#### DECREE-LAW No. 5/2009 of January 15

# LICENSING REGULATIONS, SALE AND QUALITY OF DRINKING WATER

Considering the need to regulate the activities of collecting, treating, producing, and selling drinking water, aiming essentially to defend consumer rights and food quality for health, recognized by the Constitution;

Heedful of hygiene, sanitation, and environmental concerns involving the most essential of food assets;

Thus,

The Government decrees the following to be valid as law, pursuant to Article 115, No. 1, line e) and Article 116, line d) of the Constitution of the Republic:

#### Chapter I

#### **General Provisions**

#### **Article 1**

#### **Object and Scope**

- 1. This regulation establishes procedures for the licensing of industrial and commercial activities for the collection, treatment, production, and sale of bottled water intended for human consumption and aims at protecting health, ensuring that it is wholesome and clean.
- 2. The provisions of this statute and of the respective regulations are applicable to water collection, channeling, storage, or stocking, bottling and labeling rules, excluding the public water supply system provided for under Decree-Law No. 4/2004.
- 3. It also establishes the basic principles regarding the information provided to consumers about physical, chemical, and microbiological characteristics of bottled water for human consumption.
- 4. The renewal of licenses of establishments already operating will be authorized after inspection, pursuant to the terms of this statute.

### Article 2 Definitions

The following definitions apply to this statute:

- a) Water intended for human consumption or drinking water is water that has already been submitted to chemical, physical, microbiological and radiological analyses, and is certified as proper for sale for domestic consumption, which is distributed using casks, jugs, bottles, water receptacles or tanks, under the conditions mentioned in Attachment I;
- b) Artesian and well water is water taken from a hole drilled in soil or from a well, by pressure mechanisms or other means;
- c) Fountain water or spring water is water that flows from under ground to the surface by natural means and which shall be collected exclusively from its own source or by a hole drilled directly into it;
- d) Sparkling water is water that contains gas or that is submitted to a treatment which may include carbon dioxide so that it has the same amount of this chemical element as its has at the source or origin;
- e) Drinking water is water that has been submitted to a laboratory process and found to be proper for human consumption by Health agencies, but whose processing and sale may not be licensed without a prior certification of its bacterial, chemical, radioactive, and physical characteristics.
- f) Natural mineral water is water that flows naturally beneath the ground and therefore is more protected from pollutants and is characterized by a constant level of minerals. This water cannot be submitted to any kind of treatment or addition of substances, from its extraction to its consumption;
- g) Purified or demineralized water can be either underground or surface water that has undergone distillation, deionization, reverse osmosis, or any other authorized process, before the bottling process for sale;
- h) Water sample is the amount of water collected for laboratory analysis purposes;
- i) Quality control of bottled water for human consumption a set of activities performed in an ongoing way, in order to verify whether the water offered to the population is potable, ensuring the maintenance of that condition;
- j) Hazardous substance: a toxic substance or group of substances that are persistent and susceptible to bioaccumulation and also substances or groups of substances that may be a cause for concern to Public Health;
- k) Quality surveillance of bottled water for human consumption: the set of ongoing activities undertaken by the Public Health authority to verify if the water consumed by the population meets the established standards set out in this statute.

### **Article 3 Information for businessmen**

Before commencing the licensing process for the activities mentioned in Article 1, the Ministry of Health and the Ministry of Tourism, Commerce and Industry, hereinafter referred

to simply as MTCI, make available to interested parties the information that may be required, as follows:

- a) The legal conditions established for the activities to be carried out and the necessary documentation and procedural formalities;
- b) The possibility of obtaining a temporary license, which will allow the interested party to commence activities within a shorter timeframe, subject to the terms set out in Ministerial Statute No. 1/2008, of February 6, issued by the MTCI;
- c) The foreseeable channels to be followed in the licensing process, taking into account all obvious circumstantial factors in the case in question;
- d) The mandatory sums to be paid as procedural costs and fees to cover general administrative expenses.

