

Navigating Evolving Drinking Water Regulations - A Review of the Proposed New European Union Legislation



Introduction

The newly proposed European Union provisions for safe and clean drinking water represents a major initiative to improve water quality by implementing changes to existing drinking water regulations including an update to the water quality standards established over 20 years ago, the introduction of a cost-effective-risk-based approach to monitoring contaminants, and stricter hygiene guidelines for materials in contact with drinking water supplies. Once finalized, individual member countries will be given a two-year time frame to establish these standards. However, it is strongly advised that environmental testing labs and drinking water suppliers carry out a thorough evaluation of the wide-ranging implications of this new legislation.

With an expansion in targeted analytes and more stringent detection limits, the new standards will focus on analysis of these contaminants and the watch list mechanism for future regulated compounds. The proposed water quality standards, risk-based monitoring and hygienic standards for drinking water emphasize the importance of testing laboratories having high quality, reliable analytical results. Critical to the competence demonstration of testing labs is having an ISO/IEC 17025-2107 "General Requirements for the Competence of Testing and Calibration Laboratories" certification. This accreditation is an ultimate guide to deliver accurate, reproducible and precise analytical results, complaint with the latest EU environmental regulations.

Historical Perspective and Legislative Framework

Water was first recognized as a basic human right following the United Nations Water Conference in 1977. After that, Europe began to establish directives to protect bathing water quality and over time, those directives have evolved, and now pertain to maintaining standards for drinking water, urban waste water, river basins, and even fishing grounds.

Beginning in the 1980s, frameworks like the Dangerous Substances Directive were introduced that helped protect water supplies from hazardous chemical runoff and dumping, including nitrates and phosphates. This was also the beginning of ecologically driven guidelines to protect biodiversity and natural resources. In 1991, the first order to prevent the deterioration of fresh waters was approved, and with it, a program to ensure their sustainable management and protection by 2000.

The Water Framework Directive

After the European Union (EU) was formed in 1993, it set out to create EU-wide directives on water quality. The Water Framework Directive (WFD) is a comprehensive and uniform directive that applies to all member states and helps ensure the quality and protection of all waters, including inland, surface, coastal, groundwater and transitional waters. The major components of the Directive are outlined below:

- The WFD 2000/60/EC was introduced in 2000, enacted in 2013, and replaced directives 75/439/EEC, 75/442/EEC, 91/156/EEC, 91/689/EEC and 2006/12/EC.
- Its aim was to prevent and reduce pollution and improve aquatic ecosystems conditions, with the major goal to have all groundwater classified in good condition by 2015.
- The WFD identified priority substances and how to monitor different classes of contaminants with the first watch list.
- Member States had the flexibility to apply an EQS (Environmental Quality Standard) for an alternative matrix or, where relevant, an alternative classification of biota.
- Compound levels were expressed as Environmental Quality Standard or (EQS) with the annual average (AA) and the Maximum Allowable Concentration (MAC) given.
- The EU WFD encouraged the development of novel monitoring methods.

The Drinking Water Directive

The Drinking Water Directive (DWD) ensures the protection and quality of safe and potable drinking water in member states by outlining minimum quality standards. Although those minimum requirements must be met by member states, they can provide other safety parameters to ensure sustainable water use or other appropriate objectives. The DWD does not apply to natural mineral waters and waters considered as medicinal products, as they are subject to special rules laid out in the directives.

The Directive also identifies indicator testing parameters, (e.g. radioactivity), with the objective of identifying a possible risk to human health that may require corrective action in the event of non-compliance by the member state concerned. The Directive also includes additional monitoring by member states, for specific substances and micro-organisms, for which no parameters have been set, but which may pose a potential risk to human health.

Member states may provide for exemptions from specific parameters, as long as it does not risk human health. Exemptions must be as short as possible, after which a review must be carried out to determine whether sufficient progress has been made. The exemption may not be renewed for more than two periods, and not exceeding three years. (Note: they shall not apply to water intended for human consumption that is sold in bottles or containers).

River Basin and District Establishment

To build a comprehensive framework, member states would first identify and classify bodies of water partially or wholly within their territories, according to directions laid out in the WFD. After the identification and classification stage, member states would work to create individualized management plans for each river basin district.

