

Republic of the Philippines
Department of Health
Bureau of Food and Drugs

July 23, 1993

Administrative Order
No. 18-A s. 1993

Subject: Standards of Quality and Requirements for the
Processing, Packaging and Labeling of Bottled
Drinking Water

SECTION I. AUTHORITY

This Order is issued pursuant to Articles 7, 17, 21 and 22
of R.A. 7394 known as the Consumer Act of Philippines.

SECTION II. OBJECTIVES

The Department of Health issues these rules and regulations
to protect the consumers against hazards to health and safety
and to promote fair trade practice.

SECTION III. DEFINITION OF TERMS

For the purpose of these standards and requirements for
bottled drinking water, the following definitions shall apply:

1. "Approved source" means the source of the water, either
spring, drilled well, public or community water system or any
other source that has been inspected and the water sampled,
analyzed and found safe and sanitary, with or without treatment.

2. "Bottled water" means water that is placed in a sealed
container or package and is offered for sale for human
consumption as drinking water.

3. "Drinking Water" means water obtained from an approved
source that has undergone minimum treatment consisting of
filtration (activated carbon or particulate) and ozonation or
equivalent disinfection process.

4. "Natural Water" means water derived from an underground
formation and not from a municipal system or public water supply,
unmodified by blending with water from another source or by
addition of dissolved solids except as it relates to ozonation
or equivalent disinfection and filtration.

5. "Artesian Water" means water from a well tapping a confined aquifer where the water level stands above the water table.

6. "Well Water" means water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.

7. "Spring Water" means a natural water derived from an underground formation, from which water flows naturally to the surface of the earth as determined by a BFAD recognized authority.

8. "Mineral Water" means water characterized by its content of certain mineral salts and their relative proportions, provided that when minerals are added unto it, such water shall be referred to as "Mineralized Water".

9. "Purified Water" means water produced by distillation, deionization, reverse osmosis, or other suitable process complying with the requirements for purified water provided in the latest edition of the United States Pharmacopeia (USP). If distillation is the applied purification process, the product may be called "Distilled Water".

10. "Carbonated Water" or "Sparkling Water" means water that has been made effervescent by the addition of carbon dioxide, provided that when the content of gas, after treatment, is the same with the source during the emergence of water taking into account the usual technical tolerance, the water may be called "naturally carbonated water".

11. "Fluoridated Water" means water that contains not less than 0.8 mg/L of fluoride either naturally occurring or as an added substance.

SECTION IV. LICENSING OF BOTTLED WATER PROCESSORS AND IMPORTERS/DISTRIBUTORS

1. No person or establishment shall process bottled water for introduction to commerce or for commercial distribution unless he is a holder of a valid license to operate (LTO) a processing plant for bottled water from the Bureau of Food and Drugs.

2. A license to operate a processing plant for bottled water may be issued after the applicants capability to comply with good manufacturing practice (GMP) prescribed under Section V is verified by inspections and the documentary as well as technical requirements listed in Annex "A" are evaluated.

The said lists may be amended or revised by BFAD to conform with the regulations whenever necessary.

3. No importer/distributor shall engage in the commercial importation of bottled water unless he is a holder of valid license to operate from BFAD.

4. A license to operate shall be issued to importer/distributor after he complies with the documentary requirements listed in Annex "A".

5. The license fees shall be P 3,000 for opening LTO and P5,000 for renewal LTO. The opening LTO shall be valid for a period of two (2) years and renewal LTO, for a period of three (3) years.

6. No licensed bottled water processors and importers/distributors shall undergo changes of ownership or operator unless the licensed owner or operator applies for an amendment of its LTO submitting therewith a true copy of the legal instrument or deed evidencing the transfer or change.

An amended LTO may be issued after the capability of the processing plant to comply with GMP prescribed under Section V hereof is verified by inspection and the authenticity and genuineness of transfer documents are determined.

SECTION V. GMP FOR PROCESSING BOTTLED DRINKING WATER

1. Approval of the Source

All bottled drinking water shall be derived from an approved source. Approval of the source, other than a public water supply, shall be based on a field inspection and a review of information prepared by a professionally qualified engineer/geologist who shall demonstrate the integrity of the said source and safety of the catchment operations. The recognized agencies who will approve the source are listed under the licensing requirements for bottled water processor.

