Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (Text with EEA relevance)

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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 Committee⁽¹⁾,

Having regard to the opinion of the Committee of the Regions⁽²⁾,

Acting in accordance with the ordinary legislative procedure⁽³⁾,

Whereas:

- (1) Council Directive 98/83/EC⁽⁴⁾ has been substantially amended several times⁽⁵⁾. Since further amendments are to be made, that Directive should be recast in the interests of clarity.
- (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 should 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 any substances which, in numbers or concentrations, in certain cases, constitute a potential danger to human health, and that it meets those minimum requirements.
- (3) It is necessary to exclude from the scope of this Directive natural mineral waters and waters which are medicinal products, since such types of water are covered by Directives 2009/54/EC⁽⁶⁾ and 2001/83/EC⁽⁷⁾ of the European Parliament and of the Council respectively. However, Directive 2009/54/EC deals with both natural mineral waters and spring waters, and only the former category should be exempted from the

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scope of this Directive. In accordance with the third subparagraph of Article 9(4) of Directive 2009/54/EC, spring waters should comply with this Directive and, with regard to microbiological requirements, spring water should comply with 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, such water should, as a matter of principle, continue to comply with this Directive until the point of compliance, namely the tap, and should after that point be considered as food if it is intended to be, or reasonably expected to be, ingested by humans, in accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council⁽⁸⁾. In addition, food business operators that have their own water source and use it for the specific purposes of their business should be able to be exempted from this Directive provided that they comply with relevant obligations, in particular regarding hazard analysis and critical control point principles and remedial actions under relevant Union legislation on food. Food business operators that have their own water source and act as water suppliers should comply with this Directive in the same way as any other water supplier.

(4) Following the conclusion of the European citizens' initiative on the right to water ('the Right2Water initiative'), the Commission launched a Union-wide public consultation and performed a Regulatory Fitness and Performance (REFIT) Evaluation of Directive 98/83/EC. It became apparent from that exercise that certain provisions of that Directive 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 that come into contact with water intended for human consumption and the implications such disparities have for human health. In addition, the Right2Water initiative identified as a distinct problem the fact that part of the population, in particular marginalised groups, has no access to water intended for human consumption, and providing such access is a commitment under Goal 6 of the Sustainable Development Goals (SDGs) of the United Nations 2030 Agenda for Sustainable Development.

A final issue identified is the general lack of awareness of water leakages, which are driven by underinvestment in maintenance and renewal of water infrastructure, as also pointed out in the European Court of Auditors' Special Report No 12/2017 of 5 July 2017'Implementing the Drinking Water Directive: water quality and access to it improved in Bulgaria, Hungary and Romania, but investment needs remain substantial'.

(5) In 2017, the World Health Organization (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 that list in light of technical and scientific progress. In view of the results of that review, enteric pathogens and *Legionella* should be controlled and six chemical parameters or parameter groups should be added. For four of the six new parameters or parameter groups, parametric values that are more stringent than those proposed by the WHO, though nonetheless 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 should be reduced and the value adapted. For chromium, the value remains under WHO review and a transitional period of 15 years should therefore apply before the value becomes more stringent. In addition, the WHO recommended that three representative endocrine-disrupting compounds may be considered as benchmarks, for assessing the occurrence of endocrine-disrupting compounds and their treatment efficacy where necessary, with values of 0,1 μ g/l for Bisphenol A, 0,3 μ g/l for Nonylphenol and 1 ng/l for Beta-estradiol.

However, based on a 2015 opinion of the European Food Safety Authority (EFSA), it was decided that one of those three compounds, Bisphenol A, should be added to this Directive with a health-based parametric value of 2,5 μ g/l. Furthermore, Nonylphenol and Beta-estradiol should be added to the watch list to be established by the Commission pursuant to this Directive.

- (6) In relation to lead, the WHO recommended retaining the current parametric value, but noted that concentrations should be as low as reasonably practicable. Therefore, it should be possible to retain the current value of 10 μ g/l for 15 years after the date of entry into force of this Directive. By the end of this transitional period, at the latest, the parametric value for lead should be 5 μ g/l. In addition, since existing lead pipes in houses and buildings are a persisting issue and since Member States do not always have the necessary authority to impose the replacement of those pipes, the value of 5 μ g/l should remain aspirational when it comes to obligations related to domestic distribution systems. However, for all new materials that come into contact with water intended for human consumption, 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 μ g/l should apply at the tap.
- (7)In order to address growing public concern about the effects of emerging compounds, such as endocrine-disrupting compounds, pharmaceuticals and microplastics, on human health through use of water intended for human consumption, 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 make it possible to respond to growing concerns in a dynamic and flexible way. It will also enable follow-up on new knowledge about the relevance for human health of those emerging compounds and on new knowledge about the most appropriate monitoring approaches and methodologies. This watch list mechanism for water intended for human consumption is part of the response to various relevant Union policies, as set out in the communication of the Commission of 11 March 2019'European Union Strategic Approach to Pharmaceuticals in the Environment', the communication of the Commission of 7 November 2018' Towards a comprehensive European Union framework on endocrine disruptors' and the Council Conclusions of 26 June 2019' Towards a Sustainable Chemicals Policy Strategy of the Union'.
- (8) The WHO also recommended that three parametric values be made less stringent and five parameters be removed from the list of parameters and parametric values laid down in Directive 98/83/EC. However, not all of those changes are considered necessary, as the risk-based approach introduced by Commission Directive (EU) 2015/1787⁽⁹⁾ allows water suppliers to remove a parameter from the list of parameters to be monitored under

