silver from silvered activated carbon - the use of some products is not recommended for infants and young children (under 3 years).
Tap – organic component	Use of mixer tap for hot water caused off tastes as an O-ring was not fit for use with hot water.
Bitumen and coal tar lining of pipes	Leaching of Polycyclic aromatic hydrocarbons (PAHs), problems with odour and flavour
Epoxy lining applied *in-situ*	Leaching of bisphenol A. In this case leaching possibly due to poor operational practice on site (incorrect mixing of the two components), rather than problems with the product if correctly used.
PVC pipes installed before the 1980s	Vinyl Chloride Monomer migration into drinking water concerns.
Bitumen based products	PAHs leaching from bitumen based materials; also reported formation of anthraquinone and fluorenone (PAH oxidation by chlorine used for disinfection)
Asbestos cement pipes	Release of asbestos fibres
Cast iron	Rust development, leaching of metals and enhanced microbial growth, sedimentation.
Sealing rings in water meters	Organoleptic problems, leaching of styrene and benzothiazole
PE-pipes used in contaminated soil	Contamination of the drinking water by permeation of organic volatile substances through PE-pipes in contaminated soil.
Domestic tap flexible anti-splash device	musty off-odour & flavour, bacterial & fungal slimes
“O” seals used in shower heads, and water softener resins	enhancement of microbial growth - Legionnaires disease outbreak in a hospital

Table 4.2 cont.

Product/material	Water quality issue(s)
Water supply capillary tubes to dentist turbine drills	biofilm development also restricting water flow
Water pipes made of rubber	Increased growth of actinomycetes and microfungi
Plastic aerator on tap	Phenolic odour
Black plastic supply pipe	Pencil odour
Use of epoxy paint in a steel reservoir	Primer used that was not specified in the installation manual contained solvents.
Nonylphenol and epoxy paints	Leaching of bisphenol A
clamp saddles with leather seals	Recent use to create a branch connection on a distribution pipe - bacteriological problems (coliform contamination):
Coating on a drinking water reservoir	bacteriological problems (coliform contamination)

The presence of chemical contamination within the water supply that does not give rise to an organoleptic effect is much more difficult to identify by consumers. When investigations of water quality are undertaken it is not always possible to identify all compounds, or compounds are identified that are yet to undergo toxicological evaluation and for which potential risks are not yet understood. Regulatory checks on consumer supplies tend to be relatively limited in number and would not normally involve GC-MS analysis unless there is reason to believe contamination has given rise to severe or obvious health effects. Therefore, regulators find that it is not practicable to monitor at consumers taps for all substances that potentially leach into drinking water from materials and focus on preventing use. As a consequence they highlight that many of the most obvious examples of failures are historic where a particular issue has come to light. Consequently, regulators tend to take the precautionary approach that the risks to water quality and human health from materials are best managed by preventing potentially dangerous substances being used in products in the first place.

4.2 Organoleptic contamination

Whilst the organoleptic impacts (taste, odour and appearance) are not usually harmful, they are the most likely impact on water quality to be noticed. Most consumers are able to detect low concentrations substances causing undesirable taste and odour in water and this can affect the perception of the wholesomeness of drinking water and prompt consumer complaints to their water supplier.

Taste, odour and color are indicator parameters used in the DWD (Annex 1, Part C where in each case the parametric value set as ‘acceptable to consumers and no abnormal change) and consequently, if non-compliance is detected in drinking water the Member State concerned must consider whether that non-compliance poses any risk to human health and if so take remedial action. However, regulators and the water industry consider it is essential that drinking water supplies are aesthetically acceptable to consumers so that confidence in them is not undermined and consequently take the issue of aesthetic impacts from substances and materials seriously even when they do not pose a risk to health.

A wide range of materials are associated with tastes and odours (Table 4.3). Tastes and odours arise for several reasons; the substances or contaminants in a formulation, as a consequence of the method of processing/manufacture, post-manufacture contamination (e.g. in storage or transit). In 2016, the Umweltbundesamt (UBA), environmental protection agency in Germany, conducted a survey on 36 pipes used in internal plumbing systems on the German market. The UBA also conducted odour and flavour analysis on the pipes in accordance with EN 1420 to determine Threshold Odour Number (TON) and Threshold Flavour Number (TFN) and found that, although certified, many of the pipes did not meet the German requirements for TON.

Microbial growth, encouraged by the release of organic compounds from materials, results in earthy and/or musty taste and odour problems with the consequences described above.

Table 4.3 Examples of specific materials associated with odours and flavours detected during BS6920 testing.

Material	Reported odour/flavour
Acetal	formalin (usually hot water tests only)
ABS plastic	stewed vegetables/celery
Coatings	solvent, styrene, cardboard
Glass Reinforced Plastic	Styrene
Nylon (polyamide)	plastics &/or burning plastics
Phenolic resins (thermosets)	chlorophenolic (in chlorinated water).
Polycarbonate	burning plastic
Polyethylene	waxy, lead pencil
Polyethylene – cross-linked	fruity, lemon
Polyphenylene oxide	musty
Polypropylene	waxy, lead pencil
Polyurethane	plastic, cardboard, chlorophenolic
PVC	plastic (PVC-U), chlorophenolic (PVC-P)
Silicone rubber	chlorophenolic (hot chlorinated water).
Other thermosetting rubbers – sulphur cured	bitter, astringent, rubber, burnt, lead pencil
Other thermosetting rubbers – peroxide cured	almonds, chlorophenolic

4.2.1 Chemical contamination

Leaching of organics

Organic materials are often made from complex mixtures of ingredients and these ingredients and their transformation or degradation products have potential to leach at trace levels into the water supply. Examples are shown in Table 4.4. The DWD includes a small number of organic materials in the chemical parameters (DWD Annex 1) for which parametric values in drinking water are set, and three: PVC, Acrylamide and Epichlorohydrin for which control via product specification is required (DWD Annex III).

As mentioned, toxicological data is not, yet, available for all substances so the risk potentially posed is unknown, and if there are concerns arising from testing of a material the precautionary approach used by regulators is to restrict their use until such time as toxicological data will be available. For example, to limit the concentration in drinking water of a substance detected in leaching tests, minimum sizes for pipe/fittings made from a particular material may be specified. This is consistent with the Directive’s requirement to ensure water is free from substances at concentrations that may be a potential danger to human health.

Table 4.4 Examples of organic compounds reported to potentially leach from plastic products and materials

Organic compound	Product/material responsible	Cause of leaching	Reference
N-nitrosodimethylamine (NDMA)	Rubber seals	Reaction with chlorine or chloramine in the water supply	WHO, 2014
Vinyl chloride, a	Polyvinyl chloride (PVC) pipes (monomers)	Leaching from pipes	WHO, 2014; Walter *et al*., 2011
Phthalates	PVC pipes (impart flexibility)	Leaching from pipes	Fatoki and Vernon, 1990
Dialkyltins	PVC pipes (stabilisers)	Leaching from pipes	WHO, 2004; Gachter and Muller, 1985

In the German UBA's 2016 survey on 36 pipes used in internal plumbing systems migration tests and GC/MS analysis were conducted in accordance with EN 12873-1 and EN 15768 and found that many of the pipes leached appreciable amounts of organic compounds during testing. Some of these compounds could not be identified, the other compounds released were neither regulated in council directive 98/83/EC nor had they been evaluated for their toxicological effect. The UBA speculates that where these failures (and taste and odour failures) occurred the products submitted for initial type testing did not correspond to the products on the market. It concluded that this confirmed that audit testing would be essential to ensure conformity.