2. Protection of the Source

All possible precautions should be taken within a 60 meter radius perimeter of the source to avoid pollution of or undesirable effects on the chemical and physical qualities of the water. Particular consideration should be given to the following potential pollutants: bacteria, viruses, parasites, fertilizers, pesticides, hydrocarbons, detergents, phenolic compounds, heavy metals, radioactive substances, and other soluble organic and inorganic substances.

3. Buildings and Facilities

3.1 Location

Bottled water processing plants shall be located in areas which are free from objectionable odors, smoke, dust or other contaminants and possible flood or inundation.

3.2 Plant Construction and Design

3.2.1 Buildings and facilities should be designed with partitions or other effective means separating those operations which may cause cross-contamination. Adequate working space shall be provided to allow satisfactory production and facilitate proper supervision of all operations.

3.2.2 The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination.

3.2.3 The physical conditions in water handling and processing areas shall be as follows:

- **Floors**, where appropriate, should be of water-proof, non-absorbent, washable, non-slip and non-toxic materials, without crevices, and should be easy to clean and disinfect. Where appropriate, floors should slope sufficiently for liquids to drain to trapped outlets.
- **Walls**, where appropriate, should be of water-proof, non-absorbent, washable and non-toxic materials and should be light coloured, easy to clean and disinfect. Where appropriate, angles between walls, between walls and floors, and between walls and ceilings should be sealed and covered to facilitate cleaning.
- **Ceilings**, should be so designed, constructed and finished as to prevent the accumulation of dirt and minimize condensation, mold development and flaking, and should be easy to clean.
- **Windows** and other openings should be so constructed as to avoid accumulation of dirt and those which are open should be fitted with screens. Screens should be easily movable for cleaning and kept in good repair. Internal window sills, if present, should be sloped to prevent use as shelves.

- Doors should have smooth, non-absorbent surfaces and, where appropriate, be self-closing and close fitting.
- Piping water lines should be independent of potable and non-potable waters.

3.2.4 If processing operations are to be conducted in a place other than a sealed system under pressure, adequate protection should be provided to preclude contamination of the water and the system.

3.2.5 Adequate ventilation shall be provided to minimize condensation in processing rooms, bottling rooms, and in container washing and sanitizing areas.

3.2.6 Adequate natural or artificial lighting should be provided throughout the establishment. Where appropriate, the lighting should not alter colors. Light bulbs and fixtures suspended over water in any stage of production should be of a safety type and protected to prevent contamination of water in case of breakage.

3.2.7 The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be done in the room adjacent to the bottling room, and the final rinsing shall be positioned within the bottling room so as to minimize any possible post sanitizing contamination of the containers.

3.2.8 Room in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room used for domestic household purposes.

4. Sanitary Facilities

Each plant shall provide adequate sanitary facilities including, but not limited to the following:

4.1 Water Supply

4.1.1 **Product water** The product water supply for each plant shall be from an approved source and shall be in conformance with the standards herein prescribed.

4.1.2 **Operations water** If operation of water is different from the product water supply, the operations water supply shall be obtained from an approved source properly

located, protected, and operated and shall be easily accessible, adequate, and of safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction over the same.

4.2 Effluent and Waste Disposal

The water bottling plant shall have an efficient effluent and waste disposal system which should at all times be maintained in good order. All effluent lines (including sewer system) should be large enough to carry peak loads and should be so constructed as to avoid contamination of potable water supplies.

4.3 Changing Facilities

Changing facilities shall be provided and shall be separate from plant operations and storage areas. The rooms shall be maintained in a clean and sanitary condition and refuse containers shall be provided.

4.4 Toilets

Adequate number of toilets shall be provided and conveniently located, designed to ensure hygienic removal of waste matter. These shall be well lit, ventilated and shall not open directly to water handling areas. Handwashing facilities, suitable hand-cleaning preparation and suitable hygienic means of drying hands shall be provided adjacent to toilets.

4.5 Handwashing Facilities

Adequate and conveniently located facilities for handwashing and drying shall be provided wherever the process demands. Where appropriate, facilities for hand disinfection should also be provided. There shall be hygienic means of drying hands. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided adjacent to each washing facility.

Taps of non-hand operable type are desirable. The facilities should be furnished with properly trapped waste pipes leading to drains.

4.6 Disinfection Facilities

Where appropriate, adequate facilities for cleaning and disinfection of working implements and equipment shall be provided. These facilities should be constructed of

corrosion resistant materials, capable of being easily cleaned, and should be fitted with suitable means of supplying water in sufficient quantities.