### CHAPTER II QUALITY CONTROL AND CERTIFICATIONS

# Article 4 Quality Control

- 1. All bottled water sold shall come from an approved source or origin certified by the proper authorities;
- 2. The control procedures for drinking water are the responsibility of the Health Surveillance Authorities of the Ministry of Health, which carry out the following activities jointly with the Food and Economic Inspection Service:
- a) Inspection of sanitation and collection of water data, from the spring or source through the production process, distribution channels, stored water and bottled water;
- b) Make recommendations concerning doubtful situations and propose the cancellation of licenses for any activities that lack the foregoing;
- c) Proceed with laboratory analyses under the terms and for the purposes set out in the Attachments hereto, which are an integral part hereof;
- d) Jointly with Food and Economic Inspection Service (FEIS), provide preventive recommendations to consumers.
- 3. A proper report will be drawn up of each inspection performed in the land lot, place of production, or laboratory.
- 4. Whenever possible, the presence of district authorities should be requested.
- 5. All drinking-water producers must perform the mandatory quality control set out in Attachment II.

### Article 5 Collection of water samples for quality control

- 1. Each sample container is duly identified, indicating the address, firm's name, date, full name, and signature of the person responsible.
- 2. The people responsible for the activities must collaborate with the inspecting agencies, not disallowing or preventing their activities, under penalty of an administrative fine in infringement proceedings and of cancellation or suspension of operating licenses.
- 3. The collection of samples must not coincide with days on which flooding or other calamities occur, except for preventive purposes.

### SECTION I PRODUCTION AND BOTTLING

# Article 6 Production and bottling establishments

- 1. The licensing conditions for industrial establishments comply with the sanitary and quality principles and rules determined in attachments hereto, as well as those pertaining to the inspection of machines, pumps, filters, tanks, bottling processes, and container reutilization.
- 2. Without prejudice to policies on territorial rule, as well as industrial licensing standards, the establishments engaged in the production of bottling of water shall not be located within the city limits and never in downtown areas or within a 3- kilometer radius thereof.
- 3. The industrial establishments and units already existing and in operation that do not comply with the requirements set out above must present a relocation plan to the MTCI within 3 months.
- 4. The industrial bottling units must take necessary measures and be prepared to explain to the proper authorities all procedures, including but not limited to those relating to the safety and security of buildings, employees, materials, and transport of products.
- 5. In the event the location of the industrial unit poses risks of contamination or adversely affecting the quality of the water, the license and authorization process are to be suspended until the Services mentioned in Article 14 present the appropriate technical opinion.

# Article 7 Performance requirements

- 1. All bottled or jugged water must comply with chemical, physical, and microbiological quality characteristics determined by this statute and respective attachments.
- 2. The installations for the bottling of water, regardless of its source, origin, or capacity, may only operate after the appropriate inspection, after the samples are analyzed and approved as meeting sanitation standards for human consumption.

3. The production of bottled water, including its processing, reutilization, storage, and transport must provide for preventive control mechanisms to minimize the potential for microbiologic contamination of the end product.

### Article 8 Treatment Process

- 1. The treatment of bottled water intended to prevent or remove contaminations may include the use of chemical processes, such as chlorination, ozonization, or carbonation, as well as physical treatments such as boiling, ultraviolet rays, radiation or filtering.
- 2. The treatments mentioned above may be utilized individually or successively, or a combination of both.
- 3. The removal or reduction of chemical substances may include chemical and mechanical filtering systems such as the following:
- a) Membrane-filters;
- b) Compressed-fiber filters;
- c) Activated carbon;
- d) Demineralization, such as deionization, water softening, reverse osmosis;
- e) Oxygenation;
- f) Ultraviolet sterilization;
- g) Others, duly inspected, tested and approved.
- 4. Taking in account the characteristics of the local water, it is mandatory to use a reverse osmosis system or water softening process so as not to exceed the total maximum level of water hardness set out in the attachment hereto.
- 5. In microfiltration processes, which shall be double and consecutive, the maximums permitted must not surpass 5  $\mu$  and 3 $\mu$ , respectively.

