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The Gazette of the Democratic Socialist Republic of Sri Lanka
EXTRAORDINARY

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PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B. 11/80 (ii)

Food Act No. 26 of 1980

REGULATIONS made by the Minister of Health in consultation with the Food Advisory Committee in terms of Section 32 of the Food Act, No.26 of 1980.

NIMAL SIRIPALA DE SILVA,
Minister of Health, Nutrition and Uva
Wellassa Development.

Colombo,
15th November, 2005.

Regulations

1. These regulations may be cited as the Food (Bottled or Packaged Water) Regulations -2005 and shall come into effect on the expiry of a period of six months from the date on which these regulations are published in the Gazette.

PART I

GENERAL PROVISIONS

2. The provisions of these regulations shall apply to Bottled or Packaged Natural Mineral Water and Bottled or Packaged Drinking Water.
3. (1) No person shall-
 - (a) bottled or packaged Natural Mineral Water or Drinking Water; or
 - (b) import and distribute bottled or packaged Natural Mineral Water or Drinking Water,without obtaining a Certificate of Registration in that behalf from the Chief Food Authority.

(2) Applications for obtaining the Certificate of Registration referred to in paragraph (1) of this regulation shall be made to the Chief Food Authority substantially in the Form set out in Schedule I to these regulations and shall be accompanied by such fee as is determined taking into consideration the procedures which need to be followed for obtaining a Certificate of Registration.

(3) Applicants whose applications relate to the importing and distributing of bottled or packaged Natural Mineral Water or Drinking Water shall, along with such application, forward for the purposes of paragraph (2), samples of the water, whether natural mineral water or drinking water, in respect of which the application is made.

(4) No person shall use any premises for the bottling or packaging of Natural Mineral Water or Drinking Water unless such premises have been registered with the Chief Food Authority and the Certificate of Registration to be issued for such purpose shall be substantially in the Forms set out in the Schedule 11 to these regulations.

(5) The Chief Food Authority shall, within a period of seven working days of an application being received by him, forward the same along with the samples to any Institute having the expertise in the required field, as is recommended to the Chief Food Authority by the Food Advisory Committee established under Section 8 of the Food Act, for a recommendation as to whether or not registration could be granted to the product in terms of the provisions of the Act.

(6) In the case of an imported product, the applicant shall submit along with his application, a sample of the product along with a Certificate of Analysis from an accredited laboratory relating to the content of such sample. The Chief Food Authority shall, within a period of seven working days of an application being received by him, forward the same along with the sample and the Certificate of Analysis to any Institute having the expertise in the required field, as is recommended to the Chief Food Authority by the Food Advisory Committee established under section 8 of the Food Act, for a recommendation as to whether or not registration could be granted to the product in terms of the provisions of the Act.

(7) The Chief Food Authority shall not proceed to issue to any person a Certificate of Registration for the bottling or packaging of Natural Mineral Water or Drinking Water or for the import and distribution of bottled or packaged Natural Mineral Water or Drinking Water in terms of these regulations until a report is forwarded to it from the relevant institution to which the product has been referred to for a technical opinion.

(8) Upon receipt of the sample as specified in paragraphs (5) and (6), the relevant institution shall-

- (a) satisfy itself that the drinking water or mineral water has been produced in conformity with the processes specified in relation to such product; and
- (b) satisfy itself that all the other requirements specified in this relation have been met, and forward its recommendation in the form of a report in respect of the product referred to it by the Chief Food Authority.

(9) The Chief Food Authority shall upon receipt of such report, within a period of two weeks of the said information being communicated to him issue to the applicant a Certificate of Registration as required by the Act, or inform the applicant that for stated reasons, the Certificate of Registration cannot be issued to him.

(10) Any person aggrieved by the decision under paragraph (9) may appeal to the Minister within one month of the date of such refusal.

4. No person shall sell, offer for sale, keep for sale, transport or advertise for sale any Bottled or Packaged Natural Mineral Water or Bottled or Packaged Drinking Water unless such product has been duly registered by the Chief Food Authority and a registration number in terms of the foregoing provisions of this regulation has been assigned thereto.

PART II

BOTTLED OR PACKAGED NATURAL MINERAL WATER

5. (1) For the purpose of these regulations Natural Mineral Water means water that originates from an underground water bearing strata and is extracted for human consumption from natural or drilled sources such as springs, wells or boreholes.

(2) No person shall bottle or package Natural Mineral Water originating or extracted from any source other than the sources referred to in paragraph (1).