Leaching of metals

Metals can leach from metallic materials and materials that are primarily non-metallic (organic and cementitious) but incorporate small quantities of metal in their compositions (Table 4.5). The 4MS regulators note that metals potentially leach from almost any type of material, for example PVC pipes containing lead stabilisers. The DWD sets parametric values for eight metallic chemical parameters (Antimony, Arsenic, Chromium, Cadmium, Copper, Lead, Nickel and Selenium) and three indicator parameters (Aluminum, Iron and Manganese).

The risks from lead pipe and lead based solder have long been recognised and have resulted in the banning of the use of such products and strategies for dealing with their legacy in water distribution systems. Metals also leach from a range of other materials including brasses, galvanized steel pipe and sealants. Issues have also been noted with silver leaching from some types of water treatment media and a case of aluminum from cement-mortar linings that affected dialysis patients[22].

Table 4.5 Metal release associated with materials material types tested for BS 6920-2.6 extraction of metals from non-metallic materials.

Product type	Metal(s) released
Cementitious	aluminium, barium, iron, manganese
Chromium plated plastic taps/shower heads	nickel
Paints, coatings and sealants	lead
Unplasticised PVC (PVC-U)	lead

[22] Berend, K. and Trouwborst, T. (1999). Cement-mortar pipes as a source of aluminum. J Am Water Works Assoc. 99(7):91–100.

4.3 Microbial risks

Various compounds used in the manufacture of non-metallic materials will act as a source of nutrients to encourage the growth of microorganisms if released into drinking water. Whilst most of the organisms capable of responding to these influences are harmless[23] concerns exist over the proliferation of Legionella, Pseudomonas (particularly P. aeruginosa), and more recently Mycobacteria and various fungi. These organisms are typically considered as opportunistic pathogens and tend to cause infection in individuals with underlying illness or weakened immune systems. The risks posed by these organisms are known to be greater in plumbing installations than in the supply mains to buildings[24].

The rate and extent of microbial growth is influenced by several other factors and these may exert a greater effect on water quality than material composition. Depending on its origin, drinking water will contain appreciable quantities of nutrients which will support microbial growth. The relationship between drinking water and materials as sources of nutrients and their corresponding impact on drinking water quality was investigated in studies by Van der Kooij et al. (2003)[25]. Their work led to the development of the unified biofilm approach as a means of managing biological stability in the distribution system.

Another factor of significance is the presence of a residual disinfectant. Certain supplies of drinking water contain a residual disinfectant to limit microbial growth. The residual is not stable and consequently may undergo decay during transit and no longer provide a preservative action over the entire duration of water in supply. Equally, if drinking water contains significant amounts of nutrients this will promote microbial growth, particularly where it has been obtained from a surface water source. In contrast to finite leaching of organic compounds from a material, nutrient rich drinking water will provide a continuous supply of nutrients to sustain microbial activity. Therefore, the same material would exert a greater response in nutrient poor compared with a nutrient rich drinking water.

Table 4.6 Summary of performance of material categories in the BS 6920-2.4 enhancement of microbial growth test from three designated UK laboratories during 2011, showing number of samples tested and pass rate (%).

Material type	Number tested	% Pass rate
Thermoplastic materials		
Plastics	243	94
Rubbers	10	30
Thermosetting materials		
Plastics	87	90
Rubbers (not Si or fluorocarbon)	208	55
Silicone + Fluorocarbon Rubbers	34	100
Factory applied coatings	39	90
Site applied coatings	22	82

Regardless of material composition and the potential for leaching of substances to promote microbial growth, all surfaces are susceptible to biofilm development. This process will be influenced by the same factors influencing microbial growth in the bulk water. An additional factor, however, is their

[23] WHO (2003) Heterotrophic plate counts and drinking-water safety: The significance of HPCs for water quality and the human health. Edited by J. Bartram, J. Cotruvo, M.Exner, C. Fricker, A. Glasmacher. Published on behalf of WHO by IWA Publishing. ISBN: 92 4 156226 9

[24] Pitchers R (2013) Implications of Microbial Colonisation of Water in Buildings. UKWIR Report 13/DW/02/67. ISBN:- 1 84057 663 4.

[25] Van der Kooij D, Vrouwenvelder JS and Veenendaal HR (2003) Elucidation and control of biofilm formation processes in water treatment and distribution using the unified biofilm approach. Water Science & Technology 47(5) pp.83-90.

surface properties. It is well known that rougher surfaces encourage more extensive biofilm development than smooth surface. [26]. Such an effect has been observed, for example, in flexible pipe connectors where it has been proposed that they have been responsible for a number of Legionella infections in hospitals. Current tests do not take this effect into account when assessing the suitability of a material for use in plumbing systems.

Example of legionella failure associated with rubber washers[27]

During the investigation of a hospital Legionella outbreak it was found that the introduction of chlorination and raising the water temperature controlled an outbreak but failed to decontaminate water outlets in the wards. Legionella pneumophila was isolated from rubber washers in shower fittings subsequent and laboratory experiments demonstrated the ability of L. pneumophila to grow in water in contact with these rubber components. All the components in the hospital's fittings were replaced with an approved type, after which L. pneumophila was not isolated from water or components.

It is important not to disregard the need for testing those materials within a water system that have comparatively small surface areas, particularly in regard to the enhancement of microbial growth (see box). Components such as “o” rings and seals in plumbing systems only account for a very small fraction of the total water contact surface area in the system, but the rubbers from which they made are more likely to leach the organic compounds that lead to enhanced microbial growth (Table 4.6, further details in Technical Report). Once a biofilm becomes established on such a component the growth is able to can spread to other, more inert, materials.

[26] Characklis WG. (1990) Microbial fouling. In: Characklis WG, Marshall KC, editors. Biofilms. New York: John Wiley & Sons;

[27] Colbourne et al. (1984) Colbourne J.S, D.J. Pratt, M.G. Smith, S.P. Fisher-Hoch, D. Harper, Water Fittings as Sources of Legionella pneumophila in a Hospital Plumbing System, The Lancet, Volume 323, Issue 8370, 1984, Pages 210-213, ISSN 0140-6736

5 MATERIALS/PRODUCTS IN COMMON USE AND TEST METHODS

5.1 Introduction

This section considers which materials/products are commonly used without hesitation, and which are the common test methods used and their costs.

5.2 Appropriate materials

The term appropriate materials in this context mean those materials and products that fulfil the hygienic requirements for material and substances in contact with drinking water and are therefore conducive to maintaining health and preventing disease. Hygienic requirements consist of the assessment of materials and the performance of hygienic tests on materials and/or products. Appropriate materials and products have to fulfil the hygienic requirements and are safe to use in contact with drinking water. In the absence of harmonisation, MSs have developed their own approaches for manufacturers and suppliers to demonstrate compliance of appropriate materials and products with national hygienic requirements (Section 2.2). As a consequence, ‘appropriate materials’ that are commonly used without hesitation are determined and used at the national rather than EU level based on proof of compliance with the national requirement.