### SECTION II CERTIFICATIONS

### Article 9 Certifications and respective fees

- 1. The quality certifications and their features shall be published in a joint ministerial statute issued by the Ministries of Health and of Tourism, Commerce and Industry.
- 2. This same statute will determine the applicable fees for expenses incurred with analyses.

# Article 10 Certifications of tanks and pipelines

- 1. All types of tanks, pumps, pipelines and connectors used to transport and unload water intended for human consumption must be built with non-absorbent and easy-to-clean materials, such as stainless steel.
- 2. Any tanks and tank trucks that have been used for transporting toxic substances or petroleum-based products may not be used for transporting water intended for human consumption.
- 3. The equipment such as pumps, connections and hoses used to transfer water intended for human consumption between any tanks or storage area must be properly protected and cared for so as to avoid contamination.

### CHAPTER III INFORMATION AND LABELING

### Article 11 Information to consumers

The information provided to consumers by advertisements or other means of publicity about the quality and physical, chemical and microbiological characteristics of water for human consumption must meet the following conditions:

- a) Be truthful;
- b) Be precise, clear, ostensive, and easy to understand, especially as regards aspects which may cause situations of loss of potability, posing risks to health or contingent use of the water; and
- c) Be educational, promoting the sustainable consumption of water and providing an understanding of the relationship between its quality and the health of the population.

# Article 12 Mandatory wording of information to consumers

- 1. The labels of all packages, whether cups, bottles, or jugs, must include at least the following information:
- a) The source and its country of origin;
- b) The corporate name of the company that bottles and sells it and, in the case of "mineral water", this information must be highlighted.
- c) The expiration date to be shown on containers makes a distinction between "best before" and just "expiration date", followed by the respective date;

- d) The labels of sparkling water must mention whether it is a natural characteristic or if the gas was introduced artificially, by means of the statements "Natural Sparkling Water" or just "Sparkling Water".
- 2. In the case of the "best before" information mentioned in section c) of the above item, a period of up to one month after the indicated date may be tolerated before the product is taken off the shelf, so long as the storage or selling location is not exposed to sunlight.

### CHAPTER V PENALTIES

# Article 13 Penalties and infringement proceedings. Remission

- 1. The conduct that constitutes an infraction of the rules set out in this statute follows the legal order for infringements and is subject to a fine of \$1,000 to \$10,000 American dollars, without prejudice to other applicable ancillary fines.
- 2. Licenses, whether temporary or not, may be withdrawn for a period of up to one year, where analyses show that the water sold represents a danger to public health, without prejudice to civil and criminal liability.
- 3. The circumstances described in the item above constitute aggravating factors for the application of penalties and ancillary fines.
- 4. The Minister of Health and the Minister of Tourism, Commerce and Industry or those to whom they delegate such powers are authorized to impose penalties and ancillary fines.

### CHAPTER V FINAL AND TEMPORARY PROVISIONS

### Article 14 Institutional Collaboration

- 1. In the event of signed and well-founded complaints and accusations, a team made up of IAE and the Health Surveillance Authorities will perform an inspection within 3 business days.
- 2. If the inspection team identifies the existence of spills of pollutants that may pose a risk to the environment and/or human health, it will inform the appropriate government agencies, namely Health, the State Office of the Environment, and the Ministry of Infrastructure.
- 3. In the event that risks of contamination are noted on the land lot, the inspectors will make arrangements, through the respective hierarchy, to immediately send the respective report to the Ministry responsible, as well as to the State Office of the Environment and the Ministry of Infrastructure.

#### Licensing

- 1. Without prejudice to inspection activities being performed when this statute takes effect, the brands of bottled water already existing in the market retain their respective licenses.
- 2. New commercial brands, understood to be those that are bottled or imported as of the time this decree-law takes effect, may not be sold or distributed without the proper prior analysis and certification from the Ministry of Health.