(3) Bottled or packaged Natural Mineral Water shall conform to the physical, chemical and microbiological requirements specified in Form " A " of Schedule III to these regulations.
6. For the purposes of these regulations Natural Mineral Water shall on extraction for the purpose of bottling or packaging –
 - (a) be free from dirt, foreign matter Or any other substance injurious to health ;
 - (b) be collected under conditions, which guarantee the original purity ;
 - (c) not be subjected to any treatment other than separation form unsuitable constituents by decantation and filtration or decantation or filtration, as the case may be, and if necessary, accelerated by previous aeration ;
 - (d) be bottled or packaged close to the point of emergence of the source under hygienic precautions as set out in the regulation 7.
 - (e) not be transported in bulk containers for packaging. Provided that pipeline transport may be allowed if the Chief Food Authority is satisfied that all precautions have been taken to maintain the purity of water.
7. (1) A person who bottles or packages Natural Mineral Water shall ensure that after extraction the Natural Mineral Water shall be bottled in accordance with the requirements specified below, as are aimed at ensuring the maintenance of hygienic conditions in the bottling or packaging of the Natural Mineral Water-
 - (a) all possible precautions should be taken to avoid any pollution of or external influence on the chemical, physical and microbiological qualities of Natural Mineral Water. Particular consideration shall be given to the potential pollutants; such as bacteria, viruses, fertilizers, hydrocarbons, pesticides, detergents, phenolic compounds, toxic metals, radioactive substances and any other soluble organic and inorganic substances. Even where nature

provides sufficient protection against surface pollution, potential hazards such as mining, hydraulic and engineering facilities shall be taken into consideration;

- (b) the Natural Mineral Water shall be withdrawn in conformity with the hydro-geological conditions in such a manner as to prevent any water other than the natural mineral water from entering or shall there be pumping facilities, to prevent any extraneous water from entering by reducing the supply;
- (c) the proprietor shall take appropriate precautionary measures in the immediate surrounding of springs and wells, to guarantee that no pollution whatsoever can enter the catchments ;
- (d) the proprietor shall ensure that the pumps, pipes or other possible devices coming into contact with Natural Mineral Water and used for its collection are made of such material that guarantee the original qualities of Natural Mineral Water.
- (e) shall not allow unauthorized persons into the extraction area and prohibit any other activities within such area, as are not aimed at the collection of Natural Mineral Water; and
- (f) hygienic methods and procedures shall be maintained for the extraction of Natural Mineral Water. Such methods and procedures shall not be a potential health hazard to humans or a source of contamination to Natural Mineral Water. The equipment used for extraction shall be constructed and maintained in order to minimize all hazards to human health and to avoid contamination.

(2) In addition to the hygienic requirements specified in paragraph (1), the hygienic requirements in Food Regulations -1988, published in Gazette Extraordinary No. 560/13 of June, 2, 1989, shall also apply in relation to the production of Bottled or Packaged Natural Mineral Water.

8. A person who manufactures Bottled or Packaged Natural Mineral Water shall conform to the packaging and labeling requirements specified below :-

- (a) Processing and packaging shall be carried out in the premises registered for the purpose;
- (b) Shall be packed in hermetically sealed clean food grade retail containers, which are suitable for preventing possible adulteration or contamination of water. It shall be packed under strict hygienic conditions;
- (c) Shall conform to the provisions of Food (Labeling and Advertising) Regulations -2005;
- (d) The common name "Natural Mineral Water" shall be used in the label;
- (e) Nothing shall be printed or published on the label or on the bottle or the package in respect of medical or other benefits that can be gained by a consumer using Natural Mineral Water;
- (f) Shall not print or publish on the label or on the bottle or the package any statement or any pictorial device, which may create confusion in the minds of the public or in anyway mislead the public about the nature, origin, composition and properties of Natural Mineral Water;

- (g) The registration number assigned by the Chief Food Authority shall be printed on the label in a prominent manner.