All the major groups of materials (organic, metallic and cementitious) which undergo testing for regulatory compliance for use with drinking water have been associated with failures in material testing (Chapter 4), and it therefore is not possible to label any one material type (e.g. PVC pipe, EPDM gasket or brass fitting) as able to pass all forms of testing and therefore automatically be considered reliable and not require and assessment. However, based on the experience from the test laboratories who conduct such testing within Europe, some materials are more likely to cause certain types of failure with water quality tests. For example: rubbers have been shown to cause increased failure frequencies for the enhancement of microbial growth (EMG) in comparison to plastics or cementitious products; whereas cementitious products experience larger failure rates in the extraction of metals testing than products composed of either plastic or rubber materials. Testing laboratories also find within these groups there are certain material types that pose a higher risk than others (Table 4.6): fluorocarbon rubbers and silicones are less likely to result in an EMG failure in comparison to other types of rubber, whereas plasticized PVC is more likely to result in an EMG failure than other types of plastic.

There are no centralised sources of information at EU level covering substances and materials that have passed national assessments for use in contact with drinking water. At the national level Competent Authorities/Notified Bodies provide information, usually online (listed in Technical Report), on substances deemed compliant with national requirements (Positive Lists) and materials and products that have passed assessment (approval scheme listings). Listings for REACH (SVHCs) and the BPR (Section 2.2) are available for identifying specific substances considered to represent particular risks to public health and are taken into consideration in the assessments of substances and materials formulations. There are a handful of substances which theoretically can be found in drinking water contact materials, which are now REACH restricted (Bisphenol A, Acrylamid, Asbestos, Vinylchloride, Phthalates). The restricted fields of use (conditions) are, however, other than use in materials related to drinking water. However, substances and materials that have failed national assessments are not usually stated in national listings. The 4MS initiative has compiled ‘combined’ positive lists for organic and cementitious substances from those used by Germany, France and the Netherlands but has identified issues with the information on substances requiring substantial further work before an agreed ‘common’ list can be agreed.

Harmonisation (of the performance requirements, test methods and pass/fail criteria) across the EU together with the publishing of common listings of approved products and materials and of Positive Lists of substances for use in them would facilitate the identification of, and agreement on which are the safest and therefore most appropriate materials to use across the EU. This would provide the basis for reducing the requirements for assessment and testing of those material types that are consistently compliant.

5.3 Test methods

Test standards for organic, cementitious and metallic materials have been developed within CEN over a period of 20 years, based on practical use of materials, experience, scientific information and international developments. Every MS has the opportunity to contribute to the further development or improvement of the test standard. At the moment the content of the test standard is the best practise of the participating MS. Every MS is able to take over the EN standards in their national requirements. Some MS have decided not to take over the EN standards and use their own national standards or other available standards and test methods. It is not possible to conclude that these standards do not fulfil the requirements within national legislation.

It was not feasible to consider all 28 MSs in detail and hence the attention was focused on seven comprising: the 4MS group (Germany, France, the Netherlands and the UK), Portugal (which is working with the 4MS and has drafted new regulations), Denmark (which is part of the Nordic grouping of MSs and has recently introduced a new approval scheme) and Poland (which is newer EU member and is developing its approaches). An overview of the national requirements of the 7 MS is given in ANNEX 4 to the Technical Report. Materials and products are approved and tested against these requirements.

5.3.1 Organic materials

Different requirements and test standards for assessing organic materials are used across the seven MSs reviewed comprising a mix of EN standards applied by Germany, the Netherlands, Portugal (in draft regulation) and Denmark, whilst France, Poland and the UK use their own test standards. The main parameters evaluated are common covering testing for organoleptic, enhancement of microbiological growth, release of substances; and cytotoxicity for the UK only. Some use a substances positive list to support their assessment of organics. A common approach to organics using harmonised test standards is in development by the regulators engaged in the 4MS scheme, but some pass fail criteria and a common Positive List are still required.

As has been highlighted in Chapter 2, the key harmonised test standards currently available for organics are:

- EN 12873 series (migration test) ,
- EN 1420 (TON & TFN),
- EN 16421 (EMG),
- EN 15768 (GC-MS Screening).

However the EN 16421 (EMG) consists of three different manners to establish the EMG, i.e. the W270 microbial growth test (Germany), the Biomass Production Potential (BPP) test (Netherlands) and the Mean Dissolved Oxygen Difference (MDOD) test (UK).

The reason from CEN for not being able to identify one single test method is that each test method provides the most realistic result for only a limited number of products/materials, but all three together cover the whole range of construction products in contact with drinking water. Therefore, it is decided by CEN not to select one test method only (with the risk of creating sub-optimal results for a number of products/materials) but to mention all three of them and selecting for each product/material the most precise test (Expert group on construction products in contact with drinking water, meeting 10/09/2010).). In reality however, only one of the three test methods specified is employed by each MS (e.g. UK employs method 3).

In practice the BPP-test has as advantage that it is more sensitive than the other two methods (W270 and MDOD). The BPP-test has a greater distinctive character to identify differences between materials of different manufacturers, for example in the case of the material PE[28] (van der Kooij and Veenendaal, 2007).

For all three tests it is possible to follow the test results during testing, but at the end the approval of a material depends on the test results within the established test period and the evaluation criteria. Future research is needed to determine selection criteria for mutual acknowledgement of approval/rejection.

In order to put context to the type of materials that experience the most effect on EMG, the following order of difficulty would be appropriate as a general rule: Ethylene Propylene Diene Monomer (EPDM) rubber, Styrene Butadiene Rubber (SBR), Polyvinylchloride (plasticized, PVC-P) > Polyethylene (PE) > copper > Polyvinylchloride (chlorinated, PVC-C), Polyvinylchloride (universal, PVC-U) and Stainless Steel (SS).

Pass/fail criteria are not available for:

- EN 1420 (TON & TFN),
- EN 16421 (EMG)
- EN 15768 (GC-MS Screening). Guidance is needed for the interpretation of the results of the GC-MS-Screening (especially toxicological evaluation of the commonly found substances)

Demand for the use of organic materials is increasing and organic materials comprise the most numerous of all the material types submitted for compliance assessment. Formulation assessment and the interpretation of test results are often complex and certainty is needed concerning how they are tested and pass/fail determined. The current situation has prompted the EDW, the consortium industry trade bodies, to draft its own draft approval scheme for plastic and silicone as a potential replacement for separate national approaches.

The resolution of the harmonisation of compliance for organic material assessment across the EU is a high priority among the main material types.

In order to put some context to the type of products that experience the most difficulty in passing the above mentioned test criteria for organic materials, the following order of difficulty would be appropriate as a general rule - site applied materials > elastomeric materials > factory made products, and generally are related to the variability in the curing conditions experienced, with failures mostly attributable to the GCMS analysis and/or microbial growth promoted by the materials.

5.3.2 Cementitious materials

As for organics, assessment of cementitious products is undertaken through toxicological conformity evaluation of chemical formulation. Cementitious materials are be subject to migration tests for chemicals, growth of microorganism tests and organoleptic tests (as for organics). Currently MSs apply their own methods of assessment and will use either harmonised test standards or their own (e.g. UK uses elements of BS6920). Positive substance lists are maintained for cementitious materials by some MSs. The regulators of the 4MS have developed a common approach for the assessment of cementitious materials, including a generic positive list of substances, and pass/fail criteria are available.

With cementitious products, failures occur in a similar way to organic materials with the most difficulties experienced with site applied materials > elastomeric materials > factory made products.