4.7 Waste Disposal

Waste material should be handled in such a manner as to avoid contamination of water. Care should be taken to prevent access to waste by pests. Waste shall be removed from the water handling and other working areas as often as necessary and at least daily. Immediately after disposal of the waste, receptacles used for storage and any equipment which has come into contact with the waste shall be cleaned and disinfected. The waste storage area shall also be cleaned and disinfected.

5. Sanitary Operations

5.1 The product water-contact surfaces of all multiservice containers, utensils, pipes and equipment used in the transportation, processing, handling and storage of product water shall be clean and adequately sanitized. All product water-contact surfaces shall be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to assure they are kept free of scale, evidence of oxidation, and other residue. The presence of any unsanitary condition, scale, residue, or oxidation shall be immediately remedied by adequate cleaning and sanitizing of that product water-contact surface prior to use.

5.2 A permanent cleaning and disinfection schedule should be drawn up for each establishment to ensure that all areas are properly cleaned and that critical areas, equipment and materials are designated for special attention. A single individual, who should preferably be a permanent member of the staff of the establishment and whose duties should be independent of production, should be appointed to be responsible for the cleanliness of the establishment. He should have a thorough understanding of the significance of contamination and the hazards involved. All cleaning personnel shall be well-trained in cleaning techniques.

5.3 After cleaning, all multiservice containers, utensils, and disassembled piping and equipment shall be transported and stored in such a manner as to assure drainage and shall be protected from contamination.

5.4 Filling, capping, closing, sealing, and packaging containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water.

5.5 Pest Control

5.5.1 There should be an effective and continuous program for the control of pests. Establishments and surrounding areas shall be regularly examined for evidence of infestation.

5.5.2 Pesticides should only be used if other precautionary measures cannot be used effectively. Before pesticides are applied, care should be taken to safeguard water, equipment and utensils from contamination. After application, contaminated equipment and utensils shall be thoroughly cleaned to remove residues prior to their use again.

6. Equipment and Procedures

6.1 Suitability

6.1.1 All plant equipment and utensils shall be suitable for their intended use. These include all collection and storage tanks, pipings, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package, or transport product water.

6.1.2 All product water-contact surfaces shall be constructed of non-toxic and non-absorbant material which can be adequately cleaned and sanitized.

6.1.3 Storage tanks shall be of the type that can be closed to exclude all foreign matters and shall be adequately washed.

6.1.4 All equipment and utensils in water handling areas and which may have contact with the water shall be made of material which will not transmit toxic substances, odor or taste, will be non-absorbent, will be resistant to corrosion and will be capable of withstanding repeated cleaning and disinfection. Surface shall be smooth and free from pits and crevices. The use of wood and other materials which cannot be adequately cleaned and disinfected should be avoided except when their use would clearly not be a source of contamination. The use of different materials in such a way that contact corrosion can occur should be avoided.

7. Processes and Controls

7.1 Treatment of Product Water

All treatment of product water by distillation, ion-

exchanging, filtration, ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. An appropriate monitoring program for the effectiveness of water treatment system shall be established. A record of the type and date of physical inspections of the equipment, conditions found, and the performance and effectiveness of such equipment shall be maintained by the plant.

7.2 Containers

7.2.1 Single-service containers and caps or seals shall be stored and kept in a clean, dry place until used. Prior to use they shall be examined and washed, sanitized and rinsed or sterilized by dry methods approved by BFAD and shall be handled in a sanitary manner.

7.2.2 Multiservice primary containers shall be adequately cleaned, sanitized, and inspected just prior to being filled, capped and sealed. Containers found to be unsanitary or defective by the inspector shall be reprocessed or discarded. All multiservice primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving adequate sanitary results. Mechanical washers shall be inspected as often as necessary to assure adequate performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the plant.

7.2.3 Multiservice shipping cases shall be maintained in such condition as to assure they will not contaminate the primary containers of the product water. Adequate dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in satisfactory condition.

7.3 Cleaning and Sanitizing Solutions

Disinfecting or sanitizing solutions shall be suitable for the purpose intended and accepted as prescribed in 21CFR 178.1010, Sanitizing Solution. Cleaning and sanitizing solutions shall be sampled and tested by the plant as often as necessary to assure adequate performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the plant. Any residue of these sanitizing agents on surfaces which come in contact with the product shall be removed by thorough rinsing.

