

Brussels, 5 February 2020 (OR. en)

5813/20

Interinstitutional File: 2017/0332(COD)

ENV 60 SAN 36 CONSOM 18 CODEC 82

OUTCOME OF PROCEEDINGS

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	5565/20 + COR 1 + COR 2
No. Cion doc.:	5846/18 - COM(2017) 753 final + ADD 1
Subject:	Proposal for a Directive of the European Parliament and of the Council on the quality of water intended for human consumption (recast)
	 Outcome of proceedings

Delegations will find in the <u>Annex</u> the consolidated text of the abovementioned proposal, reflecting the provisional agreement reached at the fifth and final trilogue on 18 December 2019 and including the alignment of the recitals, as confirmed by Coreper at its meeting on 5 February 2020.

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TREE.1.A EN

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the quality of water intended for human consumption (recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union and, in particular, Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Council Directive 98/83/EC³ has been substantially amended several times⁴. Since further amendments are to be made, that Directive should be recast in the interests of clarity.

¹ OJ C [...], [...], p. [...].

² OJ C [...], [...], p. [...].

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330 5.12.1998, p. 32).

⁴ See Annex V.

(2) Directive 98/83/EC set the legal framework to protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. This Directive should pursue the same objective and should improve access to such water for all in the Union. To that end, it is necessary to lay down at Union level the minimum requirements with which water intended for that purpose must comply. Member States should take the necessary measures to ensure that water intended for human consumption is free from any micro-organisms and parasites and from substances which, in certain cases, constitute a potential danger to human health, and that it meets those minimum requirements.

It is necessary to exclude from the scope of this Directive natural mineral waters and waters (3) which are medicinal products, since these waters are respectively covered by Directive 2009/54/EC of the European Parliament and of the Council⁵ and Directive 2001/83/EC of the European Parliament and of the Council⁶. However, Directive 2009/54/EC deals with both natural mineral waters and spring waters, and only the former category should be exempted from the scope of this Directive. In accordance with the third subparagraph of Article 9(4) of Directive 2009/54/EC, spring waters should comply with the provisions of this Directive and with regard to microbiological requirements spring water should satisfy the provisions of Article 5 of Directive 2009/54/EC. In the case of water intended for human consumption put into bottles or containers intended for sale or used in the manufacture, preparation or treatment of food, the water should, as a matter of principle, continue to comply with the provisions of this Directive until the point of compliance (i.e. the tap), and should afterwards be considered as food, if it is intended to be, or reasonably expected to be ingested by humans, in accordance with the second subparagraph of Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁷. In addition, food business operators that have their own water source and use it for the specific purposes of their bussiness, may be exempted from the provisions of this Directive provided they comply with relevant obligations in particular regarding hazard analysis and critical control point principles and remedial actions under relevant Union legislation on food. The food business operators that have their own water source and act as water suppliers should comply with the provisions of this Directive as any other water supplier.

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Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (Recast) (OJ L 164, 26.6.2009, p. 45).

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

(4) Following the conclusion of the European citizens' initiative on the right to water (Right2Water)⁸, a Union-wide public consultation was launched and a Regulatory Fitness and Performance (REFIT) Evaluation of Directive 98/83/EC was performed⁹. It became apparent from that exercise that certain provisions of Directive 98/83/EC needed to be updated. Four areas were identified as offering scope for improvement, namely the list of quality-based parametric values, the limited reliance on a risk-based approach, the imprecise provisions on consumer information, and the disparities between approval systems for materials in contact with water intended for human consumption and the implications this has for human health. In addition, the European citizens' initiative on the right to water identified as a distinct problem the fact that part of the population, marginalised groups, has no access to water intended for human consumption, which is also a commitment under Sustainable Development Goal 6 of UN Agenda 2030. A final issue identified is the general lack of awareness of water leakages, which are driven by underinvestment in maintenance and renewal of the water infrastructure, as also pointed out in the European Court of Auditors' Special Report on water infrastructure¹⁰.

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⁸ COM(2014) 177 final

⁹ SWD(2016) 428 final

Special report of the European Court of Auditors SR 12/2017: "Implementing the Drinking Water Directive: water quality and access to it improved in Bulgaria, Hungary and Romania, but investment needs remains substantial".

(5) The World Health Organisation (WHO) Regional Office for Europe conducted a detailed review of the list of parameters and parametric values laid down in Directive 98/83/EC in order to establish whether there is a need to adapt it in light of technical and scientific progress. In view of the results of that review¹¹, enteric pathogens and *Legionella* should be controlled, six chemical parameters or parameter groups should be added. For four of the six new parameters, parametric values that are more stringent than the ones proposed by the WHO, yet still feasible, should be laid down in light of other recent scientific opinions and the precautionary principle. For one of the new parameters the number of representative substances has been reduced and the value adapted. For chromium, the value remains under WHO review; therefore, a transitional period of fifteen years should apply before the values becomes more stringent. In addition, the WHO recommended that three representative endocrine disrupting compounds may be considered as benchmarks, for assessing their occurrence and treatment efficacy where necessary, with values of 0.1 µg/l for Bisphenol A, 0.3 µg/l for nonylphenol and 1 ng/l for Beta-estradiol. However, based on a 2015 EFSA Opinion, it was decided that one of these three compounds, Bisphenol A, should be added to this Directive with a health-based parametric value of 2.5 µg/l. Furthermore, nonylphenol and beta-estradiol should be added to the watch list, to be set up by the Commission.

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Drinking Water Parameter Cooperation Project of the WHO Regional Office for Europe "Support to the revision of Annex I Council Directive 98/83/EC on the quality of water intended for human consumption (Drinking Water Directive) Recommendation", 11

- (5aa) For lead, the WHO recommended to retain the current parametric value, but noted that concentrations should be as low as reasonably practical. Therefore, the current value of 10 μg/l can be retained for 15 years after the entry into force of this Directive. After this transitional period at the latest, the parametric value should be 5 μg/l. In addition, since existing lead pipes in houses and buildings are a persisting issue for which Member States do not always have the necessary authority to impose the replacement of lead pipes, the value of 5 μg/l should remain aspirational when it comes to obligations related to the domestic distribution systems. However, for all new materials in contact with drinking water, regardless of whether they are to be used in supply or domestic distribution systems, to be authorised in accordance with this Directive, the value of 5 μg/l should apply at the tap.
- (5a) In order to address growing public concern about the effects of emerging compounds on human health through water intended for human consumption (such as endocrine disruptors, pharmaceuticals and microplastics) and to address new emerging compounds in the supply chain, a watch list mechanism should be introduced in this Directive. The watch list mechanism will allow to respond to growing concerns in a dynamic and flexible way. It will also allow to follow up on new knowledge about their relevance for human health and new knowledge on the most appropriate monitoring approaches and methodologies. This watch list mechanism for water intended for human consumption is part of the response to different relevant Union-policies, such as the Commission Communication "European Union Strategic approach to pharmaceuticals in the environment" the Commission Communication "Towards a comprehensive European Union framework on endocrine disruptors" and the Council Conclusions "Towards a sustainable chemicals policy Strategy of the Union" of 26 June 2019.

¹² COM(2019) 128 final

¹³ COM(2018) 734 final

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- (6) The WHO also recommended that three parametric values be made less stringent and five parameters be removed from the list. Nevertheless, not all of these changes are considered necessary as the risk-based approach introduced by Commission Directive (EU) 2015/1787¹⁵ allows water suppliers to remove a parameter from the list to be monitored under certain conditions. Treatment techniques to meet those parametric values are already in place.
- (6a) The parametric values are based on the scientific knowledge available and the precautionary principle and are selected to ensure that water intended for human consumption can be consumed safely on a life-long basis, thus ensuring a high level of health protection.
- (6aa) A balance should be struck to prevent both microbiological and chemical risks and to that end, in the light of a future review of the parametric values, the establishment of parametric values applicable to water intended for human consumption should be based on public-health considerations and on a method of assessing risk.
- (6b) Indicator parameters have no direct public-health impact. However, they are important as a means of determining how water production and distribution facilities are functioning and of evaluating water quality. They can help to identify water treatment deficiencies and they also play an important role in increasing and maintaining consumer confidence in water quality. Therefore, they should be monitored by Member States.
- (7) Where necessary to protect human health within their territories, Member States should be required to set values for additional parameters not included in Annex I, based on the precautionary principle.

¹⁵ Commission Directive (EU) 2015/1787 of 6 October 2015 amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption (OJ L 260, 7.10.2015, p. 6).

(7a) Safe water intended for human consumption means not only absence of harmful microorganisms and substances, but also the presence of certain amounts of natural minerals and essential elements, taking into consideration that long-term consumption of demineralized water or water very low in essential elements such as calcium and magnesium may compromise human health. Certain amount of these minerals is also vital in order to ensure the water is neither aggressive nor corrosive and to improve taste of water. Minimum concentrations of these minerals in softened or demineralised water could be considered in accordance with local conditions.

Preventive safety planning and risk-based elements were only considered to a limited extent in Directive 98/83/EC. The first elements of a risk-based approach were already introduced in 2015 with Directive (EU) 2015/1787, which amended Directive 98/83/EC so as to allow Member States to derogate from the monitoring programmes they have established, provided credible risk assessments are performed, which may be based on the WHO's Guidelines for Drinking Water Quality¹⁶. Those Guidelines, laying down the so-called "Water Safety Plan" approach, including for small communities¹⁷, together with standard EN 15975-2 concerning security of drinking water supply, are internationally recognised principles on which the production, distribution, monitoring and analysis of parameters in water intended for human consumption are based. They should be maintained in this Directive. To ensure that those principles are not limited to monitoring aspects, to focus time and resources on risks that matter and on cost-effective source measures, and to avoid analyses and efforts on nonrelevant issues, it is appropriate to introduce a complete risk-based approach to water safety, that covers the whole supply chain, from the catchment area, abstraction, treatment, storage and distribution to the point of compliance. That approach should be based on the knowledge gained and actions carried out under Directive 2000/60/EC and should take into account more effectively the impact of climate change on water resources. The risk-based approach should consist of three components: first, an of the hazards associated with the catchment area(s) for the abstraction points ("risk assessment and risk management of the catchment area(s) for the abstraction points"), in line with the WHO's Guidelines and Water Safety Plan Manual¹⁸; second, a possibility for the water supplier to adapt monitoring to the main risks and take the necessary measures to manage the risks identified in the supply chain from the abstraction, treatment, storage and distribution of water ("risk assessment and risk management for the supply system"); and third, an assessment of the possible risks stemming from the domestic distribution systems (e.g. Legionella or lead) ("risk assessment and risk management for domestic distribution system"), with special focus on priority premises. Those assessments should be regularly reviewed, *inter alia*, in response to threats from climate-related extreme

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Guidelines for drinking water quality, Fourth Edition, World Health Organisation, 2011 http://www.who.int/water_sanitation_health/publications/2011/dwq_guidelines/en/index.html

http://www.euro.who.int/__data/assets/pdf_file/0004/243787/Water-safety-plan-Eng.pdf; https://apps.who.int/iris/bitstream/handle/10665/75145/9789241548427_eng.pdf; jsessionid=2F74141084126319713559E5F4E854C2?sequence=1

Water Safety Plan Manual: step-by-step risk management for drinking water suppliers, World Health Organisation, 2009, http://apps.who.int/iris/bitstream/ 10665/75141/1/9789241562638 eng.pdf.

weather events, known changes of human activity in the abstraction area or in response to source-related incidents. The risk-based approach ensures a continuous exchange of information between competent authorities and water suppliers.

In order to reduce the potential administrative burden for the water suppliers supplying between 10 m³ and 100 m³ per day as an average or serving between 50 and 500 people, Member States should have the possibility to exempt them from performing a supply risk assessment provided that a regular monitoring in accordance with Article 11 is carried out. As an exception, the implementation of the risk-based approach should be adapted to the specific constraints of maritime vessels that desalinate water and carry passengers. European flag maritime vessels comply with the international regulatory framework when sailing in international waters. It must be ensured that priority is given to existing international regulations or internationally acknowledged standards (e.g. the vessel sanitation programme developed by the United States Public Health Service) which are more detailed and more stringent and which apply to ships on international waters.

(9) The risk assessment and risk management of the catchment area(s) for the abstraction point(s) should take a holistic approach to risk assessment and be geared towards reducing the level of treatment required for the production of water intended for human consumption, for instance by reducing the pressures causing the pollution of, or a risk of pollution of, water bodies used for abstraction of water intended for human consumption. To that end, Member States should characterize the catchment area(s) of the abstraction point(s), identify hazards and hazardous events that could deteriorate the quality of water, for instance possible pollution sources associated with those catchment area(s) and, when necessary for the identification of the hazards, monitor pollutants which they identify as relevant (e.g. nitrates, pesticides or pharmaceuticals identified under Directive 2000/60/EC of the European Parliament and of the Council¹⁹), because of their natural presence in the abstraction area (e.g. arsenic), or because of information from the water suppliers (e.g. sudden increase of a specific parameter in raw water). Where surface waters are used for water intended for human consumption, Member States should pay particular attention in their risk assessment to microplastics and endocrinedisrupting substances, such as nonylphenol and beta-oestradiol, and should, where necessary, require water suppliers to also monitor and/or treat those and other parameters included in the watchlist if considered a potential danger to human health. Based on the risk assessment for the catchment area(s) for the abstraction point(s), management measures to prevent or control the risks identified should be taken to ensure the quality of the water intended for human consumption. Where a Member State finds, via the identification of hazards and hazardous events, that a parameter is not present in catchment area(s) for the abstraction point(s) (for instance because that substance never occurs in groundwaters or surface waters), then the Member State should inform the relevant water suppliers and may allow them to decrease the monitoring frequency for that parameter, or remove that parameter from the list of parameters to be monitored, without carrying out a supply risk assessment.

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Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

(10) Directive 2000/60/EC requires Member States to identify water bodies used for the abstraction of water intended for human consumption, monitor them, and take the necessary measures to avoid deterioration in their quality in order to reduce the level of purification treatment required in the production of water that is fit for human consumption. To avoid any duplication of obligations, Member States should, when carrying out the identification of hazards and hazardous event, use available monitoring results obtained under Articles 7 and 8 of Directive 2000/60/EC or other relevant Union legislation, which are representative of the catchment area(s). Nevertheless, in cases where such monitoring data is not available, monitoring of relevant parameters, substances or pollutants could be put in place in order to support the characterization of the catchment area(s) and assess possible risks. Such monitoring should be put in place considering local situations and pollution sources.

