L.N. 311 of 2001

PRODUCT SAFETY ACT (ACT NO. V OF 2001)

Natural Mineral Waters Regulations, 2001

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:-

1. Citation and commencement

1.1. The title of these regulations is the Natural Mineral Waters Regulations,2001.

1.2. These regulations shall become operative on the 1st July, 2002.

2. Scope

2.1. These regulations shall apply to waters extracted from the ground of a Member State or of Malta and recognized by the responsible authority of the country concerned as natural mineral waters satisfying the provisions of Section I of the First Schedule.

2.2 These regulations also concern waters extracted from the ground from a third country, imported into Malta and recognized as natural mineral waters by the responsible authority of Malta or of a Member State.

The waters referred to in the first subparagraph may be so recognized only if the responsible authority in the country of extraction has certified that they satisfy Section 1 of the First Schedule, and that regular checks are made on the application of the provisions of paragraph 2 of the Second Schedule.

The validity of the certification referred to in the second subparagraph may not exceed a period of five years. It shall not be

necessary to repeat the recognition procedure referred to in the first subparagraph if the certification is renewed before the end of the said period.

2.3. The following are excluded from the scope of these regulations:

2.3.1 waters which are medicinal products within the meaning of directive 65/65/EEC;

2.3.2 natural mineral waters used at source for curative purposes in thermal or hydrothermal establishments.

2.4 The grounds for granting the recognition referred to in regulations 2.1 and 2.2 above, shall be stated in due form by the responsible authority and shall be officially published in the Gazette.

3. Definitions

3.1 The term "natural mineral water" is defined in section 1 of the First Schedule of these regulations.

3.2 The term "Member State" shall mean any country that is a member of the European Community.

3.3 The term "third country" shall mean any country other than Malta or a Member State.

3.4 The term "responsible authority", in the context of Malta, shall mean the Directorate responsible for Foodstuffs within the Malta Standards Authority.

4. Marketing of Natural Mineral Waters

4.1. Only waters referred to in regulation 2 of these regulations and which comply with the provisions of these regulations may be marketed as natural mineral waters.

5. Bottling of Natural Mineral Waters

5.1 Natural mineral water springs may be exploited and their waters bottled only in accordance with the Second Schedule.

5.2 Natural mineral water, in its state at source, may not be the subject of any treatment other than:

5.2.1 the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, possibly preceded by oxygenation, in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties;

5.2.2 the separation of iron, manganese and sulphur compounds and arsenic from certain natural mineral waters by treatment with ozone-enriched air in so far as such treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that:

5.2.2.1 the treatment complies with any applicable conditions for use,

5.2.2.2 the treatment is notified to, and specifically controlled by, the responsible authorities;

5.2.3 the separation of undesirable constituents other than those specified in regulations 5.2.1 or 5.2.2 of these regulations, in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that:

5.2.3.1 the treatment is notified to, and specifically controlled by, the responsible authorities;

5.2.4 the total or partial elimination of free carbon dioxide by exclusively physical methods.

5.3 Natural mineral water, in its state at source, may not be the subject of any addition other than the introduction or the reintroduction of carbon dioxide under the conditions laid down in section III of the First Schedule.

5.4 In particular, any disinfection treatment by whatever means and, subject to regulations 5.3 of these regulations, the addition of bacteriostatic elements or any other treatment likely to change the viable colony count of the natural mineral water shall be prohibited.

5.5 Regulations 5.2 shall not constitute a bar to the utilization of natural mineral waters and spring waters in the manufacture of soft drinks.

5.6 The revivable total colony count of a natural mineral water at source shall conform to its normal viable colony count and give satisfactory evidence of the protection of the source against all

contamination. This total colony count shall be determined under the conditions laid down in Section II, point 1.3.3 of the First Schedule.

After bottling, the total colony count at source may not exceed 100 per millilitre at 20 to 22°C in 72 hours on agar-agar or an agar-gelatine mixture and 20 per millilitre at 37°C in 24 hours on agar-agar. The total colony count shall be measured within the 12 hours following bottling, the water being maintained at 4°C ± 1°C during this 12-hour period.

At source, these values should not normally exceed 20 per millilitre at 20 to 22°C in 72 hours and 5 per millilitre at 37°C in 24 hours respectively, on the understanding that they are to be considered as guide figures and not as maximum permitted concentrations.

5.7 At source and during its marketing, a natural mineral water shall be free from:

5.7.1 parasites and pathogenic micro-organisms;

5.7.2 Escherichia coli and other coliforms and faecal streptococci in any 250 ml sample examined;

5.7.3 sporulated sulphite-reducing anaerobes in any 50 ml sample examined;

5.7.4 Pseudomonas aeruginosa in any 250 ml sample examined.

5.8 Without prejudice to regulations 5.6 and 5.7 and the conditions of exploitation laid down in the Second Schedule, at the marketing stage:

5.8.1 the revivable total colony count of a natural mineral water may only be that resulting from the normal increase in the bacteria content which it had at source,

5.8.2 the natural mineral water may not contain any organoleptic defects.