7.4 Sanitizing Operations

7.4.1 Sanitizing operations, including those performed by chemical means or by any other means such as circulation of live steam or hot water, shall be adequate to effect sanitization of the intended water-contact surfaces and any other critical area. The plant shall maintain a record of the intensity of the sanitizing agent and the time duration that the agent was in contact with the surface being sanitized. The following frequencies and intensities shall be considered the minimum:

(a) Steam in enclosed system: At least 77 degrees C for at least 15 minutes or at least 93 degrees C for at least 5 minutes.

(b) Hot water in enclosed system: At least 77 degrees C for at least 15 minutes or at least 93 degrees C for at least 5 minutes.

(c) 0.1 part per million (ppm) ozone water solution in an enclosed system for at least 5 minutes.

(d) Chemical sanitizers shall be equivalent in bactericidal action to a 2-minute exposure of 50 ppm of available chlorine when used as an immersion or circulating solution. Chemical sanitizers applied as spray or fog shall have a minimum 100 ppm of available chlorine or its equivalent in bactericidal action.

7.4.2 The effectiveness of cleaning and sanitizing procedures should be verified by microbiological monitoring of product contact surfaces.

7.5 Unit package production code

Each unit package from a batch or segment of a continuous production run of bottled drinking water shall be identified by a production code. The production code shall identify a particular batch or segment of a continuous production run and the day produced. The plant shall record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the distribution of the finished product to wholesale and retail outlets.

7.6 Filling, Capping, or Sealing

During the process of filling, capping or sealing either single-service or multi-service containers, the

performance of the filler, capper or sealer shall be monitored and the filled containers visually or electronically inspected to assure they are sound, properly capped or sealed, coded and labeled. Containers which are not satisfactory shall be reprocessed or rejected. Only non-toxic containers and closures shall be used. All containers and closures shall be inspected to ascertain that they are free from contamination. At least once every month, a bacteriological swab and/or rinse count should be made from at least 4 containers and closures selected just prior to filling and sealing. No more than 1 of the 4 samples may exceed more than 1 bacteria per milliliter of capacity or 1 colony per square centimeter of surface area. All samples shall be free from coliform organisms. The procedure and apparatus for these bacteriological tests shall be in conformance with those recognized by the government agency or agencies having jurisdiction.

8. Product Quality Monitoring

8.1 Source Monitoring

8.1.1 The plant operator shall monitor the quality of source water for the contaminants specified in Section VII hereof. Monitoring shall be scheduled at least annually for toxic substances and at least weekly for microbiological contaminants except that microbiological analysis shall be done at start-up of bottling operations if the plant had been shut down for a period of one week or longer.

8.1.2 Monitoring for radioactive contaminants shall be done on a frequency of at least once every four years.

8.2 Finished Product Monitoring

To assure that the bottled water produced by a processing plant complies with quality standards prescribed in Section VII hereof, the following shall be performed by the plant operator:

8.2.1 Microbiological quality monitoring

(a) A representative sample from every production batch for each type of bottled water produced by the plant shall be analyzed for **coliforms**.

(b) The heterotrophic plate count (HPC) should be monitored by intensive sampling to establish baseline

data on the first year of operation of the plant until low counts are achieved consistently. Sampling frequency may be reduced after the first year of operation provided that if there would be significant increase in HPC, intensive sampling shall be undertaken.

Minimum Sampling Schedule for HPC

Intensive Sampling	1 sample /product/day
Reduced Sampling (Average Bottles/day)	HPC Samples/month*
< 2000	4
2001 - 3000	6
3001 - 4000	8
4001 - 9500	10
9501 - 15000	12
15001 - 25000	14
25001 - 35000	16
35001 - 50000	18
> 50000	20

* Minimum of 1 sample per week. Sampling day each week should be varied to eliminate sampling bias.

B.2.2 Physico-chemical quality monitoring

For physico-chemical properties and chemical contaminants, a representative sample from a production batch for each type of bottled water shall be analyzed annually. Radioactive contaminants need not be monitored for the finished product if the source is monitored for such contaminants at least once every four years. Physico-chemical tests may be done in recognized government or private laboratories. For this purpose the following are the recognized laboratories, as of date and until this particular provision is superseded/ amended by a BFAD circular, to wit:

- (1) Bureau of Research and Laboratories (BRL)
- (2) Food Development Center (FDC)
- (3) Industrial Technology Development Institute (ITDI)
- (4) Natural Science Research Institute - UP Diliman
- (5) Philippine Institute of Pure and Applied Chemistry (PIPAC)
- (6) Society Generale de Surveillance (SGS)

8.2.3 The required monitoring and analysis of samples shall be performed by qualified personnel using approved methods. Due to the frequency of microbiological tests necessary, the bottled water processing plant shall set up its own microbiological laboratory. The list of laboratory equipment and supplies for microbiological examination of water is provided in Annex "B" of this Order.