Cementitious products that are factory made are covered by harmonised test standard EN 14944, which has two parts in force:

[28] Van der Kooij, D. and H. Veenendaal (2007) Assessment of the microbiological growth potential of materials in contact with treated water – a comparison of test methods. KWR 2007.068 KWR Nieuwegein

EN 14944-1:2006 Influence of cementitious products on water intended for human consumption. Part 1 - Test methods. Influence of factory made cementitious products on organoleptic parameters

EN 14944-3:2007 *Influence of cementitious products on water intended for human consumption. Test methods. Migration of substances from factory-made cementitious products.*

Two further sections covering materials prepared *in situ* from accepted constituents or ready-mixed concrete transported to the site are in development.

The development of harmonised standards for cementitious materials is further advanced than for organics.

5.3.3 Metallic materials

Due to the nature of metals and their alloys they are manufactured and marketed to specific compositions (grades), consequently it is possible to identify their compliance with hygienic tests by grade rather than by a branded material or product.

The development of a harmonised approach for the assessment of metals is also further advanced for metals than for organics. Both Germany and the Netherlands are currently implementing the common approach developed by the 4MS through national regulations, which is based on the long term leaching test standard EN 15664. The placing of compliant metal and metal alloy grades on a public Common Composition List ensures that each only needs to be tested once against EN 15664. This approach is also included in the draft Portuguese regulation and in the and in the ecological criteria for the award of the EU Ecolabel for sanitary tapware (Commission Decision C(2013) 2826[29]). Other MSs use their own regulations for metallic products in contact with drinking water. However, some MSs, notably the UK do not test metallic materials, due to previous standards yielding poor reproducibility and repeatability.

What remains to be addressed is the harmonised assessment of metallic surface coatings deposited within the water pathway in products, such as nickel and chromium coatings derived from the application of plating to external surfaces of taps and components of fittings such as nickel plated ball valves. In this respect EN 16058:2012 defines a dynamic rig test for assessment of surface coatings with nickel layers which is used in Denmark.

Although the developments on the market show a trend of decreasing use of metallic and cementitious materials, it is still necessary to give attention of the implementation of the methods for cementitious and metallic materials and to develop the test methods further. These materials contain constituents which can release substances in concentrations which do not fulfil the requirements in the DWD 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. The test methods as described now are developed in the period 1996-2006, based on the information of practical use of materials, existing knowledge in several MS and scientific information. To involve new developments in material developments and research it is necessary to be able to approve materials as fit for use.

5.4 Costs of compliance

This section considers a rough economic asessment of the costs of the test methods and approval.

Costs for tests were obtained from Notified Bodies. Two reports on the economic impact of Article 10, published in 2016 by the Dutch Ministry of Infrastructure and Environment[30] and the German trade

[29] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D0250

[30] Economic Effects of article 10 of the Drinking Water Directive. Report to Dutch Ministry of Infrastructure and the Environment. Panteia, 2016

association figawa[31], were reviewed and average costs for hygienic testing and auditing in MSs were derived from data provided in the latter. The number of new approvals issued annually for approval schemes in France, Germany, UK and Netherlands were identified and used with the figawa data to estimate total annual spend by companies on obtaining these approvals.

5.4.1 Test costs

Under the current arrangements the cost of testing vary considerably between MSs for organic and cementitious materials, whilst the harmonised EN 15664 long term test on a dynamic test rig, for metals, that is now required by Germany and the Netherlands is the most expensive. The following costs were derived from information provided by Competent Authorities/Notified Bodies.

Organic materials

The costs for testing of organic materials range from a few thousand Euro to € 30k+ for an organic material.

- France - organic material - between €0,5k and 8 k
- France - exchanger resins - around €9 k
- France - filtration membranes - around €20 k
- Germany – organic material - €3 k
- Poland – organic material - €3.8 k
- Denmark – organic material - €10 k (including annual audit)
- UK evaluation of a non metallic material against BS6920 for plumbing use - €1.4 k.
- UK Regulation 31 approval for a non-metallic material for use in public distribution system – €30 k+.

Similar figures were provided by the European Sealing Association (representing 50 companies manufacturing sealing devices used in the water industry) from a survey of its members in 2016 to ascertain the impact of the various water testing regimes within the European market. The members reported costs of €4,000 to €7,000 for tests and having to test the same products up to 4 times (in different MS), to ensure that they are able to sell 'throughout' the European market. In most cases they needed to be recertified after five years. On average the companies reported testing costs of up to €19,000 for each material/product they manufacture in order to sell to the water industry throughout Europe.

Cementitious materials

- France - CLP approvals usually require a composition analysis against a list of approved components –€ 0.6k.
- Netherlands – €10.8k
- Germany €3.5 k
- UK - evaluation of a non metallic material against BS6920 for plumbing use €4k
- UK - Regulation 31 approval for a non-metallic material for use in the public distribution system €30 k+.

Metallic materials

For the testing and approval of a metal against the EN 15664 long term test on a dynamic test rig using three water composition costs from €25 - 75 k, and up to €130 k has been reported. Currently only one laboratory in the EU is accredited to conduct the testing and to date only around 20 metals and metal alloy grades have been subject to this evaluation and these appear on the 4MS Common Composition List. However the test only has to be performed once per metal or alloy grade. In France

[31] Effects of Article 10 of the EU Drinking Water Directive on test and certification costs for products in contact with drinking water. Member survey, figawa, 2016.

and ACS Approval is not required for metallic materials but they are checked against permitted composition for a small fee. In the UK there is no requirement for testing metals and therefore no charges apply.

5.4.2 Costs of compliance

The Dutch collected data from 46 German, French, Dutch and British companies that responded to a survey which included internal and external costs of compliance with national schemes.

Annual expenditure ranging from 10k€ to several hundred thousand Euros (averaging 165 k€) was reported for the external costs for hygienic evaluation, audits and certification of products. The reported internal staff costs ranged from several thousand Euros per annum for smaller enterprises to several hundred thousand euros for bigger enterprises that have wider product ranges. The average cost across the 46 companies was reported to be 135 k€ (82% of the external costs). Based on these averages and its estimates of numbers of companies in the sector the study estimated total annual staff costs of €327 million and for the external costs of €400 million for companies in these four MSs. Rough estimates of total costs (internal and external) for companies in the EU28 of € 1.208 billion were reported as representing 2.8% of an estimated € 43 billion annual turnover of Article 10 DWD related products.

However, these figures have to be treated with caution. Whilst the range of costs quoted by the companies are indicative of actual costs to businesses it is unclear how representative the average costs derived from them for the 46 companies are of the sector as a whole. Analysis of numbers of approvals held by companies in the major approval schemes shows that the majority of companies hold only one or two approvals in each scheme (Section 3.1.1) and very few companies hold large numbers and would be incurring the higher costs reported in the study. Consequently, the average figures quoted are likely to be an overestimate.

The figawa study presents summary statistics on test and auditing costs for hygienic assessment of products that were reported by German companies for initial licencing in Germany and for submission for assessment in other MSs. Table 5.1 summarises our analysis of the average costs per product incurred for hygienic assessment of these products in each MS based on raw data included in an Appendix to the report. The range of costs incurred reflects the fact that some products require only a basic assessment and others require several tests. The highest costs were incurred in Germany (see also note to Table 5.1) and were between €1k and €10 per product in other MSs.