# Article 16 Updates and amendments to attachments

Updates and amendments to the attachments to this statute, as well as the minimum and maximum chemical and physical indexes and levels and mandatory methods, will be established by a joint ministerial statute issued by the Ministries of Health and of Tourism, Commerce and Industry.

Commerce and Industry.	
Article 17 Effective Date	
This statute takes effect on the day after its publication.	
Approved in Cabinet Meeting on September 17, 2008.	
The Prime Minister,	
Kay Rala Xanana Gusmão	
The Minister of Health,	
Nelson Martins	
The Minister of Tourism, Commerce and Industry,	
Gil da Costa A. N. Alves	
Promulgated on 29/Dec/2008	

To be published.

The President of the Republic	
José Ramos Horta	

#### **ATTACHMENT I**

### Part A Microbiological Parameters

1. For water intended for human consumption provided by the public water supply system, distribution networks, trucks or cistern ships or used by companies in the food industry:

Parameter	Parameter Value	Units
Escherichia coli (E.coli)	0	Number/100 ml
Enterococcus	0	Number/100 ml

2 - For water sold in bottles or other containers:

Parameter	Parameter Value	Units
Escherichia coli (E.coli)	0	Number/250 ml
Enterococcus	0	Number/250 ml
Pseudomonas aeruginosa	0	Number/250 ml
Number of colonies at 22°C	100	Number/ ml
Number of colonies at 37°C	.20	Number/ ml

#### Part B Chemical Parameters

2 - For water intended for human consumption supplied by the public water supply system, distribution networks, trucks or cistern ships or used by companies in the food industry or offered for sale in bottles or other containers:

Number	Parameter	Parameter Value	Units	Notes
1	Acrylamide	0.10	μg/l	Note 1
2	Antimony	5.0	μg/l Sb	
3	Arsenic	10	μg/l As	
4	Benzene	1.0	μg/l	
5	Benzo[a]pyrene	0.010	μg/l	
6	Boron	1.0	mg/l B	
7	Bromates	10	μg/l BrO <sub>3</sub>	Note 2
8	Cadmium	5.0	μg/l Cd	
9	Chromium	50	μg/l Cr	Note 3
10	Copper	2.0	μg/l Cu	Note 3
11	Cyanides	50	μg/l Cu	
12	1.2 Dichloroethane	3.0	μg/l	
13	Epichlorohydrin	0.10	μg/l	Note 1
14	Fluorides	1.5	mg/l F	
15	Lead	Up to 25	μg PB/l	Note 3 and 4
16	Mercury	1.0	μg/l Hg	
17	Nickel	20	μg/l Ni	Note 3
18	Nitrates	50	mg/1 NO <sub>3</sub>	Note 5
19	Nitrites	0.5	mg/1 NO <sub>2</sub>	Note 5
20	Individual pesticides	0.10	μg/l	Notes 6 and 7

21	Pesticides - Total	0.50	μg/l	Notes 6 and 8
22	Polycyclic aromatic hydrocarbons (PAHs)	0.10	μg/l	The sum of concentrations of specified compounds: Note 9
23	Selenium	10	μg/l SE	
24	Tretachloroethene and Trichloroethene	10	μg/l	The sum of concentrations of specified compounds.
25	Total Trihalometanes (THMs)	100	μg/l	The sum of concentrations of specified compounds: Note 10
26	Vinyl chloride	0.50	μg/l	Note 1

Note 1 — The parameter value refers to the residual monomer concentration in water, calculated based on specifications for the corresponding polymer's maximum migration when in contact with water. This value must be confirmed at the time the product is acquired.

Note 2 – The lowest possible value without affecting the effectiveness of disinfection.

Note 3 – This value applies to samples collected from the tap of water intended for human consumption, using an adequate sampling method and collected in such a way as to be representative of the average monthly amount ingested by consumers.