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certain conditions. Treatment techniques to meet those parametric values are already in place.

- (9) The parametric values laid down in this Directive 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.
- (10) A balance should be struck to prevent both microbiological and chemical risks and, to that end and in 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 risk assessment.
- (11) Indicator parameters have no direct public health impact. However, they are important as a means of determining how production and distribution facilities for water intended for human consumption are functioning, and of evaluating water quality. Such parameters can help to identify water treatment deficiencies and play an important role in increasing and maintaining consumer confidence in water quality. Therefore, Member States should ensure that such parameters are monitored.
- (12) 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.
- (13) Safe water intended for human consumption means not only the absence of harmful micro-organisms and substances, but also the presence of certain amounts of natural minerals and essential elements, taking into consideration that long-term consumption of demineralised water or water very low in essential elements such as calcium and magnesium can compromise human health. A certain amount of such minerals is also vital in order to ensure that water intended for human consumption is neither aggressive nor corrosive and to improve the taste of such water. Minimum concentrations of such minerals in softened or demineralised water could be considered in accordance with local conditions.
- (14) 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 introduced in 2015 in Directive (EU) 2015/1787, allowing Member States to derogate from their established monitoring programmes, provided that credible risk assessments are carried out which could be based on the WHO's Guidelines for Drinking Water Quality (WHO Guidelines). The WHO Guidelines, which lay down the so-called 'Water Safety Plan' approach, including for small communities, together with standard EN 15975-2 concerning security of drinking water supply, are internationally recognised principles on which the production and distribution of water intended for human consumption, and the monitoring and the analysis of parameters in such water, are based. Those first elements of a risk-based approach should be maintained in this Directive.
- (15) To ensure that the elements of a risk-based approach introduced in Directive (EU) 2015/1787 are not limited to monitoring aspects, to focus time and resources on

relevant risks and on cost-effective source measures, and to avoid analyses of and effort being spent on non-relevant issues, it is appropriate to introduce a complete riskbased approach to water safety, covering 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 of the European Parliament and of the Council⁽¹⁰⁾ and should take into account more effectively the impact of climate change on water resources. That risk-based approach should consist of three components. First, identification of the hazards associated with the catchment areas for abstraction points ('risk assessment and risk management of the catchment areas for abstraction points of water intended for human consumption'), in line with the WHO Guidelines and Water Safety Plan Manual. Second, a possibility for the water supplier to adapt monitoring to the main risks and to 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 of the supply system'). Third, an assessment of the potential risks stemming from domestic distribution systems, such as Legionella or lead ('risk assessment of the domestic distribution systems'), with special focus on priority premises. Those assessments should be regularly reviewed, inter alia, in response to threats from climate-related extreme weather events, known changes of human activity in the abstraction area or in response to source-related incidents. The risk-based approach should ensure a continuous exchange of information between competent authorities and water suppliers.

- (16) In order to reduce the potential administrative burden for water suppliers supplying between 10 m³ and 100 m³ per day as an average or serving between 50 and 500 people, Member States should be able to exempt those water suppliers from carrying out a risk assessment of the supply system, provided that regular monitoring in accordance with this Directive 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. Union flag maritime vessels comply with the international regulatory framework when sailing in international waters. It should be ensured that priority is given to existing international regulations or internationally acknowledged standards, such as the vessel sanitation programme developed by the United States Public Health Service, which are more detailed and more stringent and apply to ships on international waters.
- (17) Risk assessment and risk management of the catchment areas for abstraction points should take a holistic approach 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, or a risk of pollution, of water bodies used for abstraction of water intended for human consumption. To that end, Member States should characterise the catchment areas of abstraction points, and identify hazards and hazardous events that could cause the quality of water to deteriorate, such as possible pollution sources associated with those catchment areas.

When necessary in light of the identification of hazards, Member States should monitor pollutants which they identify as relevant, such as nitrates, pesticides or pharmaceuticals