(11) The parametric values used to assess the quality of water intended for human consumption are to be complied with at the point where water intended for human consumption is made available to the appropriate user. However, the quality of water intended for human consumption can be influenced by the domestic distribution system. The WHO notes that, in the Union, Legionella causes the highest health burden of all waterborne pathogens. It is transmitted by warm water systems through inhalation, for instance during showering. It is therefore clearly linked to the domestic distribution system. Since imposing a unilateral obligation to monitor all private and public premises for this pathogen would lead to unreasonably high costs, a domestic distribution risk assessment is therefore more suited to address this issue. In addition, the potential risks stemming from products and materials in contact with water intended for human consumption should also be considered in the domestic distribution risk assessment. The domestic distribution risk assessment should therefore include, *inter alia*, focusing monitoring on priority premises, as identified by Member States (such as, hospitals, healthcare institutions, retirement homes, childcare facilities, schools, educational institutions, buildings with a lodging facility, restaurants, bars, sports and shopping centers, leisure, recreational and exhibition facilities, penal institutions and campgrounds), assessing the risks stemming from the domestic distribution system and related products and materials. On the basis of this assessment, Member States should take all necessary measures to ensure, inter alia, that appropriate control and management measures (e.g. in case of outbreaks) are in place, in line with the guidance of the WHO²⁰, and that the migration from construction products does not endanger human health.

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[&]quot;Legionella and the prevention of Legionellosis", World Health Organisation, 2007, http://www.who.int/water_sanitation_health/emerging/legionella.pdf

(12) The provisions of Directive 98/83/EC on quality assurance of treatment, equipment and materials did not succeed to create a uniform way to ensure hygienic requirements for products in contact with water intended for human consumption. As a result, national product approvals are in place, with different requirements from one Member State to another. This renders it difficult and costly for manufacturers to market their products all over the Union and it is costly for Member States as well. It also makes it difficult for consumers and drinking water companies to know if products meet health requirements. Establishing harmonised minimum requirements for materials in contact with water intended for human consumption in this Directive will contribute to reaching a uniform level of health protection throughout the EU, as well as a better functioning of the internal market. Moreover, Regulation 2019/1020 lays down a general Union-wide market surveillance mechanism for products, with a view to ensuring that only compliant products that fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety in the workplace, the protection of consumers, the protection of the environment and public security are made available on the Union market. That Regulation states that if new Union harmonisation legislation is adopted in the future, it will be for that legislation to specify whether Regulation 2019/1020 is also to apply to that legislation. In order to ensure that proper market surveillance measures may be taken as regards products that are not already covered by Regulation 2019/1020 but which would be affected by this Directive, it is therefore appropriate to provide for the application of that Regulation to those products.

(12a) The nature of materials in contact with water intended for human consumption can have an impact on quality of such water by migration of potentially harmful substances, enhancing microbial growth or by influencing odour, colour or taste of such water. The evaluation of Directive 98/83/EC found that the Article on quality assurance of treatment, equipment and materials provided too much legal flexibility that led to different national approval systems of materials that come into contact with water intended for human consumption across the EU territory. Therefore, there is a need to establish more specific minimum hygiene requirements for materials that are intended to be used for the abstraction, treatment or distribution of water intended for human consumption in new installations or in existing installations in case of repair works or reconstruction or new installations in order to ensure that they do not compromise either directly or indirectly human health, affect adversely the colour, odour or taste of the water, enhance microbial growth in the water or leach contaminants into the water at levels that are higher than necessary in view of the intended purpose. For this purpose, this Directive should set out minimum hygiene requirements for materials, by establishing assessment methodologies, a European positive list of starting substances, compositions or constituens, methods and (administrative) procedures for adding to or reviewing starting substances or compositions to the European positive list, and procedures and methods for testing final materials as used in a product made from combinations of starting substance, compositions or constituents on the European positive list. In order not to hamper innovation, the Commission should ensure that these procedures are proportionate, without creating undue burden to the economic operators, in particular the SMEs. To the extent possible, these procedures should be aligned with the existing Union product legislation, in order to avoid double burden obliging economic operators to carry out different conformity assessments for the same product.

(12aa) The European positive list is the list of starting substances, compositions or constituents, depending on the type of materials (organic, cementitious, metallic, enamels and ceramic or other inorganic materials) authorised to be used for manufacturing of materials, including, where appropriate, conditions for their use and migration limits. For the inclusion of a starting substance or composition in the European positive list, a risk assessment of the starting substance itself, relevant impurities and foreseeable reaction and degradation products in the intended use is required. The risk assessment by the applicant or national authority should cover health risks arising from the potential migration under worst foreseeable conditions of use and the toxicity. Based on the risk assessment the European positive list should, if necessary, set out specifications for the starting substance, composition or constituent and restrictions of use, quantitative restrictions or migration limits for the starting substance, possible impurities and reaction products or constituents to ensure the safety of the final material to be used in product in contact with water intended for human consumption. For the purpose of establishing the first European Positive list, national positive lists of starting substances and compositions or other national provisions, the methodologies that led to the establishment of such national lists and provisions, and the accompanying risk assessments for each of the starting substances and compositions should be made available to the European Chemicals Agency set up under Regulation (EC) No 1907/2006 ('the Agency'). The Agency should, on that basis, recommend a compiled list to the Commission. The Agency should review and deliver an opinion on the substances, compositions and constituents on the first European positive list in time for the Commission to review the list by 15 years after its adoption. For the purposes of updating the European positive list the Agency should deliver opinions on the inclusion or removal of substances and compositions.

In order to facilitate uniform compliance testing of products with the requirements of this Directive the Commission should request CEN to develop standards for uniform testing and assessment of products in contact with water intended for human consumption. When establishing and updating the European positive list, the Commission should ensure that any relevant acts or standardisation mandates, which it adopts pursuant to other Union legislation are consistent with the requirements of this Directive.

Furthermore, no later than 9 years after the date of transposition of this Directive, the functioning of this system should be reviewed in order to assess whether the protection of human health is ensured throughout the Union and whether the functioning of the internal market in terms of products in contact with water intended for human consumption using approved materials is properly ensured. In addition, it should be assessed whether any further legislative proposal on the matter is needed, taking into account in particular the outcome of the evaluations of Regulation (EU) No 1935/2004²¹ and Regulation (EU) No 305/2011.

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Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

- (12ab) Products in contact with water intended for human consumption should consist of a material or a combination of materials approved in accordance with this Directive. However, this Directive only addresses the health and hygiene aspects of materials and substances used in products with regards to their impact on the quality of water intended for human consumption, and the rules for conformity testing and quality control of the final products. It does not address other requirements such as rules on how to express the performance or rules on structural safety, which may be regulated or stem from provisions adopted under Union harmonisation legislation, such as Regulation (EU) No 305/2011 or Regulation (EU) 2016/426. The coexistence of health and hygiene risk aspects harmonised under this Directive and safety or other risk aspects addressed under Union harmonisation legislation would not create any conflicts provided that there is no overlap in the risks covered respectively. A potential conflict between Regulation (EU) No 305/2011 and this Directive exists, given that Annex I, point 3(e) of Regulation (EU) No 305/2011 lists "the release of dangerous substances into drinking water or substances which have an otherwise negative impact on drinking water" as one of the basic requirements for construction works. However, this overlap will not materialise if no standardisation mandate is issued under Regulation (EU) No 305/2011 concerning the health and hygiene aspects of products in contact with water intended for human consumption.
- (12ac) There is a need to ensure effective decision-making, coordination and management of the technical, scientific and administrative aspects of this Directive related to materials in contact with water at Union level. The Agency should carry out specified tasks with regard to the evaluation of substances and compositions for materials in contact with water.

 Consequently, the Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 should facilitate the carrying out of certain tasks conferred on the Agency by this Directive by providing opinions.

(12b) Treatment chemicals and filter media could be used to treat the raw water in order to obtain a water which is suitable for human consumption. However, treatment chemicals and filter media may present risks for drinking water safety. Therefore, procedures for the treatment and disinfection of water intended for human consumption should ensure the use of treatment chemicals and filter media that are effective, safe and properly managed to avoid adverse effects on consumer health. In this perspective treatment chemicals and filter media need to be assessed with regard to their characteristics, hygienic requirements, and purity and should not be used more than necessary to avoid risks for human health. Treatment chemicals should not enhance the microbial growth except where it is intended (e.g. for enhancement of microbial denitrification). Member States should guarantee the quality assurance of treatment chemicals and filter media without prejudice to Regulation (EU) No 528/2012 and using existing EN standards when available.

It is essential to ensure that each product, as well as containers of chemical reagents and filter media, in contact with drinking water placed on the market bear clearly legible and indelible marking informing consumers, water suppliers, installers, authorities and regulators that the item is fit for use in contact with drinking water (according to the required conditions).

Moreover, in accordance with Article 2(7) of Regulation (EU) No 528/2012 Member States should be allowed to restrict or ban the use of biocidal products in the supply of drinking water to the public, including in individual supplies.

- (12c) With the aim to minimise the potential presence of lead content in water intended for human consumption, components made of lead in domestic distribution systems can be substituted, in particular in case of repair or reconstruction works in existing installations. These components should be substituted by materials which comply with the minimum requirements for materials that come into contact with water as established by this Directive. In order to accelerate this process, Member States should consider, and take where relevant, measures for the substitution of components made of lead in existing domestic distribution systems if economically and technically feasible.
- (13) Each Member State should ensure that monitoring programmes are established to check that water intended for human consumption meets the requirements of this Directive. Most of the monitoring carried out for the purposes of this Directive is performed by water suppliers. A certain flexibility should be granted to water suppliers as regards the parameters they monitor for the purposes of the risk assessment and risk management of the supply system. If a parameter is not detected, water suppliers should be able to decrease the monitoring frequency or stop monitoring that parameter altogether. The risk assessment of the supply system should be applied to most parameters. However, a core list of parameters should always be monitored with a certain minimum frequency. This Directive mainly sets provisions on monitoring frequency for the purposes of compliance checks and only limited provisions on monitoring for operational purposes. Additional monitoring for operational purposes may be necessary to ensure the correct functioning of water treatment, at the discretion of water suppliers. In that regard, the water suppliers may refer to the WHO's Guidelines and Water Safety Plan Manual.
- (14) The risk-based approach should be applied by all water suppliers, including small water suppliers, as the evaluation of Directive 98/83/EC showed deficiencies in its implementation by those suppliers, which were sometimes due to the cost of performing unnecessary monitoring operations. When applying the risk-based approach, security concerns should be taken into account.

- (15) In the event of non-compliance with the standards imposed by this Directive the Member State concerned should immediately investigate the cause and ensure that the necessary remedial action is taken as soon as possible to restore the quality of the water. In cases where the water supply constitutes a potential danger to human health, the supply of such water should be prohibited or its use restricted. In addition, in the event of failure to meet the minimum requirements for values relating to microbiological and chemical parameters, Member States should consider the failure as a potential danger to human health except where the non-compliance is considered trivial. In cases where remedial action is necessary to restore the quality of water intended for human consumption, in accordance with Article 191(2) of the Treaty, priority should be given to action which rectifies the problem at source.
- (16) Member States should be authorised, under certain conditions and in duly justified circumstances, to continue to grant derogations from this Directive and in this regard it is necessary to establish a proper framework for such derogations, provided that they must not constitute a potential danger to human health and provided that the supply of water intended for human consumption in the area concerned cannot otherwise be maintained by any other reasonable means. Those derogations should be limited to specific cases. Derogations granted by Member States pursuant to Article 9 of Directive 98/83/EC and still applicable at the end-date for transposition of this Directive should continue to apply until the end of the derogation and renewed under this Directive only where the second derogation has not yet been granted.

- (17) The Commission, in its reply to the European citizens' initiative 'Right2Water' in 2014²², invited Member States to ensure access to a minimum water supply for all citizens, in accordance with the WHO recommendations. It also committed to continue to "improve access to safe drinking water [...] for the whole population through environmental policies"23. This is in line with UN Sustainable Development Goal 6 and the associated target to "achieve universal and equitable access to safe and affordable drinking water for all". To address the aspects of access to water which are related to quality and availability and as part of the reply to the European citizens' initiative and to contribute to the implementation of Principle 20 of the European Pillar of Social Rights²⁴ that states that "everyone has the right to access essential services of good quality, including water", Member States should tackle the issue of access to water at national level whilst enjoying some discretion as to the exact type of measures to be implemented. This should be done through actions aimed at improving access to water intended for human consumption for all, -notably by setting up indoors and outdoors equipment in public spaces where technically feasible, and it could also be done through actions aimed at promoting the use of tap water, for example, by encouraging the free provision of water intended for human consumption in public buildings or, for free or for a low service fee, for customers in restaurants, canteens, and catering services.
- (17a) The Union and the Member States have committed themselves, within their respective competences, to the Sustainable Development Goals, whilst recognising the primary responsibility of Member States in the follow-up and review at national, regional and global levels of progress towards the SDGs. Some of the SDGs and the right to water do not fall within the Union's environment policy or the Union's social policy, which is limited and complementary in nature. Whilst bearing in mind the limits of Union competence, it is nevertheless appropriate to ensure that Member States' continued commitment to the right to water should be in accordance with this Directive, whilst respecting the principle of subsidiarity.

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²² COM(2014)177 final

²³ COM(2014)177 final, p. 12

Interinstitutional Proclamation on the European Pillar of Social Rights (2017/C 428/09) of 17 November 2017 (OJ C 428, 13.12.2017, p. 10).

equitable access to all.

https://www.unece.org/env/water/publications/ece_mp.wh_6.html

In this regard, Member States currently undertake considerable efforts to improve access to

water intended for human consumption. In addition, the UNECE and WHO Regional Office

Member States are also parties to aim to protect human health by better water management

documents developed under the remit of this Protocol to assess the policy background²⁵ and

for Europe Protocol on Water and Health of the UNECE Water Convention that many

and by reducing water-related diseases. Member States could make use of the guidance

the baseline situation on access to water²⁶ and define the necessary actions²⁷ to improve

https://www.unece.org/env/water/publications/ece_mp.wh_8.html

https://www.unece.org/environmental-policy/conventions/water/envwaterpublicationspub/brochuresabout-the protocol-on-water-and-health/2016/guidance-note-on-the-development-of-action-plans-toensure-equitable-access-to-water-and-sanitation/doc.html

- (18) The European Parliament, in its Resolution on the "follow-up to the European citizens' initiative Right2Water" requested that Member States should pay special attention to the needs of vulnerable groups in society" The specific situation of minority cultures, such as such as Roma and Travellers, whether sedentary or not in particular their lack of access to drinking water was also acknowledged in the Commission Report on the implementation of the EU Framework for National Roma Integration Strategies and the Council Recommendation on effective Roma integration measures in the Member States In light of that general context, it is appropriate that Member States pay particular attention to vulnerable and marginalised groups by taking the necessary measures to improve access to water for those groups. Without prejudice to the right of the Member States to define those groups, it would be important that such groups include refugees, nomadic communities, homeless people and minority cultures such as Roma and Travellers, whether sedentary or not. Such measures to improve access, left to the appreciation of the Member States, might for example include providing alternative supply systems (individual treatment devices), providing water via tankers (trucks and cisterns) and ensuring the necessary infrastructure for camps.
- (19) In order to make consumers more aware of the implications of water consumption, they should receive information in an easily accessible manner, for instance on their invoice or by smart application on the volume consumed per year, changes in consumption, a comparison with average household consumption, where such information is available to the water supplier, as well as on the price per litre of water intended for human consumption, thereby allowing a comparison with the price of bottled water.