8.2.4 Records of required sampling and analysis shall be maintained at the plant for a period of not less than two (2) years and shall be available for review by officers duly designated by the BFAD Director.

9. Processing and Production Records

Permanent, legible and dated records of pertinent processing and production details should be kept concerning each lot. These records should be retained for a period of two years. Records of the initial distribution by lot should be kept. Plants shall also retain, on file at the plant, current certificates or notifications of approval issued by the government agency or agencies approving the plant's source and supply of product water and operations water. All required documents shall be available for review at reasonable times by BFAD inspectors.

10. Storage and Transport of the End-Product

The end-product should be stored and transported under such conditions that will preclude contamination with and/or proliferation of microorganisms and protect against deterioration of the product or damage to the container. During storage, periodic inspection of the end product should take place to ensure that only product water which is fit for human consumption is dispatched.

11. Product Recall

The plant operator shall establish a system for product recall in any eventuality when the product presents an eminent hazard to public health or when it does not comply or meet the prescribed quality standards. The water bottler shall be responsible for public notification, if deemed necessary.

12. Personnel

12.1 Qualification of key personnel in the production and quality control

A bottled water plant shall be operated under the

supervision of a competent person qualified by education and experience or training and maintain the plant's facilities.

As regards to educational background, an engineer, chemist, microbiologist, food technologist or a graduate of any related science course is considered appropriate.

12.2 **Disease Control** Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores or infected wounds, or any other abnormal source of microbial contamination by which there is reasonable possibility of product water, product-contact surfaces, or product-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the medical condition is corrected. All personnel shall be subjected to one medical and physical examination each year.

12.3 **Cleanliness** All persons working in direct contact with bottled water, bottled water contact surfaces, and product water packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of product water. The methods for maintaining cleanliness include, but are not limited to:

(a) Wearing outer garments suitable to the operation in a manner that protects against the contamination of bottled water, product contact surfaces, or product packaging materials.

(b) Maintaining adequate personal cleanliness.

(c) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after each absence from the work stations, and at any other time when the hands may have become soiled or contaminated.

(d) Removing all insecure jewelry and other objects that might fall into product water, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods when the process is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by materials which can be maintained in an intact, clean and sanitary condition and which effectively protects against contamination by these objects the product water, product contact surfaces or product packaging materials.

(e) Maintaining gloves in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(f) Wearing, where appropriate, in an effective manner, hairnets, headbands, caps, beard covers or other effective hair restraints.

(g) Storing street clothing or other personal belonging in areas other than where product water is exposed or where equipment or utensils are washed.

(h) Confining the following to areas other than where product water may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages or using tobacco.

(i) Taking any other necessary precautions to protect against contamination of product with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals and medicines applied to the skin.

12.4 **Education and Training** Product handlers and supervisors should receive appropriate training in proper operational techniques and bottled water protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.

12.5 **Supervision** A supervisor shall be assigned at all times to assure compliance with all requirements for GMP.

SECTION VI. REGISTRATION OF THE BOTTLED WATER PRODUCT

1. No bottled water product shall be distributed and sold without a certificate of registration (CPR) from BFAD.

2. A certificate of product registration for bottled water shall be issued after its compliance with the standards herein prescribed and requirements listed in Annex "C" hereof as verified by product evaluation.

Product evaluation includes determination of the authenticity and genuineness of technical documents submitted, product's compliance with the standards and validation of product's declaration by laboratory analysis.

3. Registration fees shall be P300.00 for initial registration which shall be valid for two (2) years; and P500.00 for renewal registration which shall be valid for five (5) years. These registration fees shall be in addition to costs of laboratory analysis.

4. No registered bottled water product shall undergo changes in specifications, packaging and labeling without BFAD's prior approval.

In cases where the changes require amendment of the certificate of registration, the holder shall apply for an amendment of the said CPR submitting therewith the supporting documents and the original CPR.

The supporting documents shall be the legal instruments/deeds evidencing the legality of the changes or statements/declaration under oath of the change of specifications with sufficient samples for validation by laboratory analysis, as the case may be.

