No. 1758

MINISTRY FOR HEALTH

Explanatory Notes

1. Introduction

Title of Regulations	Water Intended for Human Consumption Regulations, 2023
Activity to be regulated	The risk assessments that shall be followed, tests that shall be made, and regulation of parameters relative to water intended for human consumption from catchment to consumer
Responsible entity	Superintendent of Public Health with the support of various entities

2. Summary and background.

The tests to be made and parameters relative to water intended for human consumption from production to consumption, is already regulated by the existing S.L. 449.57. – Water Intended for Human Consumption Regulations. The purpose of this legislative instrument is to transpose the provisions of 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). Therefore, these regulations transpose obligations on water intended for human consumption from catchment to consumer to protect human health from the adverse effects of any contamination by ensuring that it is wholesome and clean, and to improve its access. Therefore, by means of these new regulations – the old regulations S.L. 449.57. "Water Intended for Human Consumption Regulations" are hereby repealed.

The proposed regulations were presented to Cabinet on 12th December, 2023 and subsequently tabled on 12th December, 2023.

3. Overview of the structure of the instrument.

The proposed regulations are made up of twenty-two (22) regulations, and six (6) Schedules. Said regulations establish and regulate as follows:

Regulation 1	Citation and Commencement. All the provisions of these regulations shall come into force within two (2) months from their date of publication in the Gazette. This two (2) month stand-still period applies to these regulations because they do not qualify as an exemption under S.L. 512.01.
Regulation 2	Scope
Regulation 3	Interpretation
Regulation 4	Exemptions
Regulation 5	General obligations
Regulation 6	Quality standards
Regulation 7	Points of compliance
Regulation 8	Risk based approach to water safety
Regulation 9	Risk assessment and risk management of the catchment areas for abstraction points of water intended for human consumption
Regulation 10	Risk assessment and risk management of the supply system
Regulation 11	Risk assessment of domestic distribution systems
Regulation 12	Minimum hygiene requirements for material that come into contact with water intended for human consumption
Regulation 13	Minimum requirements for treatment chemical substances and filter media that come into contact with water intended for human consumption
Regulation 14	Monitoring
Regulation 15	Remedial action and restrictions of use
Regulation 16	Derogations
Regulation 17	Access to water intended for human consumption

Regulation 18	Information to the public
Regulation 19	Information on monitoring of implementation
Regulation 20	Committee procedure
Regulation 21	Transitional period
Regulation 22	Repeal
First Schedule	List of supporting entities
Second Schedule	Minimum requirements for parametric values used to assess the quality of water intended for human consumption
Third Schedule	Monitoring
Fourth Schedule	Principles for setting methodologies
Fifth Schedule	Specifications for the analysis of parameters
Sixth Schedule	Information to the public

4. Commentary on parts and regulations.

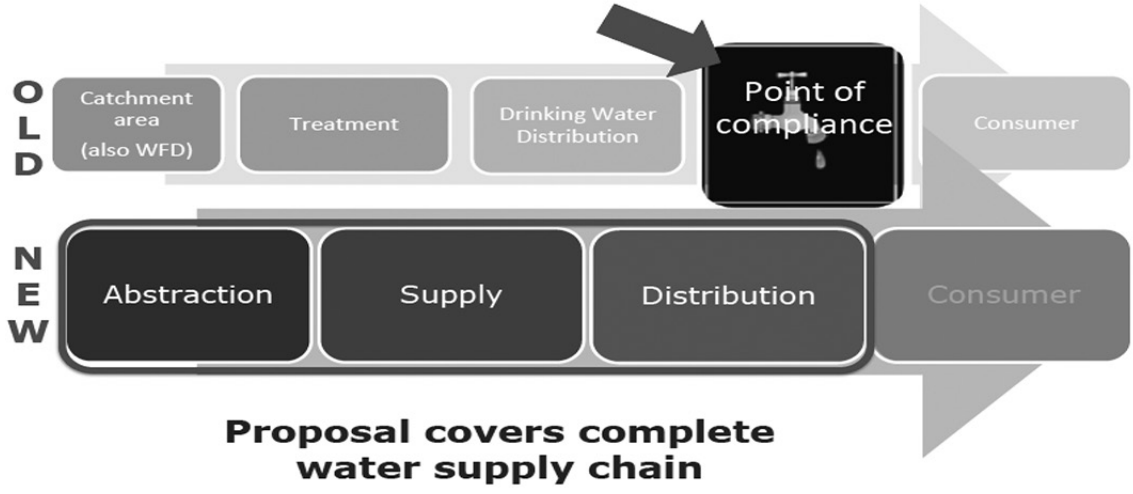
The purpose of the obligations prescribed by these regulations is to ensure that water for human consumption is wholesome and clean. The onus extends throughout the whole supply chain, i.e., from the catchment to the distribution. This means that the minimum requirements set out in the Second Schedule, Parts A, B and D and all other measures necessary to comply with the requirements set out in regulations 6 to 15, transposing Articles 5 to 14 of the Directive, are no longer applicable to the point of use only.