Table 5.1 Average cost per product for hygienic assessment and mechanical assessment incurred by German companies for products by sold in Germany and other MSs. Source: raw data in Appendix 5 of figawa Member survey, 2016.

Member State where tested	Number of products for which data provided	Range of hygienic test and audit costs (thousand €)	Total costs (thousand €)	Average hygienic test/audit cost per product (thousand €)
Austria	8	1 to 34	63	9.0
Belgium	3	1 to 5	7	2.3
Bulgaria	1	2	2	1.0
Czech Rep	3	1 to 4	6	1.5
Denmark	12	1 to 65	91	7.6
Finland	2	2 to 9	2	4.5
France, ACS	43	1 to 46	221	5.1
Germany, dvgw	77	1 to 747* (majority 1 to 12)	2809*	36.5 (14.3)*
Hungary	5	2 to 5	13	2.6
Italy	5	2 to 17	27	5.4
Netherlands	13	2 to 49	116	8.9
Poland	5	1 to 15	51	10.2
Portugal	3	1 to 5	7	2.3
Slovakia	3	2	6	2
Sweden	4	2 to 12	19	4.7
UK, WRAS BS6920	25	1 to 39	220	8.8

*German data includes three products that are outliers: a composite pipe with testing/audit costs of €747k and two titled 'fittings and connectors' (i.e. multiple products submitted together) at €402k each. Removing these gives a mean cost of 14.3k.

The numbers of new approvals issued per year and estimated costs for the approvals schemes of Germany, France, UK and Netherlands (for which only a rough cost and no numbers were available) are presented in Table 5.2. This shows that an estimated €15 million is spent on materials testing for approvals in the UK and €8 million in France by companies each year. Cost of a 'few millions' a year for the Netherlands have been quoted and an estimate of up to €7 million has been made for Germany. In total around €35 million in the 4MS countries, substantially lower than the estimate from the Dutch Study. Assuming similar expenditure in other countries that require testing is lower than for UK, France, Netherlands and Germany this suggests a figure of around €60 million per annum external costs on testing/auditing new applications. These estimates do not include all external costs such as renewing expired approvals. Overall we estimate the external cost to be not more than €100 million. Applying the same ratio of average internal costs to external costs as the Dutch study this gives a total estimated cost of €182 million or 0.42% of the estimated €43 billion value of the industry.

Table 5.2 Estimate of annual expenditures on testing/auditing for major materials approval schemes based on the number of new approvals issued per year for approval schemes in UK, Germany, France and the Netherlands and estimated average costs per product in Table 5.1.

Scheme	New approvals per year	Estimated average cost of testing/audit (from Table 5.1)	Estimated total (€)
UK WRAS Material Approval (plumbing)	512 (2014/15)	€8 800 average (range €1k to 39k)	**4 172 800**
UK WRAS Product Approval (plumbing)	1278 (2014/15)	As above	**10 415 700**
UK DWI Reg 31 (public network)	29 (average 2012 to 2016)	€30 000 (see section 5.4.1)	**870 000**
France	ACS (accessories) 1126 ACS (material) 331 CLP 101 CAS 23 Total: 1581	€5 140 for ACS (range €1k to 46k). Same value applied to CLP and CAS.	5 787 640 1 701 340 519 140 118 220 **8 125 340**
Germany DVGW	213 (including renewals)	€14 300 to €36 500	**3 045 900 to 7 114 500**
Netherlands KTW	No figure on number of new approvals issued. In total 550 products certified to Dutch hygienic regulations and subject to regular audits and tests	Not available	Annual expenditure by companies on Dutch approvals were indicated by a Notified Body as amounting to a 'few million euro'

6 CONCLUSIONS

The purpose of this report is to assess the problem of materials and products affecting the quality of drinking water in relation to Article 10, under the various headings covered in the Chapters (sub-tasks 1.1 – 1.4). This review of the current situation regarding the application of Article 10 has identified areas where a technical solution should be considered to address key issues; these are highlighted in these conclusions.

A. Context, Problem definition and Subsidiarity Check

Context

- Article 10 of the Drinking Water Directive (DWD) requires Member States (MSs) to ensure that substances and materials used in new installations in contact with drinking water do not "reduce the protection of human health" provided for in the Directive, but leaves its implementation to each MS. Therefore, the requirements have not been harmonised at EU level.
- Products in contact with drinking water comprise those used in the public water supply system from source (estimated at some 5 million km of distribution pipework) as well as the plumbing systems to the DWD points of compliance within an estimated 250 million buildings across the EU.
- The materials that the products they are made from comprise three main types: organic materials (e.g. plastic, rubber, lubricants), metallic materials (e.g. iron, steel, brass), and cementitious materials (e.g. concrete, cement).
- Materials in contact with drinking water should be inert, not dangerous to human health, and should not significantly modify the chemical, microbiological, physical or organoleptic (i.e. visual/taste/odour) properties of the water. However, in practice some inappropriate materials are being used in products sold in the EU.
- It is estimated that around 45 000 - 75 000 km of water pipes (mains and service pipes) are installed within the EU each year and traditional materials (iron and cement pipes) are being replaced by plastic pipe, mainly PVC and polyethylene pipe, whilst organic materials are replacing some uses of metals in fittings and accessories (e.g. for pipe joints and the bodies of water meters).

Problem the initiative aims to tackle

A number of existing EU Regulations and harmonised Standards partially address this issue, but they have various limitations. The Construction Products Regulation (CPR) is the only EU legislation specifically linked to Article 10. Although progress has been made in development of many harmonised supporting standards, via the CPR, for testing materials, the CPR does not cover the full scope of products covered by new installations (as it only relates to permanent civil engineering works in buildings).

Defining new installations

Section 1.4 identified the need to define the scope of the 'new installations' for a harmonised approach to materials in contact with drinking water to be implemented. The CPR has been used as the main vehicle for pursuing a harmonised approach to materials/products in contact with drinking water, but its scope does not cover all installations from source to the DWD points of compliance and leads to confusion about what products are in scope. It is limited to construction products that are used in permanent civil engineering works in distribution systems from point of treatment and in buildings.

Materials based approach

Section 1.4 highlights that in addressing the application of Article 10 the issues are not dependent on product type, but are dependent on the specific substances/materials (metallic, organic and cementitious) used within each product that are in contact with drinking water. A product type (e.g. a pipe or valve) serving a particular function can be made from different materials, and compositions thereof. These differ in their potential effects on health and water quality and require separate assessment and testing. For a given product an assessment of the actual composition of the materials it contains in contact with drinking water is necessary for evaluating potential issues and determining what evaluation is required for that product to confirm its safety. Therefore, in addressing harmonisation of the sector an approach based on assessment by substance/material type, rather than product type, is most appropriate.

Organoleptic effects

Taste, odour and appearance of water are the water quality impacts most likely to be detected by the public and generate complaints concerning water quality. These usually do not pose a direct risk to health but affect the consumer's perception of wholesomeness and, consequently, competent authorities are concerned that this undermines confidence in water supplies. Organoleptic parameters are included in the DWD only as indicators, which MSs are required to investigate to determine if they relate to a health risk. Testing for organoleptic effects is included where appropriate in harmonised testing standards. The review of Article 10 should consider extending its scope from just protection of human health to include wholesomeness and organoleptic impacts.