SECTION VII. PRODUCT SPECIFICATIONS

All types of bottled drinking water shall conform with the quality standards prescribed below.

1. Physico-chemical Properties

	Guide Level	Maximum Acceptable Level (MAL)
Turbidity	5 NTU	
Purified/Distilled	1 NTU	
Color	15 TCU	
Odor	not objectionable	
Taste	not objectionable	
pH	6.5 - 8.5	9.0
Purified/Distilled	5 - 7	
TDS		500 except mineral water
Mineral	>200	1000
Spring	>100	
Purified	<10	
Distilled	<10	
Conductivity		
Distilled	<5 uS/cm	
Mineral	>200 uS/cm	
Calcium	100	
Magnesium	30	50
Sodium	20	175
Potassium	10	12
Chloride	25	200
Sulfate	25	250

Values in mg/L (ppm) except when otherwise stated.

2. Contaminants undesirable in excessive amounts for aesthetic/organoleptic considerations and potential health significance.

	Guide Level	Maximum Acceptable Level (MAL)
Nitrates	25	45
Nitrites	not detected	0.1
Iron	0.3	1.0
Manganese	0.05	0.1
Copper	0.1	1
Zinc	0.5	5
Aluminum	0.05	0.2
Fluoride	> 0.8(fluoridated water)	2
Organic matter (mg O ₂ /L)	2	5
Surfactants (as lauryl sulfate)	not detected	2

3. Toxic Contaminants

	Maximum Acceptable Level (MAL)
Arsenic	0.05
Cadmium	0.01
Cyanide	0.01
Chromium	0.05
Lead	0.05
Mercury	0.001
Selenium	0.01
Phenolic substances	0.001
Volatile organic compounds	
Carbon tetrachloride	0.005
Benzene	0.005
Trihalomethanes	0.01
Pesticides & related substances	
carbamates, organochlorines, organophosphates	0.1 ppb
herbicides, fungicides, PCB	0.5 ppb
Radionuclides	
gross alpha activity	0.1 Bq/L
gross beta activity	1.0 Bq/L

Values in mg/L (ppm) except when otherwise indicated.

4. Guide Level values represent maximum levels attainable in good quality water sources and/or indication of product's adherence to GMP except when they are indicated as the minimum required values, like the values of TDS, conductivity, and fluoride.

5. MAL values are prescribed standards, beyond which the bottled water will be considered unacceptable due to its impaired organoleptic characteristics or probable hazards to health.

6. Microbiological Specifications

6.1 The microbiological specifications of water at the source and at critical control points, shall conform with the following parameters:

a) Coliforms, - From a set of samples analyzed at a given time, not more than one sample may contain coliform at the most probable number (MPN) of > 2.2 per 100 ml and no sample shall contain MPN of 9.2 per 100 ml.

b) Heterotrophic Plate Count (HPC) - The water may contain heterotrophic bacteria not greater than the limits established by the bottler from a baseline data accumulated under the conditions prescribed in GMP, provided that water sampled at various points before bottling shall not have an HPC of more than 300 colony forming units (cfu) per mL.

Water samples should be analyzed within 12 hours and maintained at a temperature not higher than 10 °C

6.2 End product specifications

Bottled water shall not contain parasites and pathogenic organisms.

It shall conform with the microbiological specifications indicated below. These specifications shall also apply to products obtained from distribution outlets.

	n	c	m	M
Coliforms	5	1	0	1* MPN/100 ml
Fecal Streptococci	5	1	0	1** cfu/100 ml
<i>Pseudomonas aeruginosa</i>	5	0	0	cfu/100 ml
HPC	5	1	10	10 cfu/ml
-Purified/Distilled	5	1	10	10 cfu/ml

* shall not be *E. coli*

** more samples should be analyzed; considered defective lot if another set of 5 samples yield at least one positive sample

n = number of samples tested

m = guide level

M = maximum acceptable level

c = maximum number of samples > m but not more than M

SECTION VIII. PACKAGING

1. All bottled water shall be packed in containers made of food grade materials. They shall be free from adhesives or other substances that may interact physically or chemically with the product.
2. Closures shall be so designed as to make it tamper proof to protect the product from contamination during handling, storage and distribution.
3. Bottles and caps shall be manufactured from virgin materials (i.e., materials which have not been recycled).
4. Pigments and colorants used in the manufacture of bottles and caps shall conform with those prescribed in PNS 1104, Plastic Materials for Food Contact Use: Colorants - Specifications.
5. Glass bottles shall conform with standard test limits for borosilicate and soda/lime glass prescribed in the latest edition of the United States Pharmacopeia.
6. Plastic bottles and caps shall conform with the tests for heavy metals and migratory/leachable substances prescribed by BFAD.
7. Bottles and caps made of polyvinyl chloride (PVC) shall be manufactured using PVC resin which contain not more than 0.1 mg/kg (ppm) of vinyl chloride monomer (VCM).
8. Users of PVC bottles shall be required to present test results from accredited laboratories indicating that the resin used in their bottles conform with the above prescribed VCM limit.