Note 4 – The maximum parameter value for lead concentrations will be 25  $\mu$ g/ l Pb. Insofar as is possible, all necessary measures shall be taken to decrease the concentrations of lead in water intended for human consumption to 15  $\mu$ g/l Pb.

Note 5 - It is the duty of the proper authorities to ensure that the water exiting water treatment plants meet the standard of [nitrates] 50 + [nitrites]/3"1, where the value in brackets is the concentration in mg/l for nitrates [NO3] and for nitrites [NO2], as well as the upper limit of 0.10 for nitrites.

Note 6 – Pesticides are understood to be the following:

Organic insecticides;

Organic herbicides;

Organic fungicides;

Organic nematocides;

Organic acaricides;

Organic algicides;

Organic rodenticides;

Organic controllers of viscous secretions;

Similar products, namely growth regulators and their metabolites, products causing significant degradation and reaction.

Only those pesticides whose presence is probable within a particular drinking water supply system need to be investigated.

Note 7 - This parameter value applies individually to each pesticide. For Aldrin, Dialdrin, heptachlor and chlorine epoxide, the parameter value used is  $0.030 \,\mu g/l$ .

Note 8 – Total pesticides means the sum of all pesticides detected and quantified during water quality control procedures.

Note. 9 – The specified compounds are:

Benzo[b] fluoranthene;

Benzo[k] fluoranthene;

Benzo[ghi] perylene;

Indeno[1,2,3-cd] pyrene.

Note 10 - Whenever possible, but without prejudice to disinfection, the concentrations of organochlorines in water shall be reduced. The specified compounds are: chloroform, bromoform, dibromochloromethane, bromodichloromethane.

All necessary measures must be taken to reduce to the greatest extent possible concentrations of THMs (Trihalomethanes) in water intended for human consumption. The applicable measures must primarily benefit areas where THM concentrations in water intended for human consumption are the highest.

# Part C Indicator Parameters

Established solely to control water intended for human consumption provided by the public supply system, distribution networks, trucks or cistern ships or used by companies in the food industry or offered for sale in bottles or other containers:

Number	Parameter	Parameter Value	Units	Notes
1	Aluminum	200	200 μg/l Al	
2	Ammonia	0.50	mg/l NH4	
3	Chlorides	250	mg/l Cl	Note 1
4	Clostridium	0		Note 2
	perfringens (including		N/100 ml	
	spores)			
5	Color	20	mg/l PrCo	
6	Conductivity	2500	μS/cm at 20C	Note 1
7	рН	>>6.5<<9.0	units of pH	Notes 1 and 3
8	Iron	200 μg/l Fe		
9	Manganese	50 μg/l Mn		
10	Odor at 25 ° C	3	Dilution factor	
11	Oxidizability	5.0	mg/l O2	Note 4
12	Sulphates	250	mg/l SO4	Note 1
13	Sodium	200	mg/l Na	
14	Taste at 25 ° C	3	Dilution factor	
15	Number of colonies	Without	N/ml 22 C	
		abnormal	N/ml 37 C	
		alterations		
16	Coliform bacteria	0	N/100 ml	Note 5
17	Total organic carbon	Without	mg/l C	Note 6

		abnormal alterations		
18	Turbidity	4	UNT	Note 7
19	α - total	0.1	Bq/l	
20	β- total	1.0	Bq/l	
21	Tritium	50	Bq/l	Notes 8 and 10
22	Total indicative dose	0.10	mSv/year	Notes 9 and 10