²⁸ P8 TA(2015)0294

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²⁹ P8_TA(2015)0294, paragraph 62

³⁰ COM(2014) 209 final

Council Recommendation (2013/C 378/01) of 9 December 2013 on effective Roma integration measures in the Member States (OJ C 378, 24.12.2013, p. 1).

(20) The 7th Environment Action Programme to 2020 'Living well, within the limits of our planet'³², requires that the public have access to clear environmental information at national level. Directive 98/83/EC only provided for passive access to information, meaning that Member States merely had to ensure that information was available. Those provisions should therefore be replaced to ensure that up-to-date information should be accessible to consumers on-line, in a user-friendly and customised way. Consumers should also be able to request access to this information by other means, upon justified request.

The up-to-date information should include results from the monitoring programmes, types of water treatment and disinfection applied, information on exceedance of the parametric values relevant for human health, relevant information on risk assessment and risk management of the supply system, advice on how to reduce water consumption and avoid health risks due to stagnant water, but also additional information that the public may find useful, such as information on indicators (iron, hardness, minerals, etc.), which often influence consumers' perception of tap water. In addition, as a response to consumers interests on water issues, they should be given access, upon request, to available historical data on monitoring results and exceedances.

For water suppliers supplying at least 10 000 m3 per day or serving at least 50 000 people, additional information on, *inter alia*, performance efficiency, leakage rates, ownership structure and tariff structure, should also be available on-line. The purpose of better consumer knowledge of relevant information and improved transparency should be to increase citizens' confidence in the water supplied to them, as well as in water services, and should lead to an increased use of tap water as drinking water, which could contribute to reduced plastic usage and litter and greenhouse gas emissions, and a positive impact on climate change mitigation and the environment as a whole.

Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' (OJ L 354, 28.12.2013, p. 171).

- (21) With the improvement of monitoring techniques, leakage rates have become increasingly apparent. To improve the efficiency of water infrastructure including to avoid over exploitation of scarce resources of water intended for human consumption, water leakage levels should be assessed by all Member States and reduced in case they are above a certain threshold.
- (22) Directive 2003/4/EC of the European Parliament and of the Council³³ aims at guaranteeing the right of access to environmental information in the Member States in line with the Aarhus Convention. It encompasses broad obligations related both to making environmental information available upon request and actively disseminating such information. Directive 2007/2/EC of the European Parliament and of the Council³⁴ is also of broad scope, covering the sharing of spatial information, including data-sets on different environmental topics. It is important that provisions of this Directive related to access to information and data-sharing arrangements complement those Directives and do not create a separate legal regime.

 Therefore, the provisions of this Directive on information to the public and on information on monitoring of implementation should be without prejudice to Directives 2003/4/EC and 2007/2/EC.

Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1).

- (23) Directive 98/83/EC did not set out reporting obligations for small water suppliers. To remedy this, and to address the need for implementation and compliance information, a new system should be introduced, whereby Member States are required to set up, keep up-to-date and make accessible to the Commission and the European Environmental Agency data sets containing only relevant data, such as exceedances of parametric values and incidents of a certain significance. This should ensure that the administrative burden on all entities remains as limited as possible. To ensure the appropriate infrastructure for public access, reporting and data-sharing between public authorities, Member States should base the data specifications on Directive 2007/2/EC and its implementing acts.
- (24) Data reported by Member States is not only necessary for the purposes of compliance checking but is also essential to enable the Commission to monitor and assess the performance of the legislation against the objectives it pursues in order to inform any future evaluation of the legislation in accordance with paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016³⁵. In that context, there is a need for relevant data that will allow better assessment of the efficiency, effectiveness, relevance, and EU value added of the Directive, hence the necessity to ensure appropriate reporting mechanisms that can also serve as indicators for future evaluations of this Directive.
- (25) Pursuant to paragraph 22 of the Interinstitutional Agreement on Better Law-Making, the Commission should carry out an evaluation of this Directive within a certain period of time from the date set for its transposition. That evaluation should be based on experience gathered and data collected during the implementation of the Directive, on any available WHO recommendations, and on relevant scientific, analytical and epidemiological data.

³⁵ OJ L 123, 12.5.2016, p. 1.

(26) This Directive respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union. In particular, this Directive seeks to promote the principles relating to health care, access to services of general economic interest, environmental protection and consumer protection.

(27) The effectiveness of this Directive and its aim of protection of human health in the context of the Union's environment policy, requires that natural or legal persons or, where appropriate their duly constituted organisations, be able to rely on it in legal proceedings and that the national courts be able to take that Directive into consideration as an element of Union law in order, inter alia, to review decisions of a national authority where appropriate. In addition, according to settled case-law of the Court of Justice, under the principle of sincere cooperation laid down in Article 4(3) TEU, it is for the courts of the Member States to ensure judicial protection of a person's rights under Union law, Article 19(1) TEU additionally requiring Member States to provide remedies sufficient to ensure effective judicial protection in the fields covered by Union law. This applies particularly in respect of a Directive which has the objective of protecting human health from the adverse effects of any contamination of water intended for human consumption. In addition, in accordance with the Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters³⁶, members of the public concerned should have access to justice in order to contribute to the protection of the right to live in an environment which is adequate for personal health and well-being. By Council Decision 2018/881 of 18 June 2018³⁷, the Commission was requested to carry out a study by 30 September 2019, and if appropriate in light of the study, submit by 30 September 2020 a proposal to amend Regulation (EC) No 1367/2006³⁸ in order to address the findings of the Aarhus Convention Compliance in case ACCC/C/2008/32. The Commission submitted the study by that deadline, and stated, in its Communication on the European Green Deal of 11 December 2019³⁹, that it "will consider revising the Aarhus Regulation to improve access to administrative and judicial review at EU level for citizens and NGOs who have concerns about the legality of decisions with effects on the environment". It is important that the Commission also takes action to improve access to justice of citizens and NGOs before national courts in all Member States.

³⁶ OJ L 124, 17.5.2005, p. 4.

Council Decision (EU) 2018/881 of 18 June 2018 requesting the Commission to submit a study on the Union's options for addressing the findings of the Aarhus Convention Compliance Committee in case ACCC/C/2008/32 and, if appropriate in view of the outcomes of the study, a proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1367/2006 (OJ L 155, 19.6.2018, p. 6).

Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies

³⁹ COM(2019) 640 final

(28) In order to adapt this Directive to scientific and technical progress or to specify monitoring requirements for the purposes of the hazard and domestic distribution risk assessments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to set a threshold for leakages, determine the conformity assessment procedure for products in contact with water intended for human consumption, lay down a procedure for applications to the Agency to add or remove substances from the positive lists, establish a marking for products in contact with water, adopt a methodology to measure microplastics, amend Annex III and to amend the parametric value for Bisphenol A in Annex I, part B. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. In addition, the empowerment laid down in Annex I, part C, Note 10, of Directive 98/83/EC, to set monitoring frequencies and monitoring methods for radioactive substances has become obsolete due to the adoption of Council Directive 2013/51/Euratom⁴⁰ and should therefore be deleted. The empowerment laid down in the second subparagraph of part A of Annex III to Directive 98/83/EC concerning amendments of the Directive is no longer necessary and should be deleted.

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Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ L 296, 7.11.2013, p. 12).

- (29) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission for the adoption of methodologies for testing and accepting substances, European positive lists of substances and of procedures and methods for final materials made from those substances. They should also be conferred on the Commission for the adoption of the format of, and modalities to present, the information to be provided by Member States and compiled by the European Environmental Agency on the implementation of this Directive, as well as to establish and update a watch list. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁴¹.
- (30) Without prejudice to the requirements of Directive 2008/99/EC of the European Parliament and of the Council⁴², Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. The penalties should be effective, proportionate and dissuasive.

Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law (OJ L 328, 6.12.2008, p. 28).

- (30a) In order for water suppliers to have a full set of data available when they start applying the supply risk assessment, a transition period of 3 years should be introduced for new parameters. This will allow Member States to carry out the identification of hazards and hazardous events during those first 3 years after the end-date for the transposition of this Directive, thereby already providing data to water suppliers on these new parameters, and avoiding any unnecessary monitoring by water suppliers, if it is found that a parameter does not need to be monitored via this first identification of hazards and hazardous events. During those initial 3 years, water suppliers should nevertheless carry out the suppply risk assessment (or use existing risk assessments already carried out under Directive (EU) 2015/1787) for those parameters that were part of Annex I to Directive 98/83/EC, given that data will already be available for those parameters when this Directive enters into force.
- (31) Directive 2013/51/Euratom lays down specific arrangements for the monitoring of radioactive substances in water intended for human consumption. Therefore, this Directive should not set out parametric values on radioactivity.
- (32) Since the objective of this Directive, namely the protection of human health, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.
- (33) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directives. The obligation to transpose the provisions which are unchanged arises under the earlier Directives.
- (34) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law of the Directives set out in Annex V, Part B.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Objective

- 1. This Directive concerns the quality of water intended for human consumption for all in the Union.
- 2. The objective of this Directive shall be to protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean, and to improve access to water intended for human consumption.

Article 2

Definitions

For the purposes of this Directive:

- 1. 'water intended for human consumption' shall mean:
 - a) all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes in both public and private premises, regardless of its origin and whether it is supplied from a distribution network, supplied from a tanker or-put in bottles or containers, including spring waters;
 - b) all water used in any food business for the manufacture, processing, preservation or marketing of products or substances intended for human consumption.
- 2. 'domestic distribution system' shall mean the pipework, fittings and appliances which are installed between the taps that are normally used for human consumption in both public and private premises and the distribution network but only if they are not the responsibility of the water supplier, in its capacity as a water supplier, according to the relevant national law.

- 3. 'water supplier' shall mean an entity supplying water intended for human consumption.
- 7. 'priority premises' shall mean large non-household premises with many users potentially exposed to water-related risks, in particular large premises for public use, as identified by Member States.
- 8a. 'food business' shall mean a food business as defined in point (2) of Article 3 of Regulation (EC) No 178/2002.
- 9. 'food business operator' shall mean food business operator as defined in Article 3 (3) of Regulation 178/2002.
- 10. 'hazard' shall mean a biological, chemical, physical or radiological agent in the water, or another aspect of condition of water, with the potential to cause harm to human health.
- 11. 'hazardous event' shall mean an event that introduces hazards to, or fails to remove them from, the supply system of water intended for human consumption.
- 12. 'risk' shall mean a combination of the likelihood of a hazardous event and the severity of consequences, if the hazard and hazardous event occur in the supply system of water intended for human consumption.

Article 3

Exemptions

- 1. This Directive shall not apply to:
 - (a) natural mineral waters recognised as such by the responsible authority, as referred to in Directive 2009/54/EC;

- (b) waters which are medicinal products within the meaning of Directive 2001/83/EC.
- 1c. Maritime vessels that desalinate water, carry passengers and act as water suppliers shall only be subject to Articles 1, 2, 3, 4, 5, 6, 9, 10, 11 and 12 of this Directive and its relevant Annexes.
- 2. Member States may exempt from the provisions of this Directive:
 - (a) water intended exclusively for those purposes for which the competent authorities are satisfied that the quality of the water has no influence, either directly or indirectly, on the health of the consumers concerned;
 - (b) water intended for human consumption from an individual supply providing less than 10 m³ a day as an average or serving fewer than 50 persons, unless the water is supplied as part of a commercial or public activity.
- 3. Member States that have recourse to the exemptions provided for in paragraph 2(b) shall ensure that the population concerned is informed thereof and of any action that can be taken to protect human health from the adverse effects resulting from any contamination of water intended for human consumption. In addition, when a potential danger to human health arising out of the quality of such water is apparent, the population concerned shall promptly be given appropriate advice.
- 4. Member States may exempt food business operators from the provisions of this Directive, as regards the water used for the specific purposes of the food business, if the competent national authorities are satisfied that the quality of that water cannot affect the safety of the foodstuff in its finished form and provided their water supply complies with relevant obligations in particular under the procedures on hazard analysis and critical control point principles and remedial actions under relevant Union legislation on food.

Member States shall ensure that producers of water intended for human consumption that is put in bottles or containers comply with the requirements of Articles 1 to 5 and Annexes I (A) and (B).

However, the minimum requirements set out in Annex I, Part A, do not apply to bottled spring water as referred to in Directive 2009/54/EC.

5. Water suppliers supplying less than 10m3 a day as an average or servicing fewer than 50 persons as part of a commercial or public activity shall only be subject to Articles 1, 2, 3, 4, 5, 6, 11, 12 and 12a of this Directive, as well as relevant Annexes.

Article 4 General obligations

- 1. Without prejudice to their obligations under other Union provisions, Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean. For the purposes of the minimum requirements of this Directive, water intended for human consumption shall be wholesome and clean if it meets all the following conditions:
 - (a) it is free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health;
 - (b) it meets the minimum requirements set out in Annex I, Parts A, B and C;
 - (c) Member States have taken all other measures necessary to comply with the requirements set out in Articles 5 to 12 of this Directive.
- 2. Member States shall ensure that the measures taken to implement this Directive are based on the precautionary principle and in no circumstances have the effect of allowing, directly or indirectly, any deterioration of the present quality of water intended for human consumption or any increase in the pollution of waters used for the production of water intended for human consumption.

2a. In accordance with Directive 2000/60/EC, Member States shall ensure that an assessment of the water leakage levels on their territory and of the potential for improvements in water leakage reduction is performed using the infrastructural leakage index (ILI) rating method or other appropriate method. That assessment shall take into account relevant public health, environmental, technical and economic aspects and cover at least water suppliers supplying at least 10 000 m³ per day or serving at least 50 000 people.

The results of the assessment shall be communicated to the Commission by... [3 years after the end date for the transposition of this Directive].

By... [5 years after the end date for the transposition of this Directive], the Commission shall adopt a delegated act, in accordance with Article 19, setting out a threshold based on ILI or other appropriate method above which Member States are to present an action plan. This delegated act shall be developed using the Member States' assessments and the Union average leakage rate determined on the basis of those assessments.

Member States having a leakage rate exceeding the threshold set out in the delegated act shall present an action plan to the Commission by ... [2 years after the adoption of the delegated act] laying out a set of measures to be taken in order to reduce their leakage rate.

Article 5 Quality standards

- 1. Member States shall set values applicable to water intended for human consumption for the parameters set out in Annex I.
- 1a. The values set pursuant to paragraph 1 shall not be less stringent than those set out in Parts A, B, Ba and C of Annex I. As regards the parameters set out in Part Ba of Annex I, the values shall be set only for monitoring purposes and for the sake of ensuring that the requirements set out in Article 12 are met.