The Risk Based Approach covers the whole supply chain

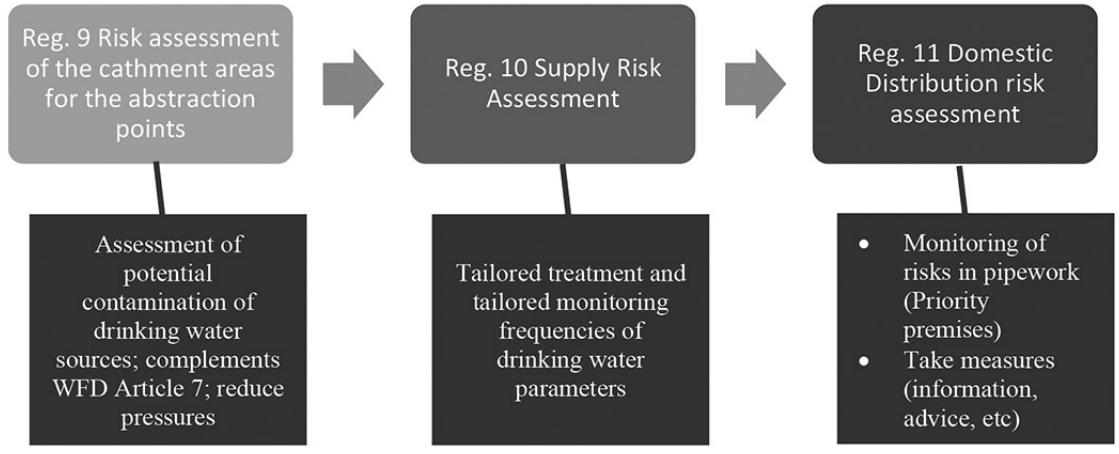


The repealed Water Intended for Human Consumption Regulations (S.L. 449.57.) mainly focused on the final product, whereas these regulations now take also into consideration the whole supply chain and the impacts on the sources of water being used (pollution being discharged, over abstraction etc.), the right to water, improving access to safe drinking-water and promotes the use of tap water. These regulations are based on the precautionary principle and the Directive obliges the competent authority to ensure no direct or indirect deterioration of the present quality of water intended for human consumption.

Risk Based Approach



In accordance with 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, an assessment of water leakage levels and the potential for improvements in water leakage reduction shall be held. That assessment shall consider relevant public health, environmental, technical and economic aspects. (Regulation 10).



The risk assessment and risk management of the catchment areas for abstraction points of water intended for human consumption shall be carried out for the first time by 12th July 2027 by the entity responsible for the implementation of the Water Policy Framework Regulations. The information obtained from the risk assessments and risk management shall be shared with the stakeholders.

Risk Assessment and Risk Management of each supply system that covers the whole supply chain, shall be carried out by 12 January 2029 by the water suppliers. A digital platform/ template shall be provided by Environmental Health Directorate ('EHD'). Testing parameters and frequencies of supplied water apply as per the Second, Third and Fifth Schedule of the regulations.

Priority premises, as defined in the regulations, shall do risk assessment of their domestic distribution system and shall carry out testing for the presence of lead in addition to Legionella as per the Control of Legionella Regulations (S.L. 465.03.) and the Registration of Cooling Towers and Evaporative Condensers Regulations (S.L. 465.04.). Other commercial and domestic premises are also encouraged to carry out a risk assessment of their water systems and test for the presence of lead.

Regulation 9 - identification of hazards and hazardous events in the catchment areas for abstraction points and an assessment of the risks that affect the quality of water.

This regulation deals with any activity carried out in the catchment area used for abstraction points to supply water intended for human consumption. Any activity carried out in the catchment area may influence surface water and ground water in the catchment areas used for abstraction to supply water intended for human consumption. Prevention of microbial and chemical contamination of the source of water is the first barrier against contamination of water intended for human consumption. Any contamination shall have an impact on the treatment steps required to ensure safe water and preventive action to limit such activities may be preferable to upgrading further treatment. The risk assessment shall be carried out to assess potential risks that might cause deterioration of the water quality to the extent that it could constitute a risk to human health.