- National legislation exists in many MSs to regulate materials in contact with drinking water, though standards and implementation (for example required testing and acceptance procedures) varies between MSs, and many operate their own mandatory or voluntary approval schemes. The principle of mutual recognition is generally not applied in this sector. As a result, MSs require manufacturers/suppliers of substances and materials that come into contact with drinking water to meet their specific national requirements in order to demonstrate that the products to be installed will be safe. This requires multiple tests to be undertaken and, where used, separate national approval schemes to be complied with before a product can be marketed across MSs. Reliance on experts for opinions on assessment and verification of compliance of materials where common acceptance criteria are not available can result in different outcomes for materials in different MSs. In some cases manufacturers would have to produce more than one version of a product in order to sell a compliant product in different MSs. These issues create a barrier to trade within the EU.
- In theory, the principle of mutual recognition (regulation EC No 764/2008) of products in contact with drinking water should apply (i.e. a product lawfully sold in one MS should be acceptable in another MS), as this is an un-harmonised sector. However, since Article 10 states that responsibility lies with MSs, and since exceptions to that principle are permitted for issues justified on the basis of overriding reasons of public interest (including 'the protection of health and life of humans'), there is a belief that the sector is exempted from the Mutual Recognition principle. The recent review by the Commission of the application of the principle of mutual recognition identified non-harmonised construction products as a sector where action should be taken and used water taps as an example, citing lack of trust between authorities and requests for national testing.
- The financial consequences of the current situation for material/product businesses include: delays to market for new products whilst evidence of compliance is obtained for multiple markets, and consequent financial loss; and the costs of undertaking multiple tests, audits and accreditations for these markets. . This is causing a significant burden for industry. In addition, suppliers that invest in material/product compliance do not operate on a 'level playing field' (i.e. in a fair market) as untested products are available in MSs. This means that there is effectively no Single Market within the EU for products in contact with drinking water.
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Subsidiarity check (and legal basis)

- Determining whether the existing un-harmonised approach is adversely impacting intra-EU trade in materials in contact with drinking water is a very difficult task using trade data, as it is necessary to disentangle the various factors influencing imports and exports for different products. There is some limited indication that trade between MSs with different requirements is lower than where a MS has no requirements. As such, other evidence gathering approaches are needed to identify the impact of the current situation on intra-EU, such as collating views from relevant industry stakeholders on their experiences of exporting (or attempting to export) these products to other MSs. There are widespread concerns amongst stakeholders about the increasing disparity between MSs with regard to national requirements and approvals, which are perceived as an obstacle to the internal market and an area where EU intervention could both reduce costs and improve product safety.
- If the problem is not addressed at the EU level then it is envisaged that the current market fragmentation will continue (impacting the business activity of an estimated 5 000 enterprises engaged in producing products in contact with drinking water that employ more than 100 000 staff, with annual sales in excess of € 40 billion), limiting consumer choice in the products available to them in each MS and potentially resulting in inappropriate materials continuing to be used in products sold in MSs.

B. Objectives and Policy options

- The objectives are to deliver a Single Market in materials and products in contact with drinking water, whilst ensuring that products made with inappropriate substances/materials which can be injurious to human health or affect the quality of drinking water are no longer sold in MSs.
- The following policy options are proposed for consideration:

- Under the ‘baseline scenario’ MSs will continue to develop and amend national regulations over the coming decades, whilst the voluntary initiatives may result in some mutual recognition between a small number of MSs. This will make it increasingly difficult to realise product harmonisation across most MSs, resulting in a fragmented market outside of those engaged in the initiative. Costs for producers and consumers will increase and competitiveness will be hindered. Innovation in the use of new materials may also be reduced.
- There are four policy options which should be considered against the baseline scenario:
  - Option A - EU regulation (e.g. CPR: European assessment and product standards, third-party verification ("notified bodies"), European Organisation for Technical Assessment route).
  - Option B – the development of performance standards under CPR addressing products covered by a harmonised European product standard(s) (hEN), whereby in addition specific performance classes need to be established (i.e. two classes instead of a "pass/fail" approach).
  - Option C - promotion of an EU-wide process to harmonise certification criteria in order to ensure that MSs accept certifications granted in other MSs for materials/products in contact with drinking water.
  - Option D - production of (non-legislative) guidance for MSs on how testing of materials in contact with drinking water is best performed in order to meet the Article 10 objectives.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

- Under the baseline there is no common approach to materials in contact with drinking water in the EU, with different protocols put in place in some MS leading to high costs to industry producing these materials, and a fragmented market.
- The impact of greater harmonisation with regard to materials/products in contact with drinking water will partly depend on the form that the policy option takes, as well as the details of the agreed framework. In all cases, though, there will be a reduction in direct (testing and approval) costs and indirect (internal staff costs) for producers of products in contact with drinking water.
- Overall there is likely to be a positive economic impact on the industry supplying materials and products in contact with drinking water, with greater gains likely from policy options A and B, reflecting their relative effectiveness in dealing with this issue.
- It is expected that under options A and B there would be a larger impact on testing and certification employment as the number of approvals is reduced, though this might be off-set if an increased number of products are brought to market and overall competitiveness improves (so that total employment in the sector may not decrease).
- Under options A, B and C there should be a reduction in the current delays to market experienced by producers as a consequence of having to obtain multiple national approvals in order to launch products across the EU. There will also be greater competitiveness, via increased economies of scale as there will be a larger market and multiple versions of a product (to meet different MS market requirements) will no longer be required. This will allow manufacturers to increase the size of production runs, encouraging both SMEs and larger companies to grow. With a faster approval process the rate of innovation for these products should increase along with investment. Lower production costs and more innovative products will boost EU competitiveness for these products, and so may help limit further increases in non-EU imports (better market surveillance of noncompliant products imported in to the EU would help with this).
- Under all policy options intra-EU trade should increase in comparison to the baseline, as currently only a limited range of manufacturers’ products are available outside of the MS of origin. The increase in product range availability across the EU could be in the order of 50%. The percentage increase in intra-EU trade would be unlikely to be as large as this, but could still be equivalent to hundreds of millions of € a year (though more detailed modelling is required to increase certainty in these estimates).
- Under option C it is more likely that some MSs will gain a comparative advantage where their industry already has to meet stringent standards, whilst those MSs (especially smaller MSs) with no system currently in place may find it difficult to put a system in place.
- With regard to SMEs, producers of materials in contact with drinking water will benefit significantly, especially where their direct and indirect costs of compliance are reduced. Those that could be adversely affected are companies currently producing products in contact with drinking water that would not meet the safety requirements of a new, relatively more restrictive scheme (options A and B) that better protects EU consumers, as they will lose sales in their current markets if they cannot easily reformulate their product to meet the new