5.9 Any containers used for packaging natural mineral waters shall be fitted with closures designed to avoid any possibility of adulteration or contamination.

5.10 The sales description of natural mineral waters shall be "natural mineral water" or, in the case of an effervescent natural mineral water as defined in Section III of the First Schedule, as appropriate,

"naturally carbonated natural mineral water", "natural mineral water fortified with gas from the spring" or "carbonated natural mineral water".

The sales description of natural mineral waters which have undergone any of the treatments referred to in regulations 5.2.2 of these regulations shall have added to it as appropriate the indication "fully de-carbonated" or "partially de-carbonated".

5.11 Labels on natural mineral waters shall also give the following mandatory information:

5.11.1 a statement of the analytical composition, giving its characteristic constituents;

5.11.2 the place where the spring is exploited and the name of the spring

5.11.3 information on any treatments referred to in regulations 5.2.2.1 and 5.2.2.2 of these regulations.

5.12 The name of a locality, hamlet or place may occur in the wording of a trade description provided that it refers to a natural mineral water the spring of which is exploited at the place indicated by that description and provided that it is not misleading as regards the place of exploitation of the spring.

5.13 When the labels or inscriptions on the containers in which the natural mineral waters are offered for sale include a trade description different from the name of the spring or the place of its exploitation, this place or the name of the spring shall be indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description.

The first subparagraph shall apply, mutatis mutandis and with the same intention as regards the importance attributed to the name of the spring or the place of its exploitation, with regard to the trade description used in advertising, in whatsoever form, relating to natural mineral waters.

6. Prohibitions

6.1 It shall be forbidden to market natural mineral water from one and the same spring under more than one trade description.

6.2 It shall be forbidden, both on packaging or labels and in advertising in whatsoever form, to use designations, proprietary names,

trade marks, brand names, illustrations or other signs, whether emblematic or not, which:

6.2.1 in the case of a natural mineral water, suggest a characteristic which the water does not possess, in particular as regards its origin, the date of the authorization to exploit it, the results of analyses or any similar references to guarantees of authenticity;

6.2.2 in the case of drinking water packaged in containers and which does not satisfy the provisions of Section 1 of the First Schedule, are liable to cause confusion with a natural mineral water, in particular the description "mineral water".

6.3 (a) All indications attributing to a natural mineral water properties relating to the prevention, treatment or cure of a human illness shall be prohibited.

(b) However, the indications listed in the Third Schedule to these regulations shall be authorized if they meet the relevant criteria laid down in that Schedule or, in the absence thereof, criteria laid down in national provisions and provided that they have been drawn up on the basis of physico-chemical analyses and, where necessary, pharmacological, physiological and clinical examinations carried out according to recognized scientific methods, in accordance with Section I, paragraph 2 of the First Schedule.

7 Specific Provisions

7.1 The indications "stimulates digestion", "may facilitate the hepato-biliary functions" or similar indications may be used in respect of natural mineral waters.

7.2 The term "spring water" shall be reserved for a water which is intended for human consumption in its natural state, and bottled at source, which:

7.2.1 satisfies the conditions of exploitation laid down in paragraphs 2 and 3 of the Second Schedule, which shall be fully applicable to spring waters,

7.2.2 satisfies the microbiological requirements laid down in regulation 5.6 of these regulations,

7.2.3 satisfies the labelling requirements of regulations 5.11.2, 5.11.3, 5.12, 5.13 and 6.1 of these regulations.

7.2.4 has not undergone any treatment other than those referred to in regulations 5.2 of these regulations or any other specifically authorized treatments.

7.3 In addition, spring waters shall comply with all applicable provisions relating to the quality of water intended for human consumption.

7.4 Where the responsible authority has detailed grounds for considering that a natural mineral water does not comply with the provisions laid down in these regulations, it may temporarily restrict or suspend trade in that product within Malta.

8. Applicability of regulations

8.1 These regulations shall not apply to natural mineral waters intended for export to third countries.

8.2 These regulations shall apply without prejudice to other provisions relating to the protection of public health or any measures which may be taken by the Superintendent of Public Health whenever he has detailed grounds for considering that a natural mineral water endangers public health.

8.3 Any measures taken by the Superintendent of Public Health pursuant to regulation 8.2 shall be immediately notified to the responsible authority.

FIRST SCHEDULE

I. DEFINITION

1. "Natural mineral water" means microbiologically wholesome water, within the meaning of paragraphs 5.6 to 5.8, originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits.

Natural mineral water can be clearly distinguished from ordinary drinking water:

(a) by its nature, which is characterised by its mineral content, trace elements or other constituents and, where appropriate, by certain effects;

(b) by its original state,

both characteristics having been preserved intact because of the underground origin of such water, which has been protected from all risk of pollution.