2. A Member State shall set values for additional parameters not included in Annex I where the protection of human health within its national territory or part of it so requires. The values set shall, as a minimum, satisfy the requirements of Article 4(1)(a).

Article 6 Point of compliance

- 1. The parametric values set in accordance with Article 5 for the parameters listed in Annex I, parts A and B, shall be complied with:
 - (a) in the case of water supplied from a distribution network, at the point, within premises or an establishment, at which it emerges from the taps that are normally used for human consumption;
 - (b) in the case of water supplied from a tanker, at the point at which it emerges from the tanker;
 - (c) in the case of water intended for human consumption put into bottles or containers, at the point at which the water is put into the bottles or containers;
 - (d) in the case of water used in a food business, at the point where the water is used in the business.
- 2. In the case of water covered by paragraph 1(a), Member States shall be deemed to have fulfilled their obligations under this Article and under Articles 4 and 12(2) where it can be established that non-compliance with the parametric values set in accordance with Article 5 is due to the domestic distribution system or the maintenance thereof except in priority premises covered by Article 10.

- 3. Where paragraph 2 applies and there is a risk that water covered by paragraph 1(a) would not comply with the parametric values established in accordance with Article 5, Member States shall nevertheless ensure that:
 - (a) appropriate measures are taken to reduce or eliminate the risk of non-compliance with the parametric values, such as advising property owners of any possible remedial action they could take, and if necessary, other measures, such as appropriate treatment techniques, are taken to change the nature or properties of the water before it is supplied so as to reduce or eliminate the risk of the water not complying with the parametric values after supply;

and

(b) the consumers concerned are duly informed and advised of any possible additional remedial action that they should take.

Article 7 Risk-based approach to water safety

1. Member States shall ensure that the supply, treatment and distribution of water intended for human consumption is subject to a risk-based approach that covers the whole supply chain from the catchment area, abstraction, treatment, storage and distribution of water to the point of compliance specified in Article 6.

The risk-based approach shall entail the following elements:

- (a) a risk assessment and risk management of the catchment area(s) for the abstraction point(s) of water intended for human consumption in accordance with Article 8;
- (b) a risk assessment and risk management for each water supply system that includes the abstraction, treatment, storage and distribution of water to the point of supply carried out by the water suppliers in accordance with Article 9;

- (c) a risk assessment for the domestic distribution systems, in accordance with Article 10.
- 1a. Member States may adapt the implementation of the risk-based approach, without compromising the objective of this Directive concerning the quality of water intended for human consumption and the health of consumers, when there are particular constraints due to geographical circumstances such as remoteness or accessibility of water supply zone.
- 1b. Member States shall ensure a clear and appropriate distribution of responsibilities between stakeholders, as defined by the Member States, for the application of the risk-based approach. Such distribution of responsibilities shall be tailored to their institutional and legal framework.
- 2. The first risk assessment and risk management of the catchment area(s) for the abstraction point(s) shall be carried out by [4 and a half years after the end date for the transposition of this Directive]. It shall be reviewed at regular intervals of no longer than 6 years, taking account of the requirement, provided for in Article 7 of Directive 2000/60/EC, and updated where necessary.
- 3. The first risk assessment and risk management for the supply system shall be carried out by [6 years after the end-date for transposition of this Directive]. It shall be reviewed at regular intervals of no longer than 6 years, and updated where necessary.
- 4. The first risk assessment for the domestic distribution systems shall be carried out by [6 years after the end-date for transposition of this Directive]. They shall be reviewed every 6 years, and updated where necessary.
- 5. The deadlines specified in paragraphs 2, 3 and 4 shall not prevent Member States to ensure that measures are taken as soon as possible once the risks are identified and assessed.

Article 8

Risk assessment and risk management of the catchment area(s) for the abstraction point(s) of water intended for human consumption

- 1. Without prejudice to Articles 4 to 8 of Directive 2000/60/EC, Member States shall ensure that a risk assessment and risk management of the catchment area(s) for the abstraction point(s) is performed. It shall include the following elements:
 - (a) characterisation of the catchment area(s) for the abstraction point(s) including:
 - (i) identification and mapping of the catchment area(s) for the abstraction point(s);
 - (ii) mapping of the safeguard zones, where those zones have been established in accordance with Article 7(3) of Directive 2000/60/EC;
 - (iii) geo-references of all abstraction points in the catchment area(s); given that the data referred to in this point are potentially sensitive, in particular in the context of public health and public security, the Member States shall ensure that such data are protected and communicated only to the relevant authorities and water suppliers;
 - (iv) description of land-use, runoff, and recharge processes in the catchment areas(s) for the abstraction point(s).

To that end, Member States may use information collected in accordance to Articles 5 and 7 of Directive 2000/60/EC;

(b) an identification of hazards and hazardous events in the catchment area(s) for the abstraction point(s) and the assessment of the risk they may pose to the quality of water intended for human consumption. The risk assessment shall assess possible risks that might deteriorate the water quality to the extent that it may constitute a risk for human health. To that end, Member States may use the review of the impact of human activity undertaken in accordance with Article 5 of Directive 2000/60/EC and information on significant pressures collected in accordance with points 1.4, 1.5 and 2.3 to 2.5 of Annex II to that Directive;

- (c) appropriate monitoring in surface water and/or groundwater in the catchment area(s) for the abstraction point(s) or in raw water of relevant parameters, substances or pollutants, selected from the following lists:
 - (i) parameters listed in parts A and B of Annex I or established in accordance with Article 5(2) of this Directive;
 - (ii) groundwater pollutants listed in Annex I to Directive 2006/118/EC of the European Parliament and of the Council⁴³, and pollutants and indicators of pollution for which threshold values have been established by Member States in accordance with Annex II to that Directive:
 - (iii) priority substances and certain other pollutants listed in Annex I to Directive 2008/105/EC of the European Parliament and of the Council⁴⁴;
 - (iiia) river basin specific pollutants established by Member States in accordance with Directive 2000/60/EC;
 - (iv) other relevant pollutants for water intended for human consumption established by Member States on the basis of the information collected in accordance with paragraph 1(b) of this Article;
 - (v) naturally occurring substances that may pose a hazard for human health through water intended for human consumption;
 - (vi) substances and compounds included in the watch list as established in accordance with Article 11(7) of this Directive.

Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19).

Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

Member States shall select from points (i) to (vi) for monitoring the parameters, substances or pollutants that are considered relevant in light of the hazards identified under point (b) or in light of the information provided by the water suppliers in accordance with paragraph 2.

For the purpose of appropriate monitoring, including to detect new substances that are harmful to human health through water intended for human consumption, Member States may use the monitoring carried out in accordance with Articles 7 and 8 of Directive 2000/60/EC or other Union legislation relevant to the catchment area(s) for the abstraction point(s).

- 2. Water suppliers that perform monitoring in the catchment area(s) for the abstraction point(s) or in their raw water shall be required to inform the competent authorities of trends and of unusual concentrations of monitored parameters, substances or pollutants.
- 5. On the basis of the outcome of the risk assessment performed in accordance with paragraph 1, Member States shall ensure that measures to prevent or control the risks identified are taken, as relevant, and starting from the preventative measures:
 - (a) defining and implementing preventive measures in the catchment area(s) for the abstraction point(s) in addition to the ones foreseen or taken in accordance to Article 11(3)(d) of Directive 2000/60/EC, where required to ensure the quality of the water intended for human consumption. Where appropriate, those measures shall be included in the programs of measures referred to in Article 11(3) of Directive 2000/60/EC.

Where appropriate, Member States shall ensure that polluters, in cooperation with water suppliers and other relevant stakeholders, take such preventive measures in accordance with Directive 2000/60/EC.

(aa) defining and implementing mitigation measures in the catchment area(s) for the abstraction point(s) in addition to the ones foreseen or taken in accordance to Article 11(3)(d) of Directive 2000/60/EC, where required to ensure the quality of the water intended for human consumption. Where appropriate, those measures shall be included in the programs of measures referred to in Article 11(3) of Directive 2000/60/EC;

Where appropriate, Member States shall ensure that polluters, in cooperation with water suppliers and other relevant stakeholders, take such mitigation measures accordance with Directive 2000/60/EC.

- (b) ensuring appropriate monitoring of parameters, substances or pollutants in surface water and/or groundwater in the catchment area(s) for the abstraction point(s) or in the raw water that may constitute a risk for human health through water consumption or lead to unacceptable deterioration of the quality of water intended for human consumption and that have not been taken into consideration in the monitoring performed in accordance to Article 7 and 8 of Directive 2000/60/EC. Where appropriate, this monitoring shall be included in the monitoring programs referred to in Articles 7 and 8 of Directive 2000/60/EC.
- (c) evaluation of the need for the establishement or adaptation of the safeguard zones for groundwater and surface water, according to Article 7(3) of Directive 2000/60/EC, and any other relevant zones.

Member States shall ensure that the effectiveness of any such measure is reviewed, at appropriate intervals.

5. Member States shall ensure that water suppliers and competent authorities have access to the information specified in paragraphs 1 and 2, and that relevant water suppliers have access to the monitoring results obtained under paragraph 1(c).

On the basis of this information, Member States may:

- (a) require water suppliers to carry out additional monitoring or treatment of certain parameters;
- (b) allow water suppliers to decrease the monitoring frequency of certain parameters, or remove a parameter from the list of parameters to be monitored by the water supplier in accordance with the provisions of Article 11 (2) (a), without being required to carry out a risk assessment of the supply system, provided that:
 - (i) they are not core parameters within the meaning of Annex II, part B, point 1, and
 - (ii) no factor that can be reasonably anticipated is likely to cause deterioration of the quality of the water.
- 5a. Where a water supplier is allowed to decrease the monitoring frequency or remove a parameter, as referred to in paragraph 5 (b), Member States shall ensure appropriate monitoring of those parameters when reviewing the risk assessment and the risk management of the catchment area(s) for the abstraction point(s), in accordance with Article 7(2).

Article 9 Risk assessment and risk management for the supply system

- 1. Member States shall ensure that a risk assessment and risk management for the supply system is performed by the water supplier.
 - 1a. Member States shall ensure that the risk assessment for the supply system:
 - (a) takes into account the results of the risk assessment and risk management carried out in accordance with Article 8 of this Directive;
 - (b) includes a description of the supply system from the abstraction point, treatment, storage and distribution of water to the point of supply;
 - (c) includes an identification of the hazards and hazardous events in the supply system and an assessment of the risks they may pose to the human health through the quality of water intended for human consumption, taking into consideration risks stemming from climate change and leakages and leaking pipes.
 - 1b. On the basis of the outcome of the risk assessment in paragraph 1a, Member States shall ensure that the following risk management measures are taken ("risk management for the supply system"):
 - (a) defining and implementing control measures for the prevention and mitigation of the risks identified in the supply chain system that may compromise the quality of water intended for human consumption;

- (b) defining and implementing control measures in the supply system in addition to the measures taken or foreseen under Article 8(4) of this Directive or under Article 11(3) of Directive 2000/60/EC for the mitigation of risks that may compromise the quality of water intended for human consumption through the catchment area(s) for the abstraction point(s);
- (c) implementing a supply-specific operational monitoring programme according to Article 11;
- (d) ensuring that, where disinfection forms part of the preparation or distribution of water intended for human consumption, the efficiency of the disinfection treatment applied is validated, and that any contamination from disinfection byproducts is kept as low as possible without compromising the disinfection and any contamination from treatment chemicals is kept as low as possible and any substances remaining in the water do not jeopardise the achievement of the general obligations set out in Article 4;
- (e) including a verification of whether materials, treatment chemicals and filter media in contact with water intended for human consumption used in the supply chain are in line with the requirements of Articles 10a and 10b.
- 1c. On the basis of the results of the risk assessment for the supply system, Member States shall:
 - a) allow the possibility for removing a parameter from the list of parameters to be monitored or decreasing the monitoring frequency in the following cases, if the competent authority is satisfied that this does not compromise the quality of water intended for human consumption:
 - (i) on the basis of the occurrence of a parameter in the raw water, in accordance with the risk assessment for the catchment area(s) for the abstraction point(s) as set out in Article 8(3);

- (ii) when a parameter can only result from the use of certain treatment technique or disinfection method, and that technique or method is not used by the water supplier; or
- (iii) on the basis of the specifications set out in Annex II, part C.
- b) ensure the list of parameters to be monitored in the water intended for human consumption in accordance with Article 11 is extended or the monitoring frequency increased in the following cases:
 - (i) on the basis of the specifications set out in Annex II, part C;
 - (ii) on the basis of the occurrence of a parameter in the raw water, in accordance with the risk assessment for the catchment area(s) for the abstraction point(s) as set out in Article 8(3).
- 1d. The supply risk assessment shall concern parameters listed in Annex I, Parts A, B and Ba that are not core parameters according to part B of Annex II, parameters set in accordance with Article 5(2) and substances or compounds included in the watch list established in accordance with Article 11(7).
- 1f. Member States may exempt water suppliers supplying between 10 and 100 m3 per day as an average or serving between 50 and 500 people, from performing the supply risk assessment and management, provided that the competent authority is satisfied that this does not compromise the quality of water intended for human consumption.

In case of such exemption, those water suppliers shall carry out regular monitoring in accordance with Article 11.

Article 10 Risk Assessment for the Domestic Distribution Systems

- 1. Member States shall ensure that a risk assessment for the domestic distribution systems is performed, comprising the following elements:
 - (a) a general analysis of the potential risks associated with domestic distribution systems, and with related products and materials, and whether they affect the quality of water at the point where it emerges from the taps normally used for human consumption. The general analysis does not entail an analysis of individual properties;
 - (b) monitoring of the parameters listed in Annex I, part C, in premises where specific risks to water quality and human health have been identified during the assessment performed under point (a).

For Legionella or lead, Member States may decide to focus the monitoring referred to in point (b) on priority premises.

2. Where Member States conclude, on the basis of the general analysis carried out under paragraph 1(a), that there is a risk to human health stemming from the domestic distribution systems or from the related products and materials, or where monitoring carried out in accordance with paragraph 1(b) demonstrates that the parametric values set out in Annex I, part C, are not met, Member States shall ensure that appropriate measures are taken to eliminate or reduce the risk of non-compliance with the parametric values set out in Part C of Annex I.

For Legionella, those measures shall target at least the priority premises.

- 2a. In order to reduce the risks connected to domestic distribution across all the domestic distribution systems, Member States shall ensure that all of the following measures are considered and that those considered relevant are taken:
 - (a) encourage owners of public and private premises to carry out a domestic distribution risk assessment;
 - (b) inform consumers and owners of public and private premises about measures to eliminate or reduce the risk of non-compliance with the quality standards for water intended for human consumption due to the domestic distribution system;
 - (c) advise consumers about the conditions of consumption and use of the water and about possible action to avoid the risk from reoccurring;
 - (d) promote training for plumbers and other professionals dealing with domestic distribution systems and the installation of construction products and materials in contact with water;
 - (e) for Legionella, ensure that effective control and management measures which are proportionate to the risk are in place to prevent and address possible outbreaks of the disease; and
 - (f) for lead, if economically and technically feasible, implement measures for substitution of components made of lead in existing domestic distribution systems.