Each plan must contain:

- A general description of the characteristics of the river basin district, including surface water, groundwater and protected areas
- An examination of the environmental impact of human activities on the status of surface water and groundwater
- An economic analysis of water use
- The establishment of one or more registers of protected areas in each river basin district

Environmental Quality Standards and Priority Substances

The concept of environmental quality standards (EQS) were first introduced in 2008 and outline the concentration limits for certain priority pollutants, while the annual average value (AA-EQS) is defined as the concentration of the substance measured that is allowed over a one year period while the maximum allowable concentration (MAC-EQS) is the concentration allowed at any one time.

Member states were also required to outline mixing zones, where higher values of the EQSs are permitted, provided that the rest of the surface water body meets the quality standards. These zones need to be clearly identified in the river basin district management plans.

In 2013, a new Directive, 2013/39/EC, updated the priority substances list and EQSs from previous Directives 2000/60/EC and 2008/105/EC. The major changes included:

- Updated EQSs for seven of the 33 original priority substances in line with the latest scientific and technical knowledge concerning the properties of those substances
- Revised EQSs for those seven existing priority substances to take into account river basin management plans from 22 December 2015 with the aim of achieving good surface water chemical status for those substances by 22 December 2021
- Twelve newly identified priority substances whose EQSs were be taken into account in drawing up supplementary monitoring programs and in preliminary programs of measures to be submitted to the European Commission by the end of 2018, with the aim of achieving good surface water chemical status for those substances by 22 December 2027

Watch List for Future Regulated Compounds

A total of 45 microbiological and chemical parameters must be monitored and tested regularly according to the World Health Organization's guidelines for drinking water and the Commission's own Scientific Advisory Committee for drinking water standards. In addition to the priority substances list, the EU also maintains watch lists for potentially hazardous substances that are updated every two years to ensure water quality throughout the region. When a substance is placed on the surface water watch list, member states must include it in testing to monitor levels in water supplies within six months and must continue monitoring for at least 12 months. The groundwater watch list framework is currently under development and is voluntary for member states, unlike the mandatory regulations in the surface water watch list.

The original watch list, compiled in 2015, included ten groups of substances: one synthetic hormone and two natural ones, one painkiller, five neonicotinoid insecticides, three macrolide antibiotics, one sunscreen agent, two herbicides, one insecticide and one industrial product.

The current surface water watch list includes the following eight groups of substances:

- 17-alpha-ethinylestradiol
- 17-beta-estradiol, extrone
- Macrolide antibiotics (erythromycin, clarithromycin, azithromycin)
- Metiocarb
- Neonicotinoids (imidacloprid, thiacloprid, thiamethoxam, clothianidin, acetamiprid)
- Metaflumizone
- Amoxicillin
- Ciprofloxacin

The EU continually monitors and updates the priority hazardous substances list to ensure the protection of human health and environmental conditions. These revisions can also include updated detection limits and best practices to test for these substances.

Analytical Methods and Monitoring Specifications

The WFD also maintains analytical and technical specifications criteria for water testing, and includes minimum efficiency criteria and rules to prove the quality of analysis results. These criteria ensure comprehensive and relevant monitoring information, as they make the use of validated methods of analysis mandatory, to ensure that any data exceeding the EQS can be reliably detected and measured.

Member states must ensure that all methods of analysis used for chemical monitoring purposes, including laboratory, field and online methods, are validated and documented in accordance with EN ISO/IEC-17025 or other internationally accepted equivalent standards.

These establish appropriate international standards for the validation of the methods of analysis used. For validation purposes, those methods shall comply with certain minimum performance criteria, including rules on measurement uncertainty and limit of quantification of methods. In order to ensure comparability of chemical monitoring results, the limit of quantification should be given a commonly accepted definition. Where there are no methods that meet the minimum performance criteria, monitoring should be carried out using best available techniques that do not entail excessive costs.

The WFD also contains criteria for the calculation of average values when the quantities of physical or chemical analytes present in a sample are below the limit of quantification. When this occurs, the measurement results are set at half the value of the sample.

Member states must also ensure that laboratories, or third parties awarded contracts by laboratories, demonstrate their competence to carry out the required analyses by participating in proficiency testing programs. These programs include the verification of test methods, and the analysis of representative reference documentation of the samples collected, at appropriate levels of concentration, against environmental quality standards. The evaluation test programs must be organized by bodies accredited or recognized at national or international level that comply with the criteria established by UNI EN 17043 - General Requirements for Proficiency Testing.