SECTION IX. LABELING REQUIREMENTS

All bottled water intended for commercial distribution shall conform with the labeling rules and regulations for prepackaged food and the following requirements:

1. In all cases, the name and address of the manufacturer shall be indicated on the label.
2. The type of water either "spring water", "mineral water", "purified water", "distilled water", "carbonated water", or just plain "drinking water", shall be prominently printed on the principal display panel of the label and shall be in accordance with the definitions in Section I.

3. Brand names should not be misleading or in any way misrepresent the true nature of the product and shall conform with BFAD existing regulations governing brandnames. The same should be cleared with BFAD before the product can be granted BFAD registration.

4. Bottled water represented as "mineral water" or "spring water" shall declare the following information on their labels:

- a) the geographical location of the underground source from which the water is obtained;
- b) the total dissolved solids in mg/L or ppm; and
- c) the typical composition in terms of the levels of the following in mg/L or ppm:

Bicarbonates	Sodium *
Calcium	Potassium *
Magnesium	Fluoride **
Chloride	
Sulfate	* optional
	** optional except for fluoridated water

5. Claims relating to the absence of certain constituents or contaminants (e.g., "sodium-free", "bacteria-free", etc.) shall be prohibited unless supported by consistent laboratory test results obtained from or issued by a recognized testing institution.

6. The ultraviolet scanning treatment shall not be referred to as a sterilization process unless the treatment actually results in a sterilized finished product as shown by appropriate sterility test.

7. Statements to the effect that the product is approved or certified by any institution/organization shall be prohibited unless the bottled water producer/distributor presents a written authorization from the concerned institution/organization.

8. Reports of analysis issued by any government or private laboratory shall not be accepted as an authorization to declare the name of the laboratory/agency on the label unless expressly stated in said report.

9. All other label claims and declarations shall be truthful and not misleading.

10. Bottled water with labels or label claim(s) not consistent with these rules shall be deemed misbranded.

SECTION X. ADMINISTRATIVE SANCTIONS

1. The Director of BFAD shall order the processor to recall and withdraw a bottled water product or a particular batch of such product from the market upon a finding that the same fails to comply with (a) the Maximum Allowable Level (MAL) for any specified parameter herein established; or (b) when the products are found adulterated or mislabeled in accordance with RA 7394 and its implementing rules and regulations.

2. In addition to the Order of recall, the Director may require the processor to notify the public of the fact of recall and the defect of the product being withdrawn. Provided that in cases of failure in complying with MAL of any of the specified parameters, the Director shall not issue an order of recall when all the following circumstances are present:

a) corrective measures have been instituted and verified, and the

b) products already in the market will not cause illness or do not present significant health risk.

3. The Director of BFAD shall suspend the license to operate a processing plant in cases of deficiencies in GMP that will likely result to adulterated or mislabelled bottled water product. The suspension of the processing operation shall be for a period of 90 days unless corrective measures are undertaken before the 90-day period. The order of suspension shall be lifted upon a report of inspection verifying the corrective measures instituted by the processor to comply with GMP.

4. The foregoing sanctions are without prejudice to other administrative sanctions and criminal actions provided for by existing laws, rules and regulations.

SECTION XI. TRANSITORY PROVISIONS

1. Except for adulterated and mislabeled bottled water products that may be hazardous to health and safety, bottled water of licensed processors shall have six (6) months from the effectivity of this Order to comply with the product's standards, specifications and labeling herein prescribed.

2. All licensed processors of bottled waters shall have six (6) months from the date of effectivity of this Order to comply with the standards and specifications for GMP.


3. Applicants for license to operate after the date of effectivity shall have to comply with the licensing and GMP standards prescribed by this Order.

SECTION XII. SEPARABILITY CLAUSE

If any reason any section or provision of this Order is declared invalid, illegal or unconstitutional, the remainder of this Order shall not be affected by such a decision.