Article 10a

Minimum hygienic requirements for materials that come into contact with water intended for human consumption

- 1. For the purposes of Article 4, Member States shall ensure that materials that are intended to be used in new installations or, in case of repair works or reconstruction, in existing installations for abstraction, treatment or distribution of water intended for human consumption and that come into contact with such water do not:
 - (a) directly or indirectly compromise human health protection as provided for by this Directive;
 - (b) adversely affect the colour, odour or taste of the water;
 - (c) enhance microbial growth;
 - (d) leach contaminants into the water at levels that are higher than necessary in view of the intended purpose.
- 2. For the purpose of ensuring the uniform application of paragraph 1, the specific minimum hygiene requirements for materials shall be established through implementing acts to be adopted in accordance with the examination procedure referred to in Article 20 and on the basis of the principles set out in Annex VII laying down:
 - (a) By 3 years after [date of entry into force of this Directive] methodologies for testing and accepting starting substances and compositions to be included in European positive lists of starting substances, compositions or constituents, including substance or material related specific migration limits and scientific pre-conditions;

- (b) By 4 years after [date of entry into force of this Directive], on the basis of lists including expiry dates compiled by the European Chemicals Agency (hereafter 'the Agency'), European positive lists of starting substances, compositions or constituents for each group of materials (organic, cementitious, metallic, enamels, ceramic or other inorganic material) authorized to be used for manufacturing of materials, including, where appropriate, conditions for their use and migration limits, determined on the basis of the uniform methodologies adopted pursuant to subparagraph (a), and taking into account paragraphs 3 and 4;
- (c) By 3 years after [date of entry into force of this Directive], procedures and methods for testing and accepting final materials as used in a product made from materials or combinations of starting substances compositions or constituents on the European positive lists, including:
 - (i) the identification of relevant substances and other parameters (such as turbidity, flavour, odour, colour, total organic carbon, the release of unsuspected substances and enhancement of microbial growth) to be tested in migration water;
 - (ii) test methods on the effects on water quality, having regard to any appropriate EN standards;
 - (iii) pass/fail criteria of the test results which take into account, inter alia, conversion factors of substances migration into levels estimated at the tap, conditions of application or use, where appropriate.

The Commission shall adopt delegated acts in accordance with Article 19 in order to determine the appropriate conformity assessment procedure applicable on the basis of the modules in Annex I to Decision 768/2008/EC. In determining which conformity assessment procedure is to be used, the Commission shall ensure compliance with the objectives referred to in Article 1(2) of this Directive, whilst taking into account the principle of proportionality. For this purpose, the Commission shall take as a starting point the System 1+ of assessment and verification of constancy of performance set out in Annex V of Regulation (EU) No 305/2011, or a broadly equivalent procedure, except where this would be disproportionate. These delegated acts shall also contain rules for the designation of conformity assessment bodies, where such are involved in the respective conformity assessment procedures.

3. The European positive lists shall contain the only substances, compositions or constituents that are authorised to be used for manufacturing of final materials or products in contact with water intended for human consumption, including, where appropriate, conditions for the use of these materials and migration limits, determined on the basis of the uniform methodologies adopted pursuant to point (a) of paragraph 2.

The European positive lists shall contain expiry dates on the basis of a recommendation from the Agency, and may also contain transitional provisions. The expiry dates shall be set in particular on the basis of the hazardous properties of the substances, the quality of the underlying risk assessments, and the extent to which those risk assessments are up-to-date.

On the basis of opinions from the Agency as referred to in paragraph 5, the Commission shall regularly review and update, where necessary, the implementing acts referred to in paragraph 2, point (b), in line with the latest scientific and technological developments.

The first review shall be completed within 15 years after the adoption of the first positive list.

The Commission shall ensure that any relevant acts, including standardisation mandates, which it adopts pursuant to other Union legislation are consistent with the requirements of this Directive.

4. The first European positive lists to be adopted in accordance with paragraph 2(b) shall be based, among others, on existing national positive lists, other existing national provisions and on the risk assessments that led to the establishment of such national lists. For this purpose, Member States shall notify the Agency of any existing national positive lists, other provisions and available assessment document(s) no later than [6 months after entry into force of this Directive].

The European positive list of starting substances for organic materials shall take into account the list established by the Commission pursuant to Article 5 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.

5. The Commission shall adopt delegated acts, in accordance with Article 19, in order to lay down a procedure including information requirements for applications from economic operators, or relevant authorities to include or remove starting substances, compositions or constituents from the European positive lists. These applications shall be submitted to the Agency.

The procedure shall ensure that applications are accompanied by risk assessments and that economic operators or relevant authorities deliver the necessary information for the risk assessment in a specific format.

The Committee for Risk Assessment of the Agency set up pursuant to Article 76(1) (c) of Regulation (EC) No 1907/2006 shall adopt an opinion on any application submitted pursuant to this paragraph within a time limit to be determined by the delegated acts referred to in the first subparagraph. Further procedural provisions on the functioning of the application process and the provision of opinions by the Committee for Risk Assessment and the Agency may also be included in those delegated acts.

6. Member States shall consider that products approved in accordance with specific requirements set out in paragraph 2 satisfy the requirements set out in paragraph 1.

Member States shall ensure that only such products in contact with water intended for human consumption using final materials approved in accordance with this Directive can be placed on the market for the purposes of this Directive.

This shall not prevent Member States, in particular when specific local, raw water quality so requires, from adopting more stringent protective measures for the use of materials in specific or duly justified circumstances, in accordance with Article 193 TFEU. Such measures shall be notified to the Commission.

Regulation 2019/1020 shall apply to products covered by this Article.

- 7. Pending the adoption of rules referred to in paragraph 2, Member States shall be entitled to maintain or adopt national measures on specific minimum hygiene requirements for starting substances or materials referred to in paragraph 1, provided they comply with the rules of the Treaty.
- 8. The Commission shall request one or several European standardisation organisations to draft a European standard for uniform testing and assessment of the products in contact with water intended for human consumption in order to facilitate compliance with this article, in accordance with Article 10 of Regulation (EU) No 1025/2012⁴⁵.

Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

- 10. The Commission shall adopt a delegated act in accordance with Article 19 in order to establish harmonised specifications for a conspicuous, clearly legible and indelible marking for products in contact with water intended for human consumption that shall be used to indicate conformity with this Article.
- 11. The Commission shall, no later than 9 years after the date of transposition of this Directive, based in particular on experience gained with the application of Regulation (EU) No 1935/2004 and Regulation (EU) No 305/2011, review the functioning of the system as set out in this Article and present a report to the European Parliament and the Council assessing whether:
 - (a) the protection of human health is adequately ensured throughout the Union;
 - (b) the proper functioning of the internal market for products in contact with water intended for human consumption is ensured;
 - (c) there is a need for any further legislative proposal on the matter.
- 12. For the national implementation of the requirements of this Article, Article 4 (2) shall apply accordingly.
- 13. For the purpose of this Article:

'starting substance' shall mean an intentionally added substance for the production of organic materials, or of admixtures for cementitious materials;

'composition' shall mean the chemical composition of a metal, enamel, ceramic or other inorganic material.

Article 10b

Minimum requirements for treatment chemicals and filter media that come into contact with water intended for human consumption

- 1. For the purposes of Article 4, Member States shall ensure that treatment chemicals and filter media that come into contact with water intended for human consumption do not:
 - a) directly or indirectly compromise human health protection as provided for by this Directive;
 - b) adversely affect the colour, odour or taste of the water;
 - c) enhance microbial growth unintentionally;
 - d) contaminate the water at levels that are higher than necessary in view of the intended purpose.
- 2. For the national implementation of the requirements of this Article, Article 4 (2) shall apply accordingly.
- 3. Pursuant to paragraph 1, and without prejudice to Regulation 528/2012 and relevant existing EN standards for specific treatment chemicals or filter media, Member States shall ensure that the characteristics and purity of treatment chemicals and filter media is verified and guaranteed.

Article 11 Monitoring

- 1. Member States shall take all measures necessary to ensure that regular monitoring of the quality of water intended for human consumption is carried out in accordance with this Article and Annex II part A and B, in order to check that the water available to consumers meets the requirements of this Directive and in particular the parametric values set in accordance with Article 5. Samples shall be taken so that they are representative of the quality of the water consumed throughout the year.
- 2. To meet the obligations imposed in paragraph 1, appropriate monitoring programmes shall be established in accordance with Annex II, Part A for all water intended for human consumption. Those monitoring programmes shall be supply-specific, taking into account the outcomes of the risk assessment for the catchment area(s) of the abstraction point(s) and for the supply systems, and shall consist of the following elements:
 - (a) monitoring of the parameters listed in Annex I, parts A, B and Ba, and of the parameters set in accordance with Article 5(2), in accordance with Annex II, and, where a risk assessment for the supply system is performed, in accordance with Article 9 and Annex II part Ba, unless a Member State decides that one of these parameters can be removed from the list of parameters to be monitored, in accordance with Article 8(3);
 - (b) monitoring of the parameters listed in Annex I, part C, for the purposes of the risk assessment for the domestic distribution systems, as provided for under Article 10(1)(b);
 - (ba) monitoring of the substances and compounds included in the watch list, in accordance with the fifth subparagraph of paragraph 7;
 - (c) monitoring, for the purposes of the identification of hazards and hazardous events, as provided for under Article 8(1)(d).

- (d) operational monitoring conducted in accordance with Annex II, part A, point 2a.
- 3. The sampling points shall be determined by the competent authorities and shall meet the relevant requirements set out in Annex II, part D.
- 4. Member States shall comply with the specifications for the analyses of parameters set out in Annex III, in accordance with the following principles:
 - (a) methods of analysis other than those specified in Annex III, Part A, may be used, provided that it can be demonstrated that the results obtained are at least as reliable as those produced by the methods specified by providing. the Commission with all relevant information concerning such methods and their equivalence;
 - (b) for those parameters listed in Annex III, Part B, any method of analysis may be used provided that it meets the requirements set out therein.
- 5. Member States shall ensure that additional monitoring is carried out on a case-by-case basis of substances and micro-organisms for which no parametric value has been set in accordance with Article 5, if there is reason to suspect that they may be present in amounts or numbers which constitute a potential danger to human health.
- 5b. By [three years after the date of entry into force of this Directive], the Commission shall adopt delegated acts in accordance with Article 19 in order to supplement this Directive by adopting a methodology to measure microplastics with a view to including them on the watch list once the conditions set out under Article 11(7) are fulfilled.
- 6. The Commission shall, no later than 3 years after entry into force of this Directive, establish technical guidelines regarding the analytical methods, including detection limits and parameter values and frequency of sampling for monitoring of 'PFAS total' and 'Sum of PFAS'.

7. The Commission shall adopt implementing acts to establish and update a watch list addressing substances or compounds of public or scientific concern to health, such as pharmaceuticals, endocrine-disrupting compounds and microplastics.

Substances and compounds shall be added to the watch list when they are likely to be present in water intended for human consumption and may pose a potential risk to human health. To that end, the Commission shall make use, in particular, of scientific research of the WHO. The addition of any new substance shall be duly justified under Articles 1 and 4 of this Directive.

Beta-estradiol (50-28-2) and Nonylphenol shall be included in the first watch list in view of their endocrine disrupting properties and risk they pose to human health. The first watch list shall be adopted by 1 year after the entry into force of this Directive.

The watch list shall indicate a guidance value for each substance or compound and where necessary a possible method of analysis not entailing excessive costs.

Member States shall put in place monitoring requirements with regard to the potential presence of the substances or compounds which are included in the watch list, at relevant points of the supply chain for water intended for human consumption.

For this purpose, Member States may take into account the information collected under Article 8 (1) and 8 (2) of this Directive and may use the monitoring data collected in accordance with Directive 2013/39/EU⁴⁶, Directive 2008/105/EC, Directive 2000/60/EC or other relevant Union legislation, in order to avoid overlapping of monitoring requirements.

The monitoring results shall be included in the data sets, set up in accordance with Article 15(1)(b), together with the monitoring results collected under Article 8(1)(d).

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Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy Text with EEA relevance (OJ L 226, 24.8.2013, p. 1)

Where those substances or compounds are detected, under Article 8(1) or under the fifth subparagraph of this paragraph, in concentrations exceeding the guidance values set out in the watch list, Member States shall ensure that the following measures are considered and shall ensure that the ones considered relevant are taken:

- (a) Preventive measures, mitigation measures or appropriate monitoring in the catchment area(s) for the abstraction point(s) or in the raw water as set out in Article 8(5)(a), (aa) and (b);
- (b) Requiring water suppliers to carry out monitoring of those substances or compounds, in accordance with Article 8(6)(a);
- (c) Requiring water suppliers to check whether treatment is adequate to reach the guidance value, or where necessary, optimise the treatment; and
- (d) remedial actions in accordance with Article 12(6) where Member States consider it necessary to protect human health.

The implementing acts foreseen in this paragraph shall be adopted in accordance with the examination procedure referred to in Article 20.

Article 12 Remedial action and restrictions in use

1. Member States shall ensure that any failure to meet the parametric values set in accordance with Article 5 is immediately investigated in order to identify the cause.

2. If, despite the measures taken to meet the obligations imposed in Article 4(1), water intended for human consumption does not meet the parametric values set in accordance with Article 5, and subject to Article 6(2) the Member State concerned shall ensure that the necessary remedial action is taken as soon as possible to restore its quality and shall give priority to their enforcement action, having regard *inter alia* to the extent to which the relevant parametric value has been exceeded and the associated potential danger to human health.

In case of non-compliance with the parametric values set out in Annex I, part C, remedial action shall include the measures set out in Article 10(2a).

3. Regardless of whether any failure to meet the parametric values has occurred, Member States shall ensure that any supply of water intended for human consumption which constitutes a potential danger to human health is prohibited or its use restricted and that any other medial action is taken that is necessary to protect human health.

Member States shall consider a failure to meet the minimum requirements for parametric values set out in Annex I, parts A and B, as a potential danger to human health, except where the competent authority considers the non-compliance with the parametric value to be trivial.

- 4. In the cases described in paragraphs 2 and 3, where the non-compliance with the parametric values is considered to be a potential danger to human health, Member States shall as soon as possible take all of the following measures:
 - (a) notify all affected consumers of the potential danger to human health and its cause, of the exceedance of a parametric value and of the remedial actions taken, including prohibition, restriction or other action;
 - (b) give, and regularly update, the necessary advice to consumers on conditions of consumption and use of the water, taking particular account of population groups with increased water related health risks;

- (c) inform consumers once it has been established that there is no longer a potential danger to human health and inform them that the service has resumed back to normal.
- 5. The competent authorities or other relevant bodies shall decide what action under paragraph 3 shall be taken, bearing in mind the risks to human health which would be caused by an interruption of the supply or a restriction in the use of water intended for human consumption.
- 6. In the event of non-compliance with the parametric values or with the specifications set out in Annex I, Part Ba, Member States shall consider whether that non-compliance poses any risk to human health. They shall take remedial action to restore the quality of the water where that is necessary to protect human health.