- Note 1 The water must not be aggressive to materials it comes in contact with;
- Note 2 Parameter to be controlled when source of water supply is superficial or influenced by it. If this parameter is not complied with, the entire supply system must be investigated to identify existing risks to human health due to the presence of other pathogenic microorganisms, for instance cryptosporidium.
- Note 3 For still water contained in bottles or other containers, the minimum pH value may be reduced to 4.5 units. For water in bottles or other containers that is naturally or artificially enriched with carbon dioxide, the minimum value may be lower.
- Note 4 If the TOC (total organic carbon) is analyzed, it is not necessary to determine the oxidizability.
- Note 5 For water contained in bottles or other containers, the units must are N/250 ml.
- Note 6 Analyses are not necessary when water supplies are less than 10,000 m<sup>3</sup>/day.
- Note 7 In the case of surface water, the standard turbidity value upon exit from the treatment plant must be 1 UNT.
- Note 8 The frequency of inspections are indicated in Attachment II, Table B1 hereof.
- Note 9 Except for tritium, potassium -40, radon, and radon byproducts, frequency of inspection and the most appropriate locations for inspection points are established in Attachment II, Table B1 hereof.
- Note 10 The proposals for water quality control program to be presented pursuant to Note 8, regarding inspection frequencies and Note 9 on inspection frequencies, control methods and the most appropriate locations for inspection points, will be adopted as set out herein.

### **ATTACHMENT II Quality control of water**

Attachment II has as its objective to define routine controls and inspection, as well as the minimum frequency for sampling and analysis of water intended for human consumption provided by the public water supply system, distribution networks, trucks or cistern ships or used by companies in the food industry or offered for sale in bottles or other containers.

1) <u>Routine control procedures</u> – The routine controls have as their objective to regularly provide information on organoleptic and microbiological quality of water intended for human consumption, as well as on the effectiveness of existing treatments (especially disinfection), with the aim of establishing its compliance with the parameter values set out herein.

Parameters and circumstances for routine control:

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Aluminum (Note 1);
Ammonia;
Color;
Conductivity;
Clostridium perfringens, including spores (Note 2)
Escherichia coli (E.coli);
pH;
Iron (Note 1);
Nitrites (Note 3);
Odor;
Pseudomonas aeruginosa (Note 4);
Taste;
Number of colonies at 22°C and 37 °C;
Coliform bacteria;
Residual disinfectant;
Turbidity.
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Note 1 – Only necessary when used as a flocking agent (see Note \*).

Note 2 – Necessary when origin of water is superficial or it is influenced by surface waters (see Note \*).

Note 3 – Necessary when chloramination for disinfection.

Note 4 – Necessary only for water sold in bottles or other containers.

(Note\*) In all other cases, these parameters are part of the inspection controls.

2) <u>Inspection controls</u> - The objective of inspection controls is to obtain the necessary information to verify compliance with the parameter values set out herein.

All parameters established in accordance with Article 6 shall be subject to inspection control, except when otherwise authorized by the Health Directorate-General, for a time period set by it, because it considers unlikely the presence of that parameter in concentrations implying failure to comply with parameter values.

#### TABLE B1)

The minimum frequency of samples and analysis of water intended for human consumption provided by the public water supply system, distribution networks, trucks or cistern ships or used by companies in the food industry.

Routine Control Parameters	Amount of water provided in supply area (cubic meters/day)	Number of samples per year (Notes 2,3 and 4)
E coli	(Note 1)	
E. coli	< 100	2
Coliform bacteria	2.100	12/5 000 : 1 1
Residual disinfectant	? 100	12/5 000 inhab.
Aluminum	122	
Ammonia	<100	2
Number of colonies at 22C		
Number of colonies at 37C	>100 and ? 1 000	4
Conductivity		
Clostridium perfringens	<1000	4+3 per 1 000 m3/d and fraction remaining to reach total volume
Color		
pН		
Iron		
Manganese		
Nitrates		
Nitrites		
Oxidizability		
Odor		
Taste		
Turbidity		