requirements.
Likely social impacts
• Greater harmonisation should increase EU competitiveness and therefore result in an increase in employment. However, the distribution of these jobs will depend on the response of individual companies. Compared with the baseline the smallest changes would occur under option D. • The greatest social benefit will be increased choice of compliant products, both better performing and at lower cost. With fewer products using inappropriate materials on sale in MSs the risks to consumer health over the long-term will be reduced, particularly in those MSs where testing of materials does not currently take place. These health benefits will be more likely under options A and B.
Likely environmental impacts
• All of the policy options are expected to result in mostly positive environmental impacts compared with the baseline, primarily through reduced leaching of chemicals into the drinking water supply which is then returned to the wider environment. There may also be environmental impacts for non-compliant products at end-of-life, when these enter the waste stream. The presence of harmful chemicals may not only pollute natural water sources but could then have a negative impact on biodiversity where species are susceptible to these pollutants. Harmonizing approvals for materials in contact with water (options A and B) would lead to a reduced risk for pollution and a reduced risk for environmental impacts stemming from these substances. • More efficient production, through investment in larger-scale manufacturing as a result of increased market size, should reduce unit energy use. In addition, greater innovation in products in contact with drinking water might focus on the use of more sustainable materials in the manufacture of these products; or products that can be installed with less environmental impact. These benefits are more likely under options A and B. • There may also be a decrease in the consumption of bottled water in MSs where inappropriate materials are perceived to result in a health risk from piped water consumption or where the materials are causing adverse impacts on odour and taste of drinking water.
Likely impacts on fundamental rights
• Beyond access to more wholesome and cleaner drinking water across the EU, there are no impacts on fundamental rights expected either inside or outside the EU (provided the policy option adopted does not favour non-EU countries with less protection of fundamental rights).
Likely impacts on simplification and/or administrative burden
• Whilst the introduction of policy options A or B would increase pan-national regulation, overall they would reduce the administrative burden of businesses wishing to trade across MSs. Obligations would only increase for those businesses producing products in contact with drinking water in MSs which currently have no regulation in this area. Additional administrative efforts would be required in MSs that are currently not active in this area. • There will also be a requirement for additional administrative resources for policy development (e.g. working groups, desk officer time) in order to establish commonly agreed standards. These costs will higher under options A and B.

ANNEX A

List of main stakeholders contacted and events attended.

Requests for data and information to support the tasks were made directly to organisations, or though requests made during presentations about the project at several workshops and meetings held by stakeholders

Meetings attended:

Round Table (EU level) stakeholders meeting on DWD Art 10 – Brussels, January 2016 - Attended by DWI, Copper Alliance, Profluid, Kiwa, WLN, Afnor, EWTA, Vewin, EurEau, DVGW, SINTEF, Boverket, PlasticsEurope, Geberit, figwa, UBA, SWEREA, Brita, French MoH.- Brussels, January 2016.

2016 TEEPFA Forum (trade body for European plastic pipes industry) – Brussels, April 2016.

2nd annual Conference on Materials and Products in Contact with Drinking Water – Brussels, May 2016 – Attended by 150+ government, regulator and manufacturers/suppliers.

Technical Commission Workshop at the Europump Annual Meeting (trade body for European pump manufacturing industry) – Ghent, May 2016.

German Round Table stakeholder meeting on Materials and Products in Contact with Drinking Water, Bonn, June 2016.

Stakeholders contacted:

Stakeholder	Date	Information
AFNOR Association Française de Normalisation, French Standardization Association	Apr	Telephone interview about norms applicable in France for materials in contact with drinking water and the CEN TC dedicated group.
BMA Bathroom Manufacturers Association	Feb	Telephone call with Technical manager about materials assessment.
BMG Federal Ministry of Health, Germany	Jun	Meeting following German Round Table (see below). BMG provided case studies on leaching from plastic and brass and a study on plastic pipes.
BPF British Plastics Federation Plastic Pipes Group	Feb	Telephone discussion with Standards Manager concerning members experiences.
Brita manufacturer	Mar	Telephone interview concerning experience in obtaining approvals across Europe
CEFIC European Chemical Industry Council	Apr	Telephone discussion following Teppfa Forum (see below) to discuss information provision from their members.
CEFIC-FCA/PlasticsEurope	Feb	Position papers on Article 10 provided position papers by PlasticsEurope and Cefic-FCA on DWD and members experiences.
CEN TC 164/WG3	Jul	Contact with convenor and secretary concerning status of test methods in contact with drinking water within CEN in 2016
Copper Alliance/IWCC International Wrought Copper Council	Mar	Telephone discussion with representatives from Copper Alliance and IWCC concerning members experiences. A guide on EU Regulations was provided.
CSTB Technical Centre for Building, France	Sep	Provided information relating to the Sanitary Assessment in France for Organic, Metallic and Cementitious products including further contacts.
Danish Transport and Construction Agency	Jun	Andreas Nawrocki Anker, Danish Transport and Construction Agency, Copenhagen. Request for information on national approval of products and materials in contact with drinking water Denmark
DVGW Deutsche Vereinigung des Gas- und Wasserfaches e.V, Germany	Feb	Telephone discusion. DVGW provided a Joint Declaration on Article 10 by German Associations and a report and data for DVGW/figawa request to national product information centres
EADIPS Ductile Iron Association	Apr	Skype interview with director. Provided EC reports on ductile iron imports

Stakeholder	Date	Information
ERSAR regulator, Portugal	Mar	Discussion at Round Table and subsequent electronic commumnication concerning Portuguese regulation and laboratories.
EDW European Drinking Water	Feb, May, Jun, July	Various discussions and electronic exchanges with convener. Provision of conference presentations on Article 10, meeting notes with regulators, including DG Grow and DWI and with TV164, concerning Article 10, draft versions of the EDW Plastics Certification Schemes, the EWTA's directory of regulations and standards in MSs, and 4MS JMC request for data concerning substances on Positive Lists. EDW also issued call to its 20+ trade association members to provide information to project.
EHI	Jun	Fanny Rateau provided position paper
EHI European Heating Industry	Feb	Regulatory Affairs Manager provided EHI Position Paper on Article 10 and Gas Regulation.
ESA European Sealing Association	Jul	Legislation and Standards Director provided a summary of members experiences of the impact of Article 10.
EurEau	Mar	Telephone discussion and electronic communications with vice President, concerning obtaining data from EurEau members about pipe materials, length of networks, replacement rates, experiences with materials related water quality failures. Data subsequently provided by members from several MS
Eurofins	Aug	Telephone interview about range of prices of tests, and advice for the guidance document.
Eurofins	Apr	Telephone interview about the type of certifications in France, their prices, reasons for failures, materials tested and origin of the clients.
European Round Table meeting	Jan	Attended January 2016 Round Table to presented project and issue information request to. DWI, Copper Aliance, Profluid, Kiwa, WLN, Afnor, EWTA, Vewin, EurEau, DVGW, SINTEF, Boverket, PlasticsEurope, Geberit, figwa, UBA, SWEREA, Brita, French MoH.
Europump	May	Attended Technical Meeting in Ghent to explain the project and request information on the market and members experiences.