Article 12a Derogations

- 1. In duly justified circumstances, Member States may provide for derogations from the parametric values set out in Part B of Annex I, or set in accordance with Article 5(2), up to a maximum value to be determined by them, provided that such derogations do not constitute a potential danger to human health and provided that the supply of water intended for human consumption in the area concerned cannot otherwise be maintained by any other reasonable means. Such derogations shall be limited to the following cases:
 - (a) a new catchment area for the abstraction of water intended for human consumption;
 - (b) a new source of pollution detected at the catchment area for the abstraction of water intended for human consumption or parameters newly searched or detected; or
 - (c) an unforeseen and exceptional situation in an existing catchment area for the abstraction of water intended for human consumption that may lead to temporary limited exceedances of the parametric values.

Derogations shall be limited to as short a time as possible and shall not exceed three years in duration, towards the end of which period Member States shall conduct a review to determine whether sufficient progress has been made.

In exceptional circumstances, a Member State may grant a second derogation in respect of points (a) and (b) of the first subparagraph. Where a Member State intends to grant such a second derogation, it shall communicate the review, along with the grounds for its decision on the second derogation, to the Commission. Such second derogation shall not exceed three years in duration.

- 2. Any derogation granted in accordance with paragraph 1 shall specify the following:
 - (a) the grounds for the derogation;
 - (b) the parameter concerned, previous relevant monitoring results, and the maximum permissible value under the derogation;
 - (c) the geographical area, the quantity of water supplied each day, the population concerned and whether or not any relevant food-production undertaking would be affected;
 - an appropriate monitoring scheme, with an increased monitoring frequency where necessary;
 - (e) a summary of the plan for the necessary remedial action, including a timetable for the work and an estimate of the cost and provisions for reviewing; and
 - (f) the required duration of the derogation.

- 3. If the competent authorities consider the non-compliance with the parametric value to be trivial, and if action taken in accordance with Article 12(2) is sufficient to remedy the problem within 30 days, the information provided for in paragraph 2 of this Article need not be specified in the derogation.
 - In that event, only the maximum permissible value for the parameter concerned and the time allowed to remedy the problem shall be set by the competent authorities or other relevant bodies in the derogation.
- 4. Recourse may no longer be had to paragraph 3, if failure to comply with any one parametric value for a given water supply has occurred on more than 30 days on aggregate during the previous 12 months.
- 5. Any Member State which has had recourse to the derogations provided for in this Article shall ensure that the population affected by any such derogation is promptly informed in an appropriate manner of the derogation and of the conditions governing it. In addition, the Member State shall, where necessary, ensure that advice is given to particular population groups for which the derogation could present a special risk.
 - The obligations referred to in the first subparagraph shall not apply in the circumstances described in paragraph 3 unless the competent authorities decide otherwise.
- 6. This Article shall not apply to water intended for human consumption offered in bottles or containers.

Article 13 Access to water intended for human consumption

1. Without prejudice to Article 9 of Directive 2000/60/EC and to the principles of subsidiarity and proportionality, whilst taking into account the local, regional and cultural perspectives and circumstances for water distribution, Member States shall take the necessary measures to improve or maintain access to water intended for human consumption for all, in particular for vulnerable and marginalised groups, as defined by the Member States.

To this end, Member States shall:

- (a) identify people without access, or with limited access, to water intended for human consumption, including vulnerable and marginalised groups, and reasons for lack of access;
- (b) assess possibilities to improve access for those people;
- (c) inform those people about possibilities of connecting to the distribution network or about alternative means to have access to such water;
- (d) take measures that they consider necessary and appropriate to ensure access to water for vulnerable and marginalised groups.
- 2. In order to promote tap water intended for human consumption, Member States shall ensure that outdoors and indoors equipment are set up in public spaces, where technically feasible, in a manner that is proportionate to the need for such measures and taking into account specific local conditions, such as climate and geography.

Member States may also take the following measures to promote tap water intended for human consumption:

(a) raising awareness of the nearest outdoors or indoors equipment;

- (b) launching campaigns to inform citizens about the quality of water;
- (c) encouraging the provision of such water in administrations and public buildings;
- (d) encouraging the provision of such water for free or for a low service fee, for customers in restaurants, canteens, and catering services.
- 3. Member States shall ensure that the necessary assistance, as defined by the Member States, to responsible authorities is facilitated in order to implement the measures reffered to in this Article.

Article 14 Information to the public

- 1. Member States shall ensure that adequate, up-to-date information on water intended for human consumption is available in accordance with Annex IV, while complying with applicable data protection rules.
- 2. Member States shall ensure that all persons supplied receive regularly and at least once a year, in the most appropriate and easily accessible form (for instance on their invoice or by digital means such as smart applications) without having to request it the following information:
 - (aa) information on the quality of water intended for human consumption, including the indicator parameters;
 - (b) the price of water intended for human consumption supplied per litre and cubic metre;
 - (c) the volume consumed by the household, at least per year or per billing period, together with yearly trends of household consumption, if technically feasible and only if this information is available to the water supplier;

- (d) comparisons of the yearly water consumption of the household with an average consumption for a household, when applicable in accordance with point (c);
- (e) a link to the website containing the information set out in Annex IV.
- 3. Paragraphs 1 and 2 are without prejudice to Directives 2003/4/EC and 2007/2/EC.

Article 15 Information on monitoring of implementation

- 1. Without prejudice to Directive 2003/4/EC and Directive 2007/2/EC, Member States, assisted by the European Environment Agency, shall:
 - (a) set up by [6 years after the end-date for transposition of this Directive], and update every 6 years thereafter, a data set containing information on measures taken to improve access to and to promote the use of water intended for human consumption, and on the share of their population that has access to water intended for human consumption. This does not include bottled water;
 - (b) set up by [four and a half years after the end-date for transposition of this Directive], and update every 6 years thereafter, a data set containing the risk assessment and risk management of the catchment area(s) for the abstraction point(s) performed in accordance with Articles 8 and set up by ... [6 years after the end-date for transposition of this Directive], and update every 6 years thereafter, a data set containing the risk assessment of the domestic distribution systems performed in accordance with Article 10, including the following elements:
 - (i) information on catchment areas for the abstraction point(s) under Article 8(1)(a);
 - (ii) the monitoring results collected in accordance with Article 8(1)(d) and Article 10(1)(b); and

- (iii) concise information on measures taken pursuant to Article 8(5) and Article 10(2) and (2a), including information on the type of measures and progress made under Article 10(2a)(f);
- (c) set up, and update annually thereafter, a data set containing monitoring results, in cases of exceedances of the parametric values set in Annex I, parts A and B, collected in accordance with Articles 9 and 11 and information about the remedial actions taken in accordance with Article 12;
- (d) set up, and update annually thereafter, a data set containing information on drinking water incidents that have caused potential risk to human health, regardless of whether any failure to meet the parametric values occurred, that lasted for more than 10 consecutive days and that affected at least 1 000 people, including the causes of those incidents and remedial actions taken in accordance with Article 12.
- (e) set up, and update annually thereafter, a data set containing information on all derogations granted in accordance with Article 12a(1), including the information foreseen in Article 12a(2).

Where possible, spatial data services as defined in Article 3(4) of Directive 2007/2/EC shall be used to present those data sets.

2. Member States shall ensure that the Commission, the European Environment Agency and the European Centre for Disease Prevention and Control have access to the data sets referred to in paragraph 1.

- 3. The European Environment Agency shall publish and update a Union-wide overview on the basis of the data collected by the Member States on a regular basis or following receipt of a request from the Commission.
 - The Union-wide overview shall include, as appropriate, indicators for outputs, results and impacts of this Directive, Union-wide overview maps and Member State overview reports.
- 4. The Commission may adopt implementing acts specifying the format of, and modalities to present, the information to be provided in accordance with paragraphs 1 and 3, including detailed requirements regarding the indicators, the Union-wide overview maps and the Member State overview reports referred to in paragraph 3.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 20(2).

5. Member States may derogate from this Article on any of the grounds referred to in Article 13(1) of Directive 2007/2/EC.

Article 17 Evaluation

- 1. The Commission shall, by [12 years after the end-date for transposition of this Directive], carry out an evaluation of this Directive. The evaluation shall be based, *inter alia*, on the following elements:
 - (a) the experience gathered with the implementation of this Directive;
 - (b) the data sets from Member States set up in accordance with Article 15(1) and the Union-wide overviews compiled by the European Environment Agency in accordance with Article 15(3);
 - (c) relevant scientific, analytical and epidemiological data;

- (d) World Health Organisation recommendations, where available.
- 2. In the context of the evaluation, the Commission shall pay particular regard to the performance of this Directive concerning the following aspects:
 - (a) the risk-based approach set out in Article 7;
 - (b) provisions related to access to water set out in Article 13;
 - (c) provisions concerning the information to be provided to the public under Article 14 and Annex IV.
- 2a. The Commission shall, no later than [6 years after the end-date for transposition of this Directive] and afterwards where appropriate submit a report to the European Parliament and to the Council on the potential threat to sources of water intended for human consumption from microplastics, medicines and, if necessary, other newly occurring pollutants and on the appropriate associated potential health risks.

Article 18 Review and amendment of Annexes

- 1. At least every five years, the Commission shall review Annexes I and II in the light of scientific and technical progress as well as the Member States' risk-based approach to water safety contained in the data sets established pursuant to Article 15 and, where appropriate, shall make legislative proposals for amendments in accordance with the Treaty.
- 2. The Commission is empowered to adopt delegated acts in accordance with Article 19 amending Annex III where necessary, to adapt it to scientific and technical progress.

The Commission is empowered to adopt a delegated act to amend the parametric value of Bisphenol-A in Annex I, part B, to the extent necessary to adapt it to technical progress, essentially based on the ongoing review carried out by EFSA.

Article 19 Exercise of the delegation

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2. The power to adopt delegated acts referred to in Articles 4(2a), 10a(2)(c)(iii)(new), 10a(5), 10a(10), 11(5b)(new), and 18(2) shall be conferred on the Commission for a period of 5 years from [date of entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension no later than three months before the end of each period.
- 3. The delegation of power referred to in Articles 4(2a), 10a(2)(c)(iii)(new), 10a(5), 10a(10), 11(5b)(new), and 18(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.
- 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 4(2a), 10a(2)(c)(iii)(new), 10a(5), 10a(10), 11(5b)(new), or 18(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 20 Committee procedure

- 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation 182/2011 shall apply.

Article 21 Penalties

Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by ... [2 years after entry into force of this Directive], notify the Commission of those rules and those measures and shall notify it of any subsequent amendment affecting them.

Article 22 Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 2 and 5 to 21 and Annexes I to IV by ... [2 years after entry into force of this Directive]. They shall immediately communicate the text of those measures to the Commission.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 22a Transitional period

- 1. Member States shall take the measures necessary to ensure that water intended for human consumption complies with the parametric values set in Annex I, part B, for the following parameters: Chlorate, Chlorite, Bisphenol-A, Haloacetic Acids, Microcystin-LR, PFAS total, Sum of PFASs, Uranium, by [3 years after end-date for transposition].
- 2. During this transitional period, water suppliers shall not be obliged to monitor the water intended for human consumption in accordance with the provisions of Article 11 for the parameters listed in paragraph 1.

Article 23 Repeal

1. Directive 98/83/EC, as amended by the instruments listed in Annex V, Part A, is repealed with effect from [day after the date in the first subparagraph of Article 22(1)], without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law of the Directives set out in Annex V, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

2. Derogations granted by Member States in accordance with Article 9(1) of Directive 98/83/EC that are still applicable by [end-date for transposition of this Directive] shall remain applicable until the end of their duration. They may be renewed in accordance with Article 12a only where a second derogation has not yet been granted. The right to ask the Commission for a third derogation in accordance with Article 9(2) of Directive 98/83/EC shall remain applicable for those derogations already granted by Member States at the time of the entry into force of this Directive.

Article 24
Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 25 Addressees

This Directive is addressed to the Member States.

ANNEX I

MINIMUM REQUIREMENTS FOR PARAMETRIC VALUES USED TO ASSESS THE QUALITY OF WATER INTENDED FOR HUMAN CONSUMPTION

PART A
Microbiological parameters

Parameter	Parametric value	Unit	Notes
Intestinal enterococci	0	Number/100 ml	For water put into bottles or containers the unit is number/250 ml
Escherichia coli (E. coli)	0	Number/100 ml	For water put into bottles or containers the unit is number/250 ml

PART B
Chemical parameters

Parameter	Parametric value	Unit	Notes
Acrylamide	0,10	μg/l	The parametric value refers to the residual
			monomer concentration in the water as
			calculated according to specifications of
			the maximum release from the
			corresponding polymer in contact with the
			water.
Antimony	10	μg/l	
Arsenic	10	μg/l	
Benzene	1,0	μg/l	
Benzo(a)pyrene	0,010	μg/l	
Bisphenol A	2,5	μg/l	
Boron	1,5	mg/l	Parametric value of 2,4 mg/l shall be
			applied when desalinated water is the
			predominant water source of the supply
			system concerned or in regions where
			geological conditions may lead to high
			levels in ground water.
Bromate	10	μg/l	
Cadmium	5,0	μg/l	
Chlorate	0,25	mg/l	Parametric value of 0,7 mg/l shall be
			applied when a disinfection method that
			generates chlorate, in particular chlorine
			dioxide, is used for disinfection of water
			intended for human consumption. Where
			possible, without compromising
			disinfection, Member States shall strive
			for a lower value.
			This parameter shall be measured only if
			such disinfection methods are used.

Chlorite	0,25	mg/l	Parametric value of 0,7 mg/l shall be applied when a disinfection method that generates chlorite, in particular chlorine dioxide, is used for disinfection of water intended for human consumption.
			Where possible, without compromising
			disinfection, Member States shall strive for a lower value.
			This parameter shall be measured only if
			such disinfection methods are used.
Chromium	25	μg/l	The value shall be met, at the latest, by
			[15 years after the entry into force of this
			Directive]. The parametric value for
			chromium until that date is 50 μg/l.
Copper	2,0	mg/l	
Cyanide	50	μg/l	
1,2-dichloroethane	3,0	μg/l	
Epichlorohydrin	0,10	μg/l	The parametric value refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.
Fluoride	1,5	mg/l	
Haloacetic acids (HAA5s)	60	μg/l	This parameter shall be measured only when disinfection methods that can generate HAAs are used for the disinfection of water intended for human consumption. Sum of the following five representative substances: monochloro-, dichloro-, and trichloro-acetic acid, mono- and dibromo-acetic acid.

