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Delegations will find attached document D038826/02.

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EUROPEAN
COMMISSION

Brussels, XXX
[…](2015) XXX draft

COMMISSION DIRECTIVE ../…/EU

of XXX

amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption

COMMISSION DIRECTIVE ../…/EU

of XXX

amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[1], and in particular Article 11(2) thereof,

Whereas:

(1) Annexes II and III to Directive 98/83/EC lay down the minimum requirements of the monitoring programmes for all water intended for human consumption and the specifications for the method of analysis of different parameters.

(2) The specifications in those Annexes II and III should be updated in the light of scientific and technical progress and so as to ensure coherence with Union legislation.

(3) Annex II to Directive 98/83/EC grants a certain degree of flexibility in performing the audit monitoring and check monitoring, allowing for less frequent sampling under certain circumstances. The specific conditions to perform the monitoring of parameters at appropriate frequencies and the range of monitoring techniques need to be clarified in the light of scientific progress.

(4) Since 2004, the World Health Organisation has developed the water safety plan approach which is based on risk assessment and risk management principles, laid down in its *Guidelines for Drinking Water Quality*[2]. Those Guidelines, 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 drinking water is based. Annex II to Directive 98/83/EC should therefore be aligned to the latest updates of those principles.

(5) To control risks to human health, the monitoring programmes should ensure that there are measures in place throughout the water supply chain and consider information from water bodies used for drinking water abstraction. The general obligations for monitoring programmes should bridge the gap between water abstraction and supply. Pursuant to Article 6 of Directive 2000/60/EC of the European Parliament and of the Council[3], Member States must ensure the establishment of register(s) of protected

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1 OJ L 330, 5.12.1998, p. 32.

2 http://www.who.int/water_sanitation_health/publications/2011/dwq_guidelines/en/index.html.

3 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).

areas. Such protected areas include all bodies of water used for the abstraction of drinking water, or intended for such use, under Article 7(1) of that Directive. Results from the monitoring of those bodies of water under the second subparagraph of Article 7(1) and Article 8 of that Directive should be used to determine the potential risk for drinking water before and after treatment for the purposes of Directive 98/83/EC.

(6) Experience has shown that, for many (particularly physico-chemical) parameters, the concentrations present would rarely result in any breach of limit values. Monitoring and reporting such parameters without practical relevance imply significant costs, especially where a large number of parameters need to be considered. Introducing flexible monitoring frequencies under such circumstances presents potential cost-saving opportunities that would not damage public health or other benefits. Flexible monitoring also reduces the collection of data that provide little or no information on the quality of the drinking water.

(7) Member States should therefore be allowed to derogate from the monitoring programmes they have established, provided credible risk assessments are performed, which may be based on the WHO *Guidelines for Drinking Water Quality* and should take into account the monitoring carried out under Article 8 of Directive 2000/60/EC.

(8) Table B2 in Annex II to Directive 98/83/EC, which concerns water put into bottles or containers intended for sale, has become obsolete, as those products are covered by Regulation (EC) No 178/2002 of the European Parliament and of the Council[4]. Those products are also covered by the principle of 'hazard analysis and critical control point' (HACCP) laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council[5] and the principles of official controls as laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council[6]. As a consequence of the adoption of those Regulations, Annex II to Directive 98/83/EC de facto no longer applies to water put into bottles or containers intended for sale.

(9) Council Directive 2013/51/Euratom[7] introduced specific arrangements for monitoring for radioactive substances. Monitoring programmes for radioactive substances should therefore exclusively be established under that Directive.

(10) Laboratories applying the specifications for the analysis of the parameters laid down in Annex III to Directive 98/83/EC should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated.

(11) Commission Directive 2009/90/EC[8] provides for standard EN ISO/IEC 17025, or other equivalent standards accepted at international level, to be used to validate the

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4 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).

5 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

6 Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

7 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).

methods of analysis. EN ISO/IEC 17025 is also one of the standards used under Regulation (EC) No 882/2004 for the accreditation of laboratories designated by the competent authorities in the Member States. It is therefore necessary to provide for that standard, or other equivalent standards accepted at international level, for the validation of the methods of analysis in the context of Directive 98/83/EC. In order to align Annex III to Directive 98/83/EC with Directive 2009/90/EC, the limit of quantification and uncertainty of measurement should be introduced as performance characteristics. However, Member States should be able to continue to allow the use of trueness, precision and limit of detection as performance characteristics under Annex III to Directive 98/83/EC for a limited period, thus providing laboratories with sufficient time to adapt to this technical advance.

(12) A number of ISO standards have been established for analysing microbiological parameters. Thus, EN ISO 9308-1 and EN ISO 9308-2 (for the enumeration of *E. coli* and coliform bacteria) and standard EN ISO 14189 (for the analysis of *Clostridium perfringens*) provide all necessary specifications for performing the analysis. Those new standards and technical developments should be reflected in Annex III to Directive 98/83/EC.

(13) For the purposes of assessing the equivalence of alternative methods with the method laid down in Annex III to Directive 98/83/EC, Member States should be permitted to use standard EN ISO 17994, which has already been established as the standard on the equivalence of microbiological methods in the context of Directive 2006/7/EC of the European Parliament and of the Council[9] and by Commission Decision 2009/64/EC[10]. Alternatively, they should be permitted to use standard EN ISO 16140 or any other similar internationally accepted protocols, as referred to in Article 5(5) of Commission Regulation (EC) No 2073/2005[11], to establish the equivalence of methods based on principles other than culturing, which are beyond the scope of EN ISO 17994.

(14) Annexes II and III to Directive 98/83/EC should therefore be amended accordingly.

(15) The measures provided for in this Directive are in accordance with the opinion of the Drinking Water Committee established under Article 12(1) of Directive 98/83/EC,

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

9 Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality (OJ L 64, 4.3.2006, p. 37).

10 Commission Decision 2009/64/EC of 21 January 2009 specifying, pursuant to Directive 2006/7/EC of the European Parliament and of the Council, ISO 17994:2004(E) as the standard on the equivalence of microbiological methods (OJ L 23, 27.1.2009, p. 32).

11 Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 98/83/EC is amended as follows:

(1) Annex II is replaced by the text set out in Annex I to this Directive.

(2) Annex III is amended in accordance with Annex II to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [**OJ Please insert the date: 24 months after the entry into force of this Directive**] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
The President