Stakeholder	Date	Information
figawa	Mar and Sep	Correspondence and telephone interview with Volker Meyer concerning the figawa study and members experiences with barriers to trade. Provided report on test and certification costs.
Force Institute	May	Provided costs of test methods for metallic materials in contact with drinking water, Nordic methods, EN
GCP Europe	Aug	Request for this association of plumbing professionals to assist with the Task 2 Guidance.
Geberit	Jun	Meeting with senior managers to discuss experience with Article 10 and national requirements.
German regulators	April	Electronic communication with Ministry of Health, DVGW and UBA concerning information on national approval of products and materials in contact with drinking water Germany
German Round Table	June and Sep	Attended June meeting of the German Round Table on Article 10 in Bonn. Policy document prepared by the Round Table on its preferred option for a new Regulation to replace Article 10 was provided in September.
HYG (Germany)	Sep	Provided information relating to the cost for the testing of Organic and Cementitious products in Germany.
Institute of Environmental Protection, Poland	May/June	Electronic communication with Institute of Environmental Protection – National Research Institute, Warsawa concerning information on national approval of products and materials in contact with drinking water Poland
IWCC International Wrought Copper Council	Mar	See Copper Alliance
Kiwa Nederland	April, May	Contact with head of departement concerning cost of test methods for organic materials in contact with drinking water
Ministère de la Santé	Aug	Telephone interview about range of prices of the tests and advice for the guidance.
MPA Mineral Products Association	April	Telephone interview with Technical Advisor, MPA Cement concerning cementitious products.
Orgalime	Feb	Telephone interview with Adviser to Orgalime Partnership (the European Engineering Industries Association), which represents CEIR (European valves association) and Europump, concerning members issues
PlasticsEurope	Jan	Provided position paper on DWD

Stakeholder	Date	Information
Profluid, CEIR & Europump	Mar	Telephone interview about the study. Reference documents and website links provided.
Public Health Institute, Netherlands	Mar/ Jun/Jul/Aug	Discussion concerning developments within Europe concerning products and materials in contact with drinking water
SINTEF	Feb/ March	Electronic communication concerning the current project of the 4 Nordic Countries comparing their approaches and how they relate to 4MS
Teepfa	Apr	Attended Annual Conference and presented the project and issued request for information to members.
TZW	Jun	Provided information on cost of test methods for metallic materials in contact with drinking water, EN
UBA (Germany)	Sep	Concerning contacts for obtaining information on testing costs in Germany.
Vewin	Jul	Electronic communication. Provided Report of ad hoc sub-group under Standing Committee on Drinking Water of 2007
Viega	Sep	Provided a case study
Water UK	Apr	Telephone communication with Policy and Business Advisor, concerning examples of materials failures.
WRAS	Feb	Meeting with Technical Manager to discuss provision of data on companies and approvals and issues experienced with materials. Subsequently, WRAS provided data on numbers of approvals, companies and countries of origin, and report on evaluation of pass rates of BS6920 tests
4MS	Jun	JMC provided its 4MS 2016 programme
4MS Joint Management Committee	Jul	In response to Project's call for information the JMC provided a copy of its letter to the Commission on effects of materials in contact with drinking water and its 4MS 2016 programme.
2016 Symposium	May	Attended the symposium and presented the project highlighting the information the project was requesting from stakeholders who were attending the event.

ANNEX B

Estimates of the water distribution network provided by EurEau Members.

Table B1 summarises the information provided by EurEau members on the length of the distribution network in different countries and the types of pipe material comprising these networks.

Table B1 Lengths of water pipe of different materials installed in the distribution systems of Member States. Source: individual members of EurEau. 🡅 use of material increasing, ➔ steady 🡇 decreasing.

Pipe mate-rial	Germ-any	Finla-nd	Switz-erland	Hung-ary	The Netherlands	UK	Denm-ark 34 companies	Luxe-mbourg	France (Suez)	Spain Seville	Czech Rep (9 municipalities)	Slovakia (2 municipalities)	Poland (1 municipality)	Greece Patras & *Thessaloniki*	Austr-ia Vienna	Total	Range
Total length of network	**530,000**	**107,000**	**55,000**	**65,576**	**119,146**	**416,928**	**27,818 (55%) of network**	**4,900**	**110,800**	**3,700**	**27420**	**4,464**	**540**	**1000 & *2,680***	**3032**	**1,480,004**	
Metal	**265,000 (50%)↓**	**8,000 (7.5%) →**	**38,500 (70%)→**	**6,800 (10.4%)**	**15,185 (12.7%)**	**208,464 (50%)↓**	**3986 (14.3%) ↓**	**1750 (37%)↓**	**59,700 (53.9%)**	**2,093 (56%)**	**12,753 (46%)**	**3,908 (51%)**	**363 (66%)**	**37 (3.8%) *509 (18%)*↑**	**2418 (80%)**	**629,466 (43%)**	**3.8 to 80%**
Cast Iron				3,220 (4.9%) →	9,294 (7.8%)↓		3399 (12%)↓	1500 (31%)↓	23,000 (20.8%)	229 (6%)↓	8,854 (32%)		86 (16%)	9 (0.1%) 331 – incl.DI (12.3%) ↑	553 (18.3%)		0.1 to 32%
Ductile iron				748 (1.1%) ↑	3,330 (2.8%)		587 (2%)↓	0	34,000 (30.7%)	1,864 (50%)↑	1,358 (5%)	2,553 (33%)	0	0.1 (0.01%)	1807 (59.8%)		0.1 to 59.9%
Steel				2,833 (4.3%) ↓	0		0	250 (5%)→	2,700 (2.4%)	0	2,541 (9%)	1,305 (17%)	0	28 (2.8%) *178 (6.6%)* ↑	58 (1.9%)		0 – 17%
Plastic	**212,000 (40%)↑**	**96,000 (89.7%) ↑**	**8,800 (16%)↑**	**26,800 (40.9%) ↑**	**71,136 (59.7%) ↑**	**158,432 (38%)↑**	**21923 (78.8%)**	**2,750 (56%)↑**	**41,500 (37.5%)**	**256 (7.5%)**	**12,158 (44%)**	**3,298 (42%)**	**182 (33%)**	**925 (92.5%) 989 (39%)↑**	**98 (3.2%)**	**657,247 (44%)**	**3.2 to 89.7%**
PE & PEHD					8,691 (7.3%)↑		8937 (32%)↑		5,700 (5.1%)	234 (6.5%) ↓				644 (64%) 120 (6.6%) ↑	73 (2.4%)		Max 32%

Pipe mate-rial	Germ-any	Finla-nd	Switz-erland	Hung-ary	The Netherlands	UK	Denm-ark 34 companies	Luxe-mbourg	France (Suez)	Spain Seville	Czech Rep (9 municipalities)	Slovakia (2 municipalities)	Poland (1 municipality)	Greece Patras & Thessaloniki	Austr-ia Vienna	Total	Range
PVC					62,445 (52.4%) ↑		12985 (47%)↓		35,800 (32.3%)	22 (1%)↓				281 (28%) *869 (32.4%)* ↓	24 (0.8%)		0.8 to 52.4%
Cement	**53,000 (10%)↓**	**3,000 (2.8%) →**	**7,700 (14%)**	**31,739 (48.4%) ↓**	**31,683 (27%)↓**	**41,693 (10%)**	**1018 (4%) ↓**		**3,400 (3.1%)**	**1,336 (37%)↓**	**0**	**0**	**0**	**38 (3.8%) *841 (31.3%)* ↓**	**434 (14.3%)**	**175,882 (12%)**	**2.8 to 48.4%**
Asbestos Cement				31,450 (48.0%) ↓	30,812 (25.9%) ↓				3,180 (2.9%)	1203 (33%)				38 (3.8%) *808 (30.1%)* ↓	389 (13.2)		2.9 to 48%
Concrete :				288 (0.4%) →	871 (0.7)				220 (0.2%)	133 (4%)				*33 (1.2%)*	35 (1.2%)		0.2 to 1.2%
Others & Unknown				**236 (0.4%)**	**1,142 (1%)↑**	**8,339 (2%)**		**400 (8%)**	**6,200 (5.6%)**		**2,370 (9%) Lead 156**	**555 (7%)**	**5 (1%)**	***314 (11.7%)***	**71 (2.3%)**	**19,632 (1%)**	**0.4 to 11.7%**