Lead	5	μg/l	The value shall be met at the latest by [15
			years after the entry into force of this
			Directive]. The parametric value for lead
			until that date is 10 µg/l.
			After the transitional period, the value of
			5 μg/l shall be met at least at the point of
			supply to the domestic distribution
			system.
			For the purposes of Article 10a (2)(b), the
			value of 5 μ g/l at the tap shall apply.
Mercury	1,0	μg/l	
Microcystin-LR	1,0	μg/l	This parameter needs to be measured
			only in case of potential blooms in source
			water (increasing cyanobacterial cell
			density or bloom forming potential).
Nickel	20	μg/l	
Nitrate	50	mg/l	Member States shall ensure that the
			condition [nitrate]/50 + [nitrite]/3 \leq 1,
			where the square brackets signify the
			concentrations in mg/l for nitrate (NO ₃)
			and nitrite (NO ₂), is complied with and
			that the value of 0,10 mg/l for nitrites is
			complied with ex water treatment works.
Nitrite	0,50	mg/l	Member States shall ensure that the
			condition [nitrate]/50 + [nitrite]/3 \leq 1,
			where the square brackets signify the
			concentrations in mg/l for nitrate (NO ₃)
			and nitrite (NO ₂), is complied with and
			that the value of 0,10 mg/l for nitrites is
			complied with ex water treatment works.

Pesticides	0,10	μg/l	'Pesticides' means:
			- organic insecticides,
			- organic herbicides,
			- organic fungicides,
			- organic nematocides,
			– organic acaricides,
			- organic algicides,
			- organic rodenticides
			- organic slimicides,
			- related products (inter alia, growth
			regulators)
			and their metabolites as defined in Article
			3(32) of Regulation (EC) No
			1107/2009 ⁴⁷ , that are considered relevant
			for water intended for human
			consumption.
			A pesticide metabolite is deemed
			relevant for water intended for human
			consumption if there is reason to
			consider that it has intrinsic properties
			comparable to those of the parent
			substance in terms of its pesticide target
			activity or that it generates (itself or its
			transformation products) a health risk to
			the consumer.
			The parametric value applies to each
			individual pesticide.
			In the case of aldrin, dieldrin, heptachlor
			and heptachlor epoxide, the parametric
			value is 0,030 μg/l.

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5813/20 81 CSM/dk **ANNEX** TREE.1.A EN

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309 24.11.2009, p. 1).

			Member States shall define a guidance
			value to manage the presence of non-
			relevant metabolites of pesticides in
			drinking water.
			Only those pesticides which are likely to
			be present in a given supply need be
			monitored.
			Based on the data reported by Member
			States, Commission may establish a
			database of pesticides and their relevant
			metabolites taking into account their
			possible presence in water intended for
			human consumption.
Pesticides — Total	0,50	μg/l	'Pesticides — Total' means the sum of all
			individual pesticides, as defined in the
			previous row, detected and quantified in
			the monitoring procedure.
PFASs - Total	0,50	μg/l	'PFASs Total' means the totality of per-
			and polyfluoroalkyl substances.
			This value shall only apply once
			technical guidelines for monitoring this
			parameter are developed in accordance
			with Article 11(6). Member States may
			then decide to use either one or both of
			the parameters 'PFAS Total' or 'Sum of
			PFAS'.
Sum of PFASs	0,10	μg/l	'Sum of PFASs' means the sum of per-
			and polyfluoroalkyl substances
			considered a concern for water intended
			for human consumption listed in Annex
			III, part B, point 3. This is a subset of
			PFASs Total substances that contain a
			perfluoroalkyl moiety with three or more
	i i	1	

			carbons (i.e. –CnF2n–, $n \ge 3$) or a
			perfluoroalkylether moiety with two or
			more carbons (i.eCnF2nOCmF2m-, n
			and $m \ge 1$).
Polycyclic aromatic	0,10	μg/l	Sum of concentrations of the following
hydrocarbons			specified compounds:
			benzo(b)fluoranthene,
			benzo(k)fluoranthene,
			benzo(ghi)perylene, and indeno(1,2,3-
			cd)pyrene.
Selenium	20	μg/l	Parametric value of 30 µg/l shall be
			applied for regions where geological
			conditions may lead to high levels in
			ground water.
Tetrachloroethene and	10	μg/l	Sum of concentrations of specified
Trichloroethene			parameters.
Trihalomethanes — Total	100	μg/l	Where possible, without compromising
			disinfection, Member States shall strive
			for a lower value.
			Sum of concentrations of the following
			specified compounds: chloroform,
			bromoform, dibromochloromethane,
			bromodichloromethane.
Uranium	30	μg/l	
Vinyl chloride	0,50	μg/l	The parametric value refers to the
			residual monomer concentration in the
			water as calculated according to
			specifications of the maximum release
			from the corresponding polymer in
			contact with the water.

PART Ba

Indicator parameters (new)

Parameter	Parametric value	Unit	Notes
Aluminium	200	μg/l	
Ammonium	0,50	mg/l	
Chloride	250	mg/l	The water should not be
			corrosive.
Clostridium	0	Number/100 ml	This parameter is to be
perfringens including			measured if the risk assessment
spores			indicates it.
Colour	Acceptable to consumers		
	and no abnormal change		
Conductivity	2500	μS cm ⁻¹ at 20 °C	The water should not be
			aggressive.
Hydrogen ion	\geq 6,5 and \leq 9,5	pH units	The water should not be
concentration			aggressive.
			For still water put into bottles
			or containers, the minimum
			value may be reduced to 4,5 pH
			units. For water put into bottles
			or containers which is naturally
			rich in or artificially enriched
			with carbon dioxide, the
			minimum value may be lower.
Iron	200	μg/l	
Manganese	50	μg/l	
Odour	Acceptable to consumers		
	and no abnormal change		
Oxidisability	5,0	mg/l O ₂	This parameter need not be
			measured if the parameter TOC
			is analysed.
Sulphate	250	mg/l	The water should not be

			corrosive.
Sodium	200	mg/l	
Taste	Acceptable to consumers and no abnormal change		
Colony count 22°	No abnormal change		
Coliform bacteria	0	number/100 ml	For water put into bottles or containers the unit is number/250 ml.
Total organic carbon (TOC)	No abnormal change		This parameter need not be measured for supplies of less than 10 000 m3 a day.
Turbidity	Acceptable to consumers and no abnormal change		

Waters should not be aggressive or corrosive. This applies particularly to waters undergoing treatment (demineralization, softening, membrane treatment, reverse osmosis, etc.).

Where water intended for human consumption is derived from treatment that significantly demineralizes or softens water, calcium and magnesium salts could be added to condition the water in order to reduce possible negative health impact, as well as corrosion or aggression of water and to improve taste. Minimum concentrations of calcium and magnesium or total dissolved solids in softened or demineralized water could be established taking into account the characteristics of water that enters these processes.

PART C

Parameters relevant for the domestic distribution risk assessment

Legionella	<1000	CFU/I	This parametric value is set for the purposes of Articles 10 and 12. Actions foreseen under those Articles could be considered even below the parametric value, e.g. in case of infections and outbreaks. In these cases the source of infection should be confirmed and the species to which it belongs should be identified.
Lead	10	μg/l	This parametric value is set for the purposes of Articles 10 and 12. Member States should use their best endeavours to achieve a lower value of 5 µg/l by 15 years after the entry into force of this Directive.

ANNEX II

MONITORING

PART A

General objectives and monitoring programmes for water intended for human consumption

- 1. Monitoring programmes established pursuant to Article 11(2) for water intended for human consumption shall:
 - (a) verify that the measures in place to control risks to human health throughout the water supply chain from the abstraction area through treatment and storage to distribution are working effectively and that water at the point of compliance is wholesome and clean;
 - (b) provide information on the quality of the water supplied for human consumption to demonstrate that the obligations set out in Article 4 and the parametric values set in accordance with Article 5 are being met;
 - (c) identify the most appropriate means of mitigating the risk to human health.
- 2. Monitoring programmes established pursuant to Article 11(2) shall include one or a combination of the following:
 - (a) collection and analysis of discrete water samples;
 - (b) measurements recorded by a continuous monitoring process.

In addition, monitoring programmes may consist of:

(a) inspections of records of the functionality and maintenance status of equipment;

- (b) inspections of the abstraction area, and of the treatment, storage and distribution infrastructure without prejudice to monitoring requirements provided under Article 8(1)(c) and Article 10(1)(b).
- 2a. Monitoring programmes shall also include an operational monitoring programme, providing rapid insight in operational performance and water quality problems, and allowing rapid preplanned remedial action. Such operational monitoring programmes shall be supply-specific, taking into account the outcomes of the identification of hazards and hazardous events and supply risk assessments, and intended to confirm the effectiveness of all control measures in abstraction, treatment, distribution and storage.

The operational monitoring programme shall include the monitoring of the parameter turbidity at the water supply plant to regularly control the efficacy of physical removal by filtration processes, in accordance with the reference values and frequencies indicated in the following table (not applicable for groundwater sources where turbidity is caused by iron and manganese):

Operation parameter	Reference value
Turbidity	0.3 NTU in 95% of samples and none to exceed 1 NTU

Volume (m³) of water distributed or produced each day within a supply zone	Minimum frequency
≤ 1000	Weekly
> 1000 to ≤ 10 000	Daily
>10 000	Online

The operational monitoring programme shall also include the monitoring of the following parameters in the raw water to control the efficacy of the treatment processes against microbiological risks:

Operational Parameter	Reference value	Unit	Notes	
Somatic	50 (for raw	Plaque	This parameter is to be	
coliphages	water)	Forming	measured if the risk	
		Units	assessment indicates it. If it is	
		(PfU) /100	found in raw water at	
		ml	concentrations > 50 PfU /100	
			ml, it should be analysed	
			after steps of the treatment	
			train in order to determine log	
			removal by the barriers in	
			place and to assess whether	
			the risk of breakthrough of	
			pathogenic viruses is	
			sufficiently under control.	

3. Member States shall ensure that monitoring programmes are reviewed on a continuous basis and updated or reconfirmed at least every 6 years.

Part B Parameters and sampling frequencies

1 List of parameters

Group A

The following parameters (Group A) shall be monitored in accordance with the monitoring frequencies set out in Table 1 of point 2:

- (a) Escherichia coli (E. coli), intestinal enterococci, coliform bacteria, colony count 22 °C, colour, turbidity, taste, odour, pH, conductivity;
- (b) other parameters identified as relevant in the monitoring programme, in accordance with Article 5(2) and, where relevant, through a risk assessment of the supply system as set out in Article 9 and Annex II Part C

Under specific circumstances, the following parameters shall be added to the Group A Parameters:

- (a) ammonium and nitrite, if chloramination is used;
- (b) aluminium and iron, if used as water treatment chemicals.

Escherichia coli (E. coli) and intestinal enterococci are considered 'core parameters' and may not be subject to a reduction due to a supply risk assessment in accordance with Article 9 and part C of this Annex. They shall always be monitored at the frequencies set out in Table 1 of point 2.

Group B

In order to determine compliance with all parametric values set out in this Directive, all other parameters not analysed under Group A and set in accordance with Article 5, except for parameters in Annex I, Part C, shall be monitored at least at the frequencies set out in Table 1 of point 2, unless a different sampling frequency is determined on the basis of a supply risk assessment carried out in accordance with Article 9 and part C of this Annex.

2. Sampling frequencies

Table 1. Minimum frequency of sampling and analysis for compliance monitoring

Volume of water distributed or produced each day within a supply zone (See Notes 1 and 2) m^3		Group A parameter number of samples per	Group B parameter number of samples per year	
		year		
	< 10	> 0	> 0	
		(See Note 4)	(See Note 4)	
≥ 10	≤ 100	2	1	
			(See Note 5)	
> 100	≤ 1000	4	1	
> 1000	≤ 10000	4 for first 1000 m ³ /d	1 for first 1000 m ³ /d	
		+ 3 for each additional	+ 1 for each additional	
		1000 m ³ /d and part thereof	4500 m ³ /d and part thereof	
		of the total volume	of the total volume	
		(See Note 3)	(See Note 3)	
> 10000	≤ 100000		3 for first 10000 m ³ /d	
			+ 1 for each additional	
			10000 m ³ /d and part thereof	
			of the total volume	
			(See Note 3)	
> 100000			12 for first $100000 \text{ m}^3/\text{d} + 1$	
			for each additional 25000	
			m ³ /d and part thereof of the	
			total volume	
			(See Note 3)	

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and water quality may be considered as being approximately uniform.

- Note 2: The volumes are calculated as averages taken over a calendar year. The number of inhabitants in a supply zone may be used instead of the volume of water to determine the minimum frequency, assuming water consumption of 200 l/(day*capita).
- *Note 3*: The frequency indicated is calculated as follows: e.g. $4300 \text{ m}^3/\text{d} = 16 \text{ samples for group A}$ parameters (four for the first $1000 \text{ m}^3/\text{d} + 12$ for additional $3300 \text{ m}^3/\text{d}$).
- Note 4: For water suppliers, where an exemption has not been granted under Article 3(2)(b), Member States shall lay down the mimimum sampling frequency for parameters of group A and B, provided that core parameters are monitored at least once per year.
- *Note 5:* Member States may reduce the sampling frequency, provided that all parameters set in accordance with Article 5 are monitored at least once every six years as well as in cases where a new water source is integrated or changes to the water supply system, where a potentially adverse effect on the quality of water is to be expected, are made.

PART C

Risk assessment of the supply system

- 2. Based on the outcome of the risk assessment for the supply system as referred to in Article 9, the list of parameters considered in the monitoring shall be extended and the sampling frequencies set out in Part B increased, where any of the following conditions is fulfilled:
 - (a) the list of parameters or frequencies set out in this Annex is not sufficient to fulfil the obligations imposed under Article 11(1);
 - (b) additional monitoring is required for the purposes of Article 11(5);
 - (c) it is necessary to provide the assurances set out in point (1)(a) of Part A;
 - d) increasing the sampling frequencies is necessary pursuant to Article 8(5)(a).

- 3. Following a risk assessment for the supply system, the list of parameters considered in the monitoring and the sampling frequencies set out in Part B may be reduced provided all of the following conditions are met:
 - (a) the location and frequency of sampling is determined in relation to the parameter's origin, as well as the variability and long-term trend of its concentration, taking into account Article 6;
 - (b) for reducing the minimum sampling frequency of a parameter the results obtained from samples collected at regular intervals over a period of at least 3 years from sampling points representative of the whole supply zone are all less than 60 % of the parametric value;
 - (c) for removing a parameter from the list of parameters to be monitored the results obtained from samples collected at regular intervals over a period of at least 3 years from points representative of the whole supply zone are all less than 30 % of the parametric value;
 - (d) for removing a parameter from the list of parameters to be monitored, the decision is based on the result of the risk assessment, informed by the results of monitoring of sources of water intended for human consumption and confirming that human health is protected from the adverse effects of any contamination of water intended for human consumption, as laid down in Article 1;
 - (e) for reducing the sampling frequency of a parameter or for removing a parameter from the list of parameters to be monitored, the risk assessment confirms that no factor that can be reasonably anticipated is likely to cause deterioration of the quality of the water intended for human consumption.