Close collaboration between the competent authority, supporting entities and water supplier, is essential to the recognise health hazards potentially occurring in the catchment area. It is also important for ensuring that the protection of water for human consumption is considered when taking decisions for land use or other decision which might affect the water resources.

The water supplier is not responsible for the management of the catchment area which might affect his supply. However, he shall collaborate with the competent authority or any supporting entity as needed, understand the risks arising from potentially contaminating activities and, or incidents, and use such information when assessing risks in the supply system and apply appropriate risk management.

Even though, water suppliers may not be responsible for the catchment area, they may be asked to perform additional monitoring of certain parameters and inform the entity responsible for the Water Policy Framework Regulations (S.L. 549.100.) of trends and, or unusual numbers or concentrations of monitored parameters, substances or pollutants as per regulation 9(3). Water suppliers shall have access to the relevant information of the risk assessment in the catchment areas.

Regulation 10 – Risk Assessment and Risk Management of the Supply System

This shall be carried out by water suppliers producing more than 100m3 per day, using the information gathered under regulation 9 (the Risk Assessment on the Catchment Area). A risk-based approach shall be adopted to have an overall microbial and chemical control to produce water intend for human consumption. Following the identification of risks in the supply system, the necessary control measures shall be adopted to ensure that pathogens and concentrations of chemicals present a negligible risk to water.

The risk assessment on the supply system performed by water suppliers shall:

(a) take into consideration the results of the risk assessment and risk management of the catchment areas for abstraction points carried out in accordance with regulation 9;

(b) include an assessment on the system and design i.e. have a description of the whole supply chain (including the abstraction point, treatment, storage and distribution of water);

(c) include an operational monitoring (testing for parameters) as per legislation;

(d) identify the hazards and hazardous events in the supply system and include an assessment of the risks that may affect human health. These shall include risks arising from climate change, leaking pipes or other sources of contamination;

(e) have management plans, including documentation and communication.

The elements of a risk assessment shall be built on the multiple-barrier principle, the principles of hazard analysis and critical control points and other systematic management approaches. The plans should address all aspects of the water intend for human consumption of the supply system and focus on the control of abstraction, treatment, storage and delivery. In addition, the risk assessment shall provide an organised and structured system to minimize the chance of failure through oversight or lapse of management and for contingency plans to respond to system failures or unforeseen events that may have an impact on water quality.

Based on the outcome of the risk assessment carried out in accordance with regulation 10(2), the following risk management measures shall define and implement control measures for the prevention and mitigation of the risks identified in the supply system that could compromise the quality of water. These measures shall also include any risk that may have come from the risk assessment on the catchment area and, or from the risk assessment on the domestic distribution. Furthermore, materials, filters and treatment that come into contact with water intend for human consumption shall be in accordance with the requirement of the minimum hygiene requirements for material in contact with water to prevent an ill-health to consumers.

When a disinfection forms part of the preparation or distribution of water:

(a) the efficiency of the disinfection applied is validated,
(b) any contamination from disinfection by-products is kept as low as possible without compromising the disinfection,
(c) any contamination from treatment chemicals is kept as low as possible,
(d) any substances remaining in the water do not compromise the fulfilment of the general obligations set out in regulation 5.

Regulation 11 - Risk Assessment of Domestic Distribution Systems

The competent authority shall ensure that a risk assessment of the domestic distribution system is carried out by priority premises. The risk assessment shall comprise of the following elements:

(a) a general analysis of the potential risks associated:

- with domestic distribution systems, and
- with related products and materials, and whether those potential risks affect the quality of water at the point where it emerges from the taps that are normally used for water intended for human consumption;

(b) monitoring of the parameters listed in Part D of the First Schedule (legionella and lead).

In order to reduce the risks connected with domestic distribution systems, the competent authority assisted by other entities shall consider and where appropriate:

(a) encourage owners of public and private premises to carry out a risk assessment of the domestic distribution system;

(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 water and about possible action to avoid the reoccurrence of those risks;

(d) promote training for plumbers and other professionals dealing with domestic distribution systems and the installation of construction products and materials that come into contact with water;

(e) in relation to 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;

(f) in relation to lead, if economically and technically feasible, implement measures for substitution of components made of lead in existing domestic distribution systems.

Regulation 12 - Materials in contact with water

This regulation applies to materials that are intended to be used in:

- new installations,
- repair works or reconstruction,
- existing installations for the abstraction, treatment, storage or distribution of water intended for human consumption and that come into contact with such water that do not:

(a) directly or indirectly compromise the protection of human health as provided for by the Directive and these regulations;

(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 of the material.