PART III

BOTTLED OR PACKAGED DRINKING WATER

9. For the purpose of these regulations Bottled or Packaged Drinking Water means water that is sealed in bottles (containers) ready for human consumption; but shall not include Natural Mineral Water as is referred to in Part II of these regulations.
10. Bottled or Packaged Drinking Water may contain, naturally present or intentionally added minerals and carbon dioxide but shall not contain sugars, sweeteners, flavorings or other food additives.
11. Bottled or Packaged Drinking Water shall conform to the physical, chemical and microbiological requirements specified in Form "B" of Schedule III to these regulations.
12. (1) A person who manufactures Bottled or Packaged Drinking Water using water from a specific environmental source for such purpose shall register such environmental source with the Chief Food Authority.
- (2) A person who registers an environmental source under Paragraph (I) shall not utilize water for the bottling) or packaging of Bottled or Packaged Drinking Water from any other source, other than the specific water source so registered.
- (3) A person who bottles or packages Bottled or Packaged Drinking Water using community water which is pipe 'f, borne and/or a supply system managed by a local authority or any other organization shall register such source of water with the Chief Food Authority.
- (4) A person registered under Paragraph (3) shall not utilize water for bottling or packaging of Bottled or Packaged Drinking Water, from any other source, other than the water source registered under that paragraph.
13. (1) A person who bottles or packages Bottled or Packaged Drinking Water shall ensure that after extraction the Bottled or Packaged Drinking Water shall be bottled or packaged in accordance with the requirements specified below, as are aimed at ensuring the maintenance of hygienic conditions in the bottling or packaging of the Bottled or Packaged Drinking Water :
- (a) All possible precautions shall be taken within the protected perimeters to avoid any pollution of or external influence on the quality of the ground water source ;
- (b) Methods and procedures for maintaining the extraction facilities shall be hygienic and not be a potential hazard to humans or a source of contamination to the ground water source ;
- (c) Transport and storage of water from the point of extraction to the processing plant shall be conducted in a hygienic manner to prevent contamination of the source water with micro-organisms or any other contaminants;
- (d) The hygienic requirements specified in Food Regulations -1988 published in *Gazette Extraordinary* No. 560/13 of June 2, 1989 shall apply to the manufacture of Bottled or Packaged Drinking Water ;

(e) (i) The treatments to be applied to water during processing to reduce, remove or prevent growth of micro-organisms may include :-

(A) physical treatment such as-

- (1) high heat ;
- (2) ultraviolet radiation ;
- (3) filtration ;

(B) chemical treatment such as-

- (1) chlorination ;
- (2) ozonation and ;
- (3) carbonation.

(ii) the treatments specified in Sub paragraph (i) may be used singly or in combination ;

(f) The treatment to be applied to water used to remove or reduce chemical ingredients from water may include-

- (i) particular (mechanical) filtration ;
- (ii) depth filters such as sand or compressed fibre filters ;
- (iii) cartridge filters ;
- (iv) surface filters such as pleated membrane filters;
- (v) activated carbon filters ;
- (vi) aeration ;
- (vii) demineralization, de-ionization and/or water softening ;

(g) Raw materials or ingredients used in treatment of water shall be of good quality so that no harmful substances pass on to the water. Where appropriate, specifications for raw ingredients shall be identified and applied and laboratory testing shall be carried out to establish fitness for use ;

(h) Bottling operations shall be conducted in an enclosed area where the air should be free of dust and microorganisms.

14. A person who manufactures Bottled or Packaged Drinking Water shall conform to the packaging and labeling requirements specified below :-

(a) Processing and packaging shall be carried out in the premises registered for the purpose ;

(b) Shall be packed in hermetically sealed clean food grade retail containers, which are suitable for preventing possible adulteration or contamination of water. It shall be packed under strict hygienic conditions ;

(c) Shall conform to the provisions of Food (Labeling and Advertising) Regulations -2005 ;

(d) The common name "Drinking Water" shall be used in the label ;

(e) Nothing shall be printed or published on the label or on the bottle or the package in respect of medical or other benefits that can be gained by a consumer using Drinking Water ;

- (f) Shall not print or publish on the label or on the bottle or the package any statement or any pictorial device, which may create confusion in the minds of the public or in any way mislead the public about the nature, origin, composition and properties of Drinking Water ;
- (g) The registration number assigned by the Chief Food Authority shall be printed on the label in a prominent manner.

PART IV

INTERPRETATION

15. For the purpose of these regulations –

"Chief Food Authority" means the Director General of Health Services as defined in the Food Act, No. 26 of 1980 ; and

"manufacture" shall have the same meaning as is assigned to it in the Food Act, No.26 of 1980.

SCHEDULE 1

[Regulation 3(2)]

SPECIMEN APPLICATION FORM FOR REGISTRATION OF PREMISES FOR THE MANUFACTURE OF BOTTLED OR PACKAGED NATURAL MINERAL WATER AND BOTTLED OR PACKAGED DRINKING WATER

1. Name of the manufacturing unit for which registration is applied:	
2. Full address of the premises to be registered (with House No., Ward No., Street No., Street, Boundaries) – Attach Sketch	
3. Nature of food article manufactured or proposed to be manufactured:	Bottled Packaged Drinking Water / Bottled or Packaged Natural Mineral Water (Strike whatever inapplicable).
4. Nature of firm – whether public; private ltd., Partnership or proprietary concern, with name and address of the Managing Director and Technical Director if any / partners/proprietor (as the case may be):	
5. Name and address of the person authorized to apply for the registration and position held by him in the firm:	
6. Brand Name of the Product:	
7. No. and date of previous registration, if any:	
8. Particulars of amount remitted as registration fee:	Rs:..... Receipt No:..... Date:.....
9. SLS Certification	

i. Local products : (Certified copy of award to be attached)	SLS No :..... Date :.....
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All necessary documents required for registration are attached.