Testing Laboratory Accreditation

The accreditation of a laboratory is recognition of competence to carry out certain tests requested by the individual country's national accreditation body, in compliance with the requirements defined in the international reference standard ISO/IEC 17025:2017- *General Requirements for the Competence of Testing and Calibration Laboratories*. It is issued for single tests and therefore it should not be confused with a recognition extended to the laboratory as a whole. The goal of accreditation is to confirm the level of quality of a test laboratory's work, verifying the conformity of its management system and technical expertise with internationally recognized regulatory requirements and mandatory legislative demands.

Since the management requirements of ISO/IEC 17025:2017 are aligned with those of ISO 9001:2008/2015, an accredited laboratory is in compliance with regard to testing activities even if they are not ISO 9001 certified. However, it's important to emphasize that the test results provided are always and exclusively the responsibility of the Laboratory. Compliance with ISO/IEC 17025:2017 requires a laboratory to adopt its operational and organizational structure in the standard, under five distinct and complementary categories including: General, Structural, Resources, Process and Management system requirements.

General Requirements of ISO/IEC 17025:2017

ISO/IEC 17025:2017 specifies the general requirements for the competence of laboratories to perform tests and/or calibrations, including sampling. It covers tests and calibrations performed using standardized methods, non-normalized methods and methods developed by laboratories. It is applicable to all laboratories regardless of the number of persons or the scope of their testing and calibration activities. When a laboratory does not perform one or more of the activities covered by this International Standard, such as sampling, design/development of new methods, the requirements of the relevant points are not applicable. Accredited laboratories see their test reports recognized as valid in all countries that have concluded a mutual recognition agreement at the European level.

The European Accreditation Multilateral Agreement (EA MLA) is a signed agreement between the EU Members whereby the signatories recognize and accept the equivalence of the accreditation systems operated by the signing members, which covers the full range of laboratory testing, including certification, inspection, validation, verification, reference standards and proficiency protocols. Acceptance in the marketplace of the EA MLA and thereby of conformity assessment results provided by the signatories is of major importance for the internal market in Europe in facilitating cross border trade as well as in demonstrating compliance with European legislation for products and services contributing to protect health, safety and the environment. For an up-to-date list of countries that have signed the agreement, please refer to the European Cooperation for Accreditation website.

In Summary

This white paper was designed to provide an overview of the evolving regulations as laid out in the proposed new EU drinking water standards. It is meant to offer a summary of standards and targeted analytes covered under the 2020 EU provisional revisions to Directive 98/83/EC, in addition to giving a summary of the Watch List for future regulated compounds. Moreover, it explains the significance of the ISO/IEC 17025:2017 Standard as well as best practices in achieving accreditation. It should serve as an educational primer for the global environmental community to have a better understanding of the direction of drinking water

regulations in the European Union. However, for specific details about how different member countries are approaching and implementing these new regulations, please refer to each country's environmental regulatory authority.

For Additional Information on the New EU Drinking Water Directives:

1. The EU Water Framework Directive - Integrated River Basin Management for Europe: https://ec.europa.eu/environment/water/water-framework/index_en.html
2. The European Commission Drinking Water Directive (Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption): https://ec.europa.eu/environment/water/water-drink/legislation_en.html
3. ISO/IEC 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories: https://webstore.ansi.org/standards/iso/isoiec170252017?gclid=EAlaIqObChMlvqHv8biZ7QIV7cuGCh3fRADGEAAYASAAEgluCPD_BwE
4. European Cooperation for Accreditation (EA): Directory of EA Members and Multilateral Agreement Signatories: <https://european-accreditation.org/ea-members/directory-of-ea-members-and-mla-signatories/>
5. ISO 9001:2015 and ISO 9001:2008 - Quality Management Transition Set: https://webstore.ansi.org/Standards/ISO/ISO900120152008Quality?gclid=EAlaIqObChMljpwXLob7QIVA7KGCh1CPALTEAAYAiAAEgL6W_D_BwE
6. Directives 2013/39/EU, 2008/105/EC, 2000/60/EC of the European Parliament - Priority Substances in the Field of Water Policy: <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:226:0001:0017:EN:PDF>
7. Water, Sanitation and Health: World Health Organization Standards for Drinking Water: <https://www.who.int/health-topics/water-sanitation-and-hygiene-wash>
8. ISO/IEC 17043:2010 Conformity Assessment — General Requirements for Proficiency Testing: <https://www.iso.org/standard/29366.html>