The Superintendent of Public Health supported by entities responsible for building and construction and the entity responsible for the implementation of Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, shall ensure that only materials identified in the previous paragraph shall be used when in contact with water for human consumption.

Regulation 13 - Minimum Requirements for treatment chemicals and media - into contact with water.

This follows the same concept as regulation 12; along the water supply chain.

The competent authority, supported by the entity established by the First Schedule, shall ensure that treatment chemical substances and filter media that come into contact with water intended for human consumption do not:

(a) directly or indirectly compromise the protection of human health as provided for by the Directive and these regulations;

(b) adversely affect the colour, odour or taste of the water;

(c) unintentionally enhance microbial growth;

(d) contaminate the water at levels that are higher than necessary in view of the intended purpose.

The above shall be without prejudice to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products and the provisions of Biocidal Products (Implementation of Regulation (EU) No 528/2012) Regulations (S.L. 430.09).

Both materials in contact with water intend for human consumption or the materials, filters and, or chemicals used to treat water which are approved in accordance with the relevant directives and regulations shall be placed on the market.

Regulation 14 - Monitoring

The water supplier shall carry out monitoring of parameters as established by the Second, Third and Fifth Schedule of the regulations.

Regulation 18 - Information to the Public

Water suppliers shall provide information to their customers at least once a year on the quality and cost of the water supplied.

5. Concluding section.

All the provisions of these regulations shall come into force on their date of publication in the Gazette.

For further information please contact **EHD**:

https://deputyprimeminister.gov.mt/en/environmental/Pages/Home-Page.aspx

Telephone: +356 2334-3000
Email: wrau.ehd@gov.mt

Please also refer to the User Guidelines published concurrently with this Explanatory Note for further information.

N.B. These Explanatory Notes are not intended to be an exhaustive description of the instrument nor a substitute thereof or legislative supplement to it. These Notes do not purport to be an authoritative ruling on the interpretation of the legislation.

15th December, 2023

ANNEX

(for the purpose of paragraph (vi) of Schedule III of Chapter 512 of the Laws of Malta)

Transposition Notes for the transposition of 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).

Directive Article Number	Transposing Regulation
2	3 (alphabetical)
3(1)(a) & (b)	4(1)(a) & (b)
3(2) Premise 16	4(2) Proviso
3(3)(a) & (b)	4(3)(a) & (b)
3(4)	4(4)
3(5)	4(5)
3(6)	4(6)
4(1)	5(1)
4(2)	5(2)
4(3)	5(3)
5(1)	6(1)
5(2)	6(2)
5(3)	6(3)
6(1)	7(1)
6(2)	7(2)
6(3)	7(3)
7(1)	8(1)
7(2)	8(2)
7(3)	8(3)
7(4)	8(4)
7(5)	8(5)
7(6)	8(6)
	Added: sharing of information Added: 8(7)
8(1)	9(1)
	Added: sharing of information
8(2)	9(2)
8(3)	9(3)
8(4)(a) to (d)	9(4)(a) to (d)
8(5)	9(5)
8(6)	9(6)
	9(7) Added: obligation of sharing of information
9(1)	10(1)
9(2)	10(2)
9(3)	10(3)
9(4)	10(4)
9(5)	10(5)

9(6)	10(6)
10(1)	11(1)
10(2)	11(2)
	11(3)
10(3)	11(4)
11(1)	12(1)
	Added 12(2)
	Added 12(3)
12(1) (a) to (d)	13(1) (a) to (d)
12(2)	13(2)
12(3)	13(3)
13(1)	14(1)
13(2) (a) to (e)	14(2) (a) to (e)
13(3)	14(3)
13(4)	14(4)
13(5)	14(5)
Fifth paragraph of 13(8)	14(6)
14(1)	15(1)
14(2)	15(2)
14(3)	15(3)
14(4)	15(4)
14(5)	15(5)
14(6)	15(6)
15(1) (a) to (c)	16(1) (a) to (c)
15(2)	16(2)
15(3)	16(3)
15(4)	16(4)
15(5)	16(5)
16(1)	17(1)
16(2)	17(2)
16(3)	17(3)
17(1)	18(1)
17(2)	18(2)
17(3)	18(3)
18(1) (a) to (e)	19(1) (a) to (e)
18(2)	19(2)
	Added 20
23	21
25(1)	22(1)
25(2)	22(2)
Annex I – Parts A to D	SecondSchedule – Parts A to D
Annex II	ThirdSchedule
Annex III	FifthSchedule
Annex IV	SixthSchedule
Annex V	Fourth Schedule