The information furnished above is true and correct to the best of my knowledge and belief.

.....
Signature of Applicant.

Date:

SCHEDULE II

[Regulation 3(4)]

(Specimen Certificate of Registration)

REGISTRATION OF PREMISES FOR MANUFACTURE AND SALE OF BOTTLED OR PACKAGED NATURAL MINERAL WATER OR BOTTLED OR PACKAGED DRINKING WATER

Registration No:.....

Subject to the provisions of the Food Act, No.26 of 1980 as amended by the Food (Amendment) Act, No.20 of 1991, the under mentioned premises is hereby registered for the purpose of manufacture and sale of Bottled or Packaged Drinking Water or Bottled or Packaged Natural Mineral Water.

Name and Address of Applicant:.....

Location of the Manufacturing Plant :.....

Brand Name of the Product :

Note :- The Registration is liable to be cancelled in the event of any of the provisions of the regulations referred to above being violated.

Director (E&OH)
for Chief Food Authority.

Date:

Official Seal :

SCHEDULE III FORM A

[Regulation 5 (3)]

*Physical Chemical and Microbiological requirements for
Bottled or Packaged Natural Mineral Water*

<u>Characteristic</u>	<u>Requirement</u>
Colour Hazen Units (Max.)	5
Odour	Unobjectionable
Taste	Unobjectionable
Turbidity, NTU (max)	5.0
Total dissolved solids, mg/l (max)	1500.0
Arsenic as as mg/l (max)	0.01
Aluminium as Al mg/l (max)	0.2
Cadmium as Cd mg/l (max)	0.003
Cyanide as CN mg/l (max)	0.07
Chromium as Cr mg/l (max)	0.05
Mercury as Hg mg/l (max)	0.001
Nickel as Ni mg/l (max)	0.02
Selenium mg/l (max)	0.01
Lead mg/l (max)	0.01
Copper as Cu mg/l (max)	1.0
Antimony as Sb mg/l (max)	0.005
Barium as Ba mg/l (max)	0.7
Manganese as Mn mg/l (max)	0.5
Chloride as Cl mg/l (max)	250.0
Fluoride as F mg/l (max)	1.5
Nitrate as NO ₃ mg/l (max)	50.0
Nitrite as NO ₂ mg/l (max)	3.0
Sulphide as H ₂ S mg/L (max)	0.05
Phenolic compounds and mineral oil	Absent
E.coli and Coliforms	Absent
Pathogenic organisms	Absent
Grease and oil	Absent

FORM B

[Regulation 11]

*Physical Chemical and Microbiological requirements for
Bottled or Packaged Drinking Water*

<u>Characteristic</u>	<u>Requirement</u>
Colour Hazen Units (max)	15.0
Odour	Unobjectionable
Taste	Unobjectionable

Turbidity, NTU (max)	5.0
pH	6.5 to 8.5
Total dissolved solids, mg/l (max)	1000.0
Chloride as Cl mg/L (max)	250.0
Free residual chlorine as Cl ₂ mg/L (max)	0.2
Alkalinity as CaCO ₃ mg/l (max)	200.0
Free ammonia, mg/l (max)	0.06
Nitrate as NO ₃ mg/l (max)	50.0
Nitrite as NO ₂ mg/l (max)	3.0
Fluoride as F, mg/l (max)	1.5
Total hardness as CaCO ₃ mg/l (max)	250.0
Sulphates as SO ₄ mg/l (max)	250.0
Chromium as Cr mg/l (max)	0.05
Nickel as Ni mg/l	0.02
Total iron as Fe, mg/l (max)	0.3
Copper as Cu, mg/l (max)	1.0
Manganese as Mn, mg/l (max)	0.5
Zinc as Zn, mg/L (max)	3.0
Aluminium as Al, mg/l (max)	0.2
Arsenic as As mg/l (max)	0.01
Cadmium as Cd, mg/l (max)	0.003
Lead as Pb, mg/l (max)	0.01
Mercury as Hg, mg/l (max)	0.001
Selenium as Se, mg/l (max)	0.01
Cyanide as CN, mg/l (max)	0.07
Chemical Oxygen Demand (COD) mg/l (max)	10.0
Phenolic compounds as Phenolic OH, mg/l (max)	Absent
Grease and oil, mg/L (max)	Absent
E.Coli and Coliforms	Absent
Pathogenic organisms	Absent