Inspection Control	Amount of water provided in	Number of samples per year
Parameters	supply area	2 2
	(cubic meters/day) (*)	
Antimony	? 100	1
Arsenic		
Benzene	> 100 and ? 1 000	1
Benzo[a]pyrene		
Boron	>1 000 and ? 10 000	1
Bromate		+ 1 for each 3 300 m3/d of
		the fraction remaining to
		reach total volume
Cadmium		
Lead		
Cyanides	> 10 000 and ? 100 000	3
Chlorides		+ 1 for each 10 000 m3/d and
		fraction remaining to reach
		total volume
Copper		
Chromium		
1,2-Dichloroethane		10
Enterococcus	>100 000	+1 for each 25 000 m3/d and
		fraction remaining to reach
		total volume

Fluorides	
Mercury	
Nickel	
PAH	
Individual pesticides	
Pesticides (Total)	
Selenium	
Chlorides	
Tetrachloroethene and	
Trichloroethene	
Trihalomethanes	
Sodium	
Oxidizability	
Total organic carbon	
Sulphates	
Vinyl chloride	
Epichloridrine	
Acrylamide	
Tritium	
$\alpha$ - total	
β- total	
Total indicative dose	

Note 1 – The amounts are calculated as averages during one fiscal year and obtained by measuring the stream at entry to the supply zone.

Whenever this type of information is not available, the highest value must be used.

Note 2 – In the event of short-term intermittent water supply, it is the duty of the Health General-Directorate to determine mandatory supply frequencies to be observed.

Note 3 – For the parameters listed on Attachment I, the establishment may request the proper authorities to reduce the supply frequency described in Table B1) whenever:

- a) The results obtained from assessing the quality of water for human consumption during a period of at least two consecutive years are constant and significantly better than the parameter values established in Attachment I;
- b) There are no factors detected likely to compromise the quality of the water.

The minimum frequency applicable will be no less than 50% of the number of samples specified in the table, except in special cases when the water supply is less than 100m3/day, where this frequency reduction is not applicable.

Note 4 – The number of samples taken for assessment of compliance must be distributed equally in space and time.

The minimum frequency of samples and analysis of water sold in bottles or other containers is:

Amount of water produced	Routine control	Inspection Control
per day (Note 1)		
to be sold in bottles and other	Number of samples per year	Number of samples per year
containers (cubic meters)		
? 10	1	1
>10 and ? 60	12	1
>60	1 for each 5m3 and fraction	1 for each 100m3 and
	remaining to reach total	remaining fraction to reach
	volume	total volume

# ATTACHMENT III Specifications for Analyzing Parameters

The analyses of routine control and inspection procedures must be performed in laboratories that guarantee the quality of the respective analytical results and that are supervised on a regular basis by qualified authorities or by an independent agency to which the task is delegated, if they are unable to perform the work themselves.

- 1) <u>Parameters using specified analysis methods</u> The principles relating to methods for establishing microbiological parameters are listed below.
- Alternative methods may be used, provided they are authorized by the Ministry of Health.
- a) Coliform bacteria and Escherichia coli (E. coli) (ISO 9308-1);
- b) Enterococcus (ISO 7899-2);
- c) Pseudomona aeruginosa (pr EM ISO 12780);
- d) Counting of viable microorganisms number of colonies at 22 ° C (pr EN ISO6222);
- e) Counting of viable microorganisms number of colonies at 37 ° C (pr EN ISO6222);
- f) Clostridium perfringens (including spores);
- g) Membrane filtration followed by anaerobic incubation of membrane in m-CP Agar (Note 1) at  $44BC \pm 1BC$  for  $21 \pm 3$  hours. Counting of opaque yellow colonies that turn pink or red after being exposed to ammonia hydroxide vapors for 20 to 30 seconds.