Where monitoring results, demonstrating that the conditions set out in paragraph 3, points (b) to (e) are met, are already available by [the date of entry into force of this Directive], those monitoring results may be used to adapt the monitoring following the risk assessment for the supply system from that date.

Where adjustments of monitoring have already been implemented following the supply risk-assessment in accordance, inter alia, to Part C of the Commission Directive 2015/1787, Member States may provide for the possibility for confirming their validity without requiring monitoring according to paragraphs 3(b) and 3(c) over another period of at least 3 years from points representative of the whole supply zone.

PART D

Sampling methods and sampling points

- 1. Sampling points shall be determined so as to ensure compliance with the points of compliance as defined in Article 6. In the case of a distribution network, a Member State may take samples within the supply zone or at the treatment works for particular parameters if it can be demonstrated that there would be no adverse change to the measured value of the parameters concerned. As far as possible, the number of samples shall be distributed equally in time and location.
- 2. Sampling at the point of compliance shall meet the following requirements:
 - (a) compliance samples for certain chemical parameters (in particular copper, lead, and nickel) shall be taken at the consumer's tap without prior flushing. A random daytime sample of one litre volume is to be taken. As an alternative, Member States may use fixed stagnation time methods that better reflect their national situation, such as the average weekly intake by consumers, provided that, at the supply zone level, this does not result in fewer cases of non-compliance than using the random daytime method;

- b) compliance samples for microbiological parameters at the point of compliance shall be taken and handled according to EN ISO 19458, sampling purpose B.
- 2a. Samples for *Legionella* in domestic distribution systems shall be taken at risk points for proliferation of and/or points representative for systemic exposure to *Legionella*. Member States shall establish guidelines for sampling methods for *Legionella*.
- 3. Sampling in the distribution network, with the exception of sampling at the consumers' tap, shall be in accordance with ISO 5667-5. For microbiological parameters, sampling in the distribution network shall be taken and handled according to EN ISO 19458, sampling purpose A.

ANNEX III

SPECIFICATIONS FOR THE ANALYSIS OF PARAMETERS

Member States shall ensure that the methods of analysis used for the purposes of monitoring and demonstrating compliance with this Directive, with the exception of online turbidity, are validated and documented in accordance with EN ISO/IEC 17025 or other equivalent standards accepted at international level. Member States shall ensure that laboratories or parties contracted by laboratories apply quality management system practices in accordance with EN ISO/IEC 17025 or other equivalent standards accepted at international level.

For the purposes of assessing the equivalence of alternative methods with the methods laid down in this Annex, Member States may use standard EN ISO 17994, established as the standard on the equivalence of microbiological methods or standard EN ISO 16140 or any other similar internationally accepted protocols, to establish the equivalence of methods based on principles other than culturing, which are beyond the scope of EN ISO 17994.

In the absence of an analytical method meeting the minimum performance criteria set out in Part B, Member States shall ensure that monitoring is carried out using best available techniques not entailing excessive costs.

PART A

Microbiological parameters for which methods of analysis are specified

The methods for microbiological parameters are:

- (a) Escherichia coli (E. coli) and coliform bacteria (EN ISO 9308-1 or EN ISO 9308-2)
- (b) Intestinal enterococci (EN ISO 7899-2)
- (d) colony count or heterotrophic plate counts at 22°C (EN ISO 6222)

- (e) Clostridium perfringens including spores (EN ISO 14189)
- (g) Legionella (EN ISO 11731 for compliance with the value in Annex I Part C)

 For risk based verification monitoring and to complement culture methods, also other methods, such as ISO/TS 12869, rapid culture methods, non-culture-based methods, and molecular-based methods, in particular qPCR, can be used.
- (h) Somatic coliphages
 For operational monitoring, Annex II Part A EN ISO 10705-2, EN ISO 10705-3 can be used.

PART B

Chemical and indicator parameters for which performance characteristics are specified

1. Chemical and indicator parameters

For the parameters set out in Table 1, the method of analysis used shall, as a minimum, be capable of measuring concentrations equal to the parametric value with a limit of quantification, as defined in Article 2(2) of Commission Directive 2009/90/EC⁴⁸, of 30 % or less of the relevant parametric value and an uncertainty of measurement as specified in Table 1. The result shall be expressed using at least the same number of significant figures as for the parametric value considered in Parts B and Ba of Annex I.

The uncertainty of measurement laid down in Table 1 shall not be used as an additional tolerance to the parametric values set out in Annex I.

Commission Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status (OJ L 201, 1.8.2009, p. 36).

Table 1. Minimum performance characteristic 'Uncertainty of measurement'

Parameters	Uncertainty of measurement	Notes
	(See Note 1)	
	% of the parametric value (except	
	for pH)	
Aluminium	25	
Ammonium	40	
Acrylamide	30	
Antimony	40	
Arsenic	30	
Benzo(a)pyrene	50	See Note 2
Benzene	40	
Bisphenol A	50	
Boron	25	
Bromate	40	
Cadmium	25	
Chloride	15	
Chlorate	40	
Chlorite	40	
Chromium	30	
Copper	25	
Cyanide	30	See Note 3
1,2-dichloroethane	40	
Epichlorohydrin	30	
Fluoride	20	
HAAs	50	
Hydrogen ion concentration pH	0,2	See Note 4
Iron	30	
Lead	30	
Manganese	30	

Mercury	30	
Microcystin-LR	30	
Nickel	25	
Nitrate	15	
Nitrite	20	
Oxidisability	50	See Note 5
Pesticides	30	See Note 6
PFASs	50	
Polycyclic aromatic hydrocarbons	40	See Note 7
Selenium	40	
Sodium	15	
Sulphate	15	
Tetrachloroethene	40	See Note 8
Trichloroethene	40	See Note 8
Trihalomethanes — total	40	See Note 7
Total organic carbon (TOC)	30	See Note 9
Turbidity	30	See Note 10
Uranium	30	
Vinyl chloride	50	

2. Notes to Table 1

Note 1: Uncertainty of measurement is a non-negative parameter characterising the dispersion of the quantity values being attributed to a measurand, based on the information used. The performance criterion for measurement uncertainty (k = 2) is the percentage of the parametric value stated in the table or any stricter value. Measurement uncertainty shall be estimated at the level of the parametric value, unless otherwise specified.

Note 2: If the value of uncertainty of measurement cannot be met, the best available technique should be selected (up to 60 %).

- *Note 3:* The method determines total cyanide in all forms.
- Note 4: The value for the uncertainty of measurement is expressed in pH units.
- *Note 5:* Reference method: EN ISO 8467.
- Note 6: The performance characteristics for individual pesticides are given as an indication. Values for the uncertainty of measurement as low as 30 % can be achieved for several pesticides, higher values up to 80 % may be allowed for a number of pesticides.
- *Note 7:* The performance characteristics apply to individual substances, specified at 25 % of the parametric value in Part B of Annex I.
- *Note 8:* The performance characteristics apply to individual substances, specified at 50 % of the parametric value in Part B of Annex I.
- Note 9: The uncertainty of measurement should be estimated at the level of 3 mg/l of the total organic carbon (TOC). CEN 1484 Guidelines for the determination of TOC and dissolved organic carbon (DOC) shall be used for the specification of the uncertainty of the test method.
- *Note 10:* The uncertainty of measurement should be estimated at the level of 1,0 NTU, (nephelometric turbidity units) in accordance with EN ISO 7027 or other equivalent standard method.

3. Sum of PFASs

The following relevant substances shall be analysed based on the technical guidelines developed in accordance with Article 11 (6) of this Directive:

- Perfluorobutanoic acid (PFBA)
- Perfluoropentanoic acid (PFPA)
- Perfluorohexanoic acid (PFHxA)
- Perfluoroheptanoic acid (PFHpA)
- Perfluorooctanoic acid (PFOA)
- Perfluorononanoic acid (PFNA)
- Perfluorodecanoic acid (PFDA)

- Perfluoroundecanoic acid (PFUnDA)
- Perfluorododecanoic acid (PFDoDA)
- Perfluorotridecanoic acid (PFTrDA)
- Perfluorobutanesulfonic acid (PFBS)
- Perfluoropentanesulfonic acid (PFPS)
- Perfluorohexanesulfonic acid (PFHxS)
- Perfluoroheptane sulfonic acid (PFHpS)
- Perfluorooctanesulfonic acid (PFOS)
- Perfluorononane sulfonic acid (PFNS)
- Perfluorodecane sulfonic acid (PFDS)
- Perfluoroundecane sulfonic acid
- Perfluorododecane sulfonic acid
- Perfluorotridecane sulfonic acid

These substances shall be monitored when the risk assessment and risk management of the catchment area(s) performed in accordance with Article 8 of this Directive conclude that these substances are likely to be present in a given water supply.

ANNEX IV

INFORMATION TO THE PUBLIC

The information in points 1 to 8 shall be accessible to consumers on-line, in a user-friendly and customized way.

Consumers may request access to this information by other means, upon justified request.

- (1) identification of the relevant water supplier, the area and number of people supplied, and the method of water production, including general information on types of water treatment and disinfection applied. Member States may derogate from this requirement in accordance with Article 13(1) of Directive 2007/2/EC;
- (2) the most recent monitoring results for parameters listed in Annex I, parts A, B and Ba, including frequency together with the parametric value set in accordance with Article 5. The monitoring results must not be older than one year, except where the monitoring frequency set by this Directive provides otherwise.
- (2a) information on the following parameters not listed in Annex I part Ba and associated values:
 - (a) Hardness;
 - (b) Minerals, anions/cations dissolved in water:
 - Calcium Ca
 - Magnesium Mg
 - Potassium K
- (3) in case of potential danger to human health as determined by competent authorities or other relevant bodies following an exceedance of the parametric values set in accordance with Article 5, information on the potential danger to human health and the associated health and consumption advice or a hyperlink providing access to such information;

- (4) relevant information on supply risk assessment;
- (6) advice to consumers including on how to reduce water consumption, where appropriate, use water responsibly according to local conditions and avoid health risks due to stagnant water;
- (7) for water suppliers supplying at least 10 000 m³ per day or serving at least 50 000 people, annual information on:
 - (a) the overall performance of the water system in terms of efficiency, and leakage rates, once that information is available and at the latest on the date set out in Article 4(2a);
 - (b) information on the ownership structure of the water supply by the water supplier
 - (d) where costs are recovered through a tariff system, information on the structure of the tariff per cubic meter of water, including fixed and variable costs and costs related to measures for the purposes of Article 13, where such measures have been taken by water suppliers;
 - (g) where available, a summary and statistics of consumer complaints received by the water suppliers on aspects within the scope of this directive,
- (8) Upon justified request, consumers shall be given access to historical data for information under points (2) and (3), dating back up to 10 years, if available, and not earlier than the date of transposition of this Directive.

ANNEX VII (new)

PRINCIPLES FOR SETTING COMMON METHODOLOGIES

Groups of materials

1 Organic materials

Organic materials shall only be made of:

- (a) the starting substances listed in the European positive list of substances to be established by the Commission in accordance with Article 10a(2)(b); and
- (b) substances for which it can be ruled out that the substance and its reaction products are present at levels exceeding 0.1 μg/l in water for human consumption unless for specific substances a more stringent value is needed taking into account their toxicity.

Organic materials shall be tested according to Table 1 in line with testing methods specified in relevant European standards or, in the absence thereof, an internationally or nationally recognised method and shall must satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into levels expected at the tap.

2 Metallic materials

Only metallic materials included in the European positive list of compositions to be established by the Commission in accordance with Article 10a(2)(b) shall be used. The limitations stipulated in the European positive list in respect of the composition of these materials, their use for certain products and the use of these products shall be complied with.

Compositions shall be tested according to Table 1 in line with testing methods specified in relevant European standards or, in the absence thereof, an internationally or nationally recognised method and shall satisfy the requirements stipulated therein.

3 Cementitious materials

Cementitious materials shall only be made of one or more of the following:

- (a) organic constituents listed in the European positive list of constituents to be established by the Commission in accordance with Article 10a(2)(b);
- (b) organic constituents for which it can be ruled out that the substances and their reaction products are present at levels exceeding 0.1 μg/l in water for human consumption; or
- (c) inorganic constituents.

Cement-bound materials shall be tested according to Table 1 in line with testing methods specified in relevant European standards or, in the absence thereof, an internationally or nationally recognised method and shall satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into levels expected at the tap.

4 Enamels and ceramic materials

Enamels and ceramic materials shall only be made of the starting substances types given in the European positive list of compositions to be established by the Commission in accordance with Article 10a(2)(b), after carrying out an assessment of the elements used in the composition of these materials.

Enamels and ceramic materials shall be tested according to Table 1 in line with testing methods specified in relevant European standards or, in the absence thereof, an internationally or nationally recognised method and shall satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into levels expected at the tap.

5 Exceptions for assessment of materials used in minor and assembled components

For assembled products: minor components, parts and materials shall be described in detail and testing shall be reduced accordingly. For this purpose 'minor' refers to a level of influence on the quality of water intended for human consumption that does not require the full testing.

Table 1. Testing related to material types

Criteria	Organic (1)	Metallic (2)	Cementitious	Enamels and ceramic materials
European Positive lists				
European positive lists of starting substances organic materials	X	N.N.	X	N.N
European positive lists of accepted metallic compositions	N.N.	X	N.N.	N.N
European positive lists of Constituents Cementitious materials	N.N.	N.N.	X	N.N.
European positive list of compositions for enamels and ceramic materials	N.N	N.N	N.N	X
Organoleptic tests				
Odour and flavour	X	N.N.	X	N.N.
Color and Turbidity	X	N.N.	X	N.N.
General hygiene assessments				
Leaching of total organic carbon	X	N.N.	X	N.N.
Surface residues (metals)	N.N.	X	N.N.	N.N.
Migration testing				
Relevant DWD parameters	X	X	X	X
MTC _{tap} of PL substances	X	N.N.	X (3)	N.N.
Unsuspected substances (GCMS)	X	N.N.	X (3)	N.N.
CL compliance	N.N.	X	N.N.	X
Enhancement of microbial growth	X	N.N.	X (3)	N.N.

N.N: Not necessary

 MTC_{tap} : Maximum tolerable concentration at the tap (either derived in the opinion of the Agency for inclusion of the substance in the positive list, or based on Specific Migration Limit of Regulation Nr. 10/2011 and considering a 10% allocation factor and 2 l water consumption

GCMS: Gas Chromatography – Mass Spectrometry (screening method)

Note 1: Specific exceptions to be determined in line with paragraph 5 of this Annex;

Note 2: Metals shall not be subject to organoleptic testing because it is generally accepted that if the parametric values set out in Annex I are met, organoleptic problems are unlikely to arise;

Note 3: Depending on the existence of organic substances in the composition.