SECTION XIII. EFFECTIVITY

This Order shall take effect fifteen (15) days following the date of its publication in a newspaper of general circulation.


JUAN M. FLAVIER, M.D., MPH
Secretary of Health

Date Published:

REQUIREMENTS FOR LICENSING OF BOTTLED WATER PROCESSORS
AND IMPORTERS/DISTRIBUTORS

I. DOCUMENTARY REQUIREMENTS

A. GENERAL REQUIREMENTS

1. Accomplished Petition Form duly notarized
2. ID Picture of Owner / Gen. Manager
3. If Corporation, a copy of Registration with SEC and Articles of Inc.
4. If Single Proprietorship, a copy of Registration with BDT
5. Location Plan
6. Contract of Lease of building and warehouse (if not owned by the applicant)
7. List of products to be processed/ imported/ distributed indicating brandname/s.

B. SPECIFIC REQUIREMENTS

1. FOR PROCESSOR

Floor plan of working area with complete dimension in meters.

2. FOR IMPORTER/DISTRIBUTOR

- 2.1. Foreign agency Agreement duly authenticated by the Territorial Philippine Consulate.
- 2.2. Certification from the appropriate Health Authority that the company is registered or duly approved manufacturer of bottled water, and the bottled water conforms with the standards and regulations in the country of origin.

II. TECHNICAL REQUIREMENTS

1. Organizational chart (if a corporation) indicating qualification of key personnel in the production and quality control.
2. List of production equipment with specification.
3. Flow chart of manufacturing process with emphasis on identification of critical control points.
4. Description of salient points in the manufacturing procedures.
5. Quality control procedures and facilities .

6. Certification for approval of the source of water;

6.1 From the City/ Municipal Health Officer with a copy of the report of the Sanitary Engineer, including laboratory test results.

6.2 If the source is claimed to be a spring, certification from a qualified engineer/ geologist attesting to the veracity of the claim.

7. Certification from the supplier of container indicating suitability for bottled water. *

8. Adequacy of Process Controls with current report of analysis.

* In case of PVC bottles, certificate of analysis of PVC resin indicating VCM (vinyl chloride monomer) content.

Reviewer/ Date

LABORATORY EQUIPMENT AND SUPPLIES FOR THE MICROBIOLOGICAL EXAMINATION OF BOTTLED WATER

Listed below are the basic equipment required in the microbiological laboratory to be set up in bottled water processing establishments.

1. Autoclave Temperature range: 105 to 127°C
2. Water Bath -ditto- : 30 to 70°C
3. Incubator -ditto- : ambient to 60°C
4. Sterilizing Oven Maximum temperature: 260°C
5. Beam Balance or Top Loading Electronic Balance
6. Bunsen Burner or Alcohol Lamp
7. Electric or Gas Stove (for preparation of culture media)
8. pH meter
9. Microscope
10. Colony Counter

Glasswares and Supplies:

Test Tubes 200 ml and 15-20 ml capacity
Durnham fermentation tubes
Petri Dishes
Pipettes
Erlenmeyer Flasks/Beakers
Autoclavable Bottles for culture media
Graduated Cylinders
Slides and Cover Slips
Inoculating Loops
Silicon or Cotton Plugs for test tubes
Culture media and reagents needed for the test methods

The Microbiological Laboratory may or may not be equipped with a laminar flow hood. The working table must be made of material which can be cleaned with alcohol or other disinfectants.

For establishments that will use microfiltration methods for the microbiological examination of water, a laminar flow hood or a separate "clean" room should be provided.

ANNEX "C"

CHECKLIST OF REQUIREMENTS FOR THE
REGISTRATION OF BOTTLED WATER

- _____ 1. Letter of application from the processor/
importer
- _____ 2. Valid License to Operate (LTO).
- _____ 3. Certificate of Brandname Clearance from
BFAD.
- _____ 4. Samples of the product in its commercial
presentation, five (5) bottles of at least 500
mL.
- _____ 5. Labels and Labeling materials to be used for the
product. (Artwork or facsimile)
- _____ 6. Certificate of Analysis (indicate analytical
method used).
- _____ 7. Registration Fee.

RENEWAL REGISTRATION

- 1. Letter of application from the processor/ importer.
- 2. Valid License to Operate.
- 3. Previous Certificate of Product Registration (CPR).
- 4. Labels and Labeling materials used for the product, in case
of change made to previously approved label.
- 5. Samples of the product in its commercial presentation.
- 6. Registration Fee.