*Note 1* – The composition of the m-CP agar base medium is the following:

Product	Amount
Tryptose	30g
Yeast Extract	20g
Saccharose	5g
L-cisteine hydrochloride	1g
MgSO4.7H20	0.1 g
Bromocresol Purple	40mg

Agar	15g
Water	1000ml

The base medium components are dissolved and the pH adjusted to 7.6. Sterilize at 121 BC for fifteen minutes. Let cool and add:

Product	Amount
D-Cycloserine	400mg
Polymyxine-B sulphate	25mg
Indoxil B-D glucoside dissolved in 8ml of previously sterilized	60mg
water	
0.5% solution of phenolphthalein diphosphate, previously	20ml
filtered and sterilized	
4.5% solution FeCl3.6H2O	2ml

### 2) Parameters for which the performance characteristics of analysis methods are specified:

- 2.1 For the parameters listed in the following table, the performance characteristics for the methods utilized must at least be able to measure concentrations equal to the parameter value with the specified accuracy, precision and detection limits. Whatever the sensitivity of the analysis method used, the results must be expressed using at least the same number of decimal places as the values specified in Attachment I, parts B and C.
- 2.2 For the pH, the method specifications are as follows: the method must be capable of measuring the parameter value with an accuracy of 0.2 pH units and with a precision of 0.2 pH units.

	Accuracy	Precision	Detection Limit	Conditions	Notes
	Percentage of parameter value (Note 1)	Percentage of parameter value (Note 2)	Percentage of parameter value (Note 3)		
Acrylamide				To be controlled based on product specification	
Aluminum	10	10	10		
Ammonia	10	10	10		
Antimony	25	25	25		
Arsenic	10	10	10		
Benzo(a) pyrene	25	25	25		
Benzene	25	25	25		
Boron	10	10	10		
Bromates	25	25	25		
Cadmium	10	10	10		
Chlorides	10	10	10		

Chromium	10	10	10		
Conductivity	10	10	10		
Copper	10	10	10		
Cyanides	10	10	10		Note 4
1,2-Dichloroethane	25	25	10		
Epichlorohydrin				To be controlled based on product specification	
Fluorides	10	10	10		
Iron	10	10	10		
Lead	10	10	10		
Manganese	10	10	10		
Mercury					
Nickel	10	10	10		
Nitrates	10	10	10		
Nitrites	10	10	10		
Oxidizability	25	25	10		Note 5
Pesticides	25	25	25		Note 6
Polycyclic aromatic hydrocarbon	25	25	25		Note 7
Selenium	10	10	10		
Sodium	10	10	10		
Sulphates	10	10	10		
Tetrachloroethene	25	25	10		Note 8
Trichloroethane	25	25	10		Note 8
Total	25	25	10		Note 7
Trihalomethanes					
(THM)					
Vinyl chloride				To be controlled based on product specification	

Note 1(\*) – Accuracy refers to systematic error and is equal to the difference between the mean value of a large number of repeat measurements and the real value.

Note 2(\*) – Precision refers to random error and is usually obtained based on the standard deviation (within each lot and between lots) of the dispersion of results around the mean. An acceptable precision is equal to twice the standard deviation.

(\*) These definitions were taken from ISO 5725.

Note 3 – The detection limit is three times the standard deviation within each lot of an experimental sample containing a low concentration of the parameter or five times the standard deviation within each lot of the control sample.

Note 4 – The method shall determine total of cyanides, i.e., present in all forms.

- Note 5 The determination of oxidizability must be performed in an acid medium, with permanganate, at 100 BC for ten minutes.
- Note 6 The performance characteristics of the analytical methods apply to each individual pesticide and shall depend on the pesticide in question. The detection limit may not actually be obtained for all pesticides, but all efforts must be directed to this end.
- Note 7 The performance characteristics of the analytical methods apply to the individual substances specified as 25% of the parameter value contained in Attachment I.
- Note 8 The performance characteristics of the analytical methods apply to the individual substances specified as 50% of the parameter value contained in Attachment I.
- 3) Parameters for which no analytical method is specified:

Color;

Odor;

Taste:

Total organic carbon;

Turbidity (note 1).

Note 1 – For control of turbidity of treated surface water, the performance characteristics of the analytical method must at least be able to determine concentrations equal to the parameter values with an accuracy of 25%, a precision of 25%, and a detection limit of 25%.