2. These characteristics, which may give natural mineral water properties favourable to health, must have been assessed:

(a) from the following points of view:

1. geological and hydrological,

2. physical, chemical and physico-chemical,

3. microbiological,

4. if necessary, pharmacological, physiological and clinical;

(b) according to the criteria listed in Section II;

(c) according to scientific methods approved by the responsible authority.

The analyses referred to in (a) (4) may be optional where the water presents the compositional characteristics on the strength of which it was considered a natural mineral water in the Member State of origin prior to the entry into force of Directive 80/777/EEC. This is the case in particular when the water in question contains, per kg, both at source and after bottling, a minimum of 1,000 mg of total solids in solution or a minimum of 250 mg of free carbon dioxide.

3. The composition, temperature and other essential characteristics of natural mineral water must remain stable within the limits of natural fluctuation; in particular, they must not be affected by possible variations in the rate of flow.

Within the meaning of paragraph 5.6 of the regulations, the normal viable colony count of natural mineral water means the reasonably constant total colony count at source before any treatment, whose qualitative and quantitative composition taken into account in the recognition of that water is checked by periodic analysis.

II. REQUIREMENTS AND CRITERIA FOR APPLYING THE DEFINITION

1.1 **Requirements for geological and hydrological surveys**

There must be a requirement to supply the following particulars:

1.1.1 the exact site of the catchment with indication of its altitude, on a map with a scale of not more than 1:1000;

1.1.2 a detailed geological report on the origin and nature of the terrain;

1.1.3 a stratigraphy of the hydrogeological layer;

1.1.4 a description of the catchment operations;

1.1.5 the demarcation of the area or details of other measures protecting the spring against pollution.

1.2 **Requirements for physical, chemical and physico-chemical surveys**

These surveys shall establish:

1.2.1 the rate of flow of the spring;

1.2.2 the temperature of the water at source and the ambient temperature;

1.2.3 the relationship between the nature of the terrain and the nature and type of minerals in the water;

1.2.4 the dry residues at 180°C and 260°C;

1.2.5 the electrical conductivity or resistivity, with the measurement temperature having to be specified;

1.2.6 the hydrogen ion concentration (pH);

1.2.7 the anions and cations;

1.2.8 the non-ionised elements;

1.2.9 the trace elements;

1.2.10 the radio-actinological properties at source;

1.2.11 where appropriate, the relative isotope levels of the constituent elements of water, oxygen ($^{16}O - ^{18}O$) and hydrogen (protium, deuterium, tritium);

1.2.12 the toxicity of certain constituent elements of the water, taking account of the limits laid down for each of them.

1.3 Criteria for microbiological analyses at source

These analyses must include:

1.3.1 demonstration of the absence of parasites and pathogenic micro-organisms;

1.3.2 quantitative determination of the revivable colony count indicative of faecal contamination:

(a) absence of *Escherichia coli* and other coliforms in 250 ml at 37°C and 44.5°C;

(b) absence of faecal streptococci in 250 ml;

(c) absence of sporulated sulphite-reducing anaerobes in 50 ml;

(d) absence of *Pseudomonas aeruginosa* in 250 ml.

1.3.3 determination of the revivable total colony count per ml of water:

(i) at 20 to 22°C in 72 hours on agar-agar or an agar-gelatine mixture,

(ii) at 37°C in 24 hours on agar-agar.

1.4 Requirements for clinical and pharmacological analyses

1.4.1 The analyses, which must be carried out in accordance with scientifically recognised methods, should be suited to the particular characteristics of the natural mineral water and its effects on the human organism, such as diuresis, gastric and intestinal functions, compensation for mineral deficiencies.

1.4.2 The establishment of the consistency and concordance of a substantial number of clinical observations may, if appropriate, take the place of the analyses referred to in 1.4.1. Clinical analyses may, in appropriate cases, take the place of the analyses referred to in 1.4.1 provided that the consistency and concordance of a substantial number of observations enable the same results to be obtained.

III. SUPPLEMENTARY QUALIFICATIONS RELATING TO EFFERVESCENT NATURAL MINERAL WATERS

At source or after bottling, effervescent natural mineral waters give off carbon dioxide spontaneously and in a clearly visible manner under normal conditions of temperature and pressure. They fall into three categories to which the following descriptions respectively shall apply:

(a) "naturally carbonated natural mineral water" means water whose content of carbon dioxide from the spring after decanting, if any, and bottling is the same as at source, taking into account where appropriate the reintroduction of a quantity of carbon dioxide from the same water table or deposit equivalent to that released in the course of those operations and subject to the usual technical tolerances;

(b) "natural mineral water fortified with gas from the spring" means water whose content of carbon dioxide from the water table or deposit after decanting, if any, and bottling is greater than that established at source;

(c) "carbonated natural mineral water" means water to which has been added carbon dioxide of an origin other than the water table or deposit from which the water comes.

SECOND SCHEDULE

CONDITIONS FOR THE EXPLOITATION AND MARKETING OF NATURAL MINERAL WATER

1. Exploitation of a natural mineral water spring shall be subject to permission from the responsible authority of the country where the water has been extracted, after it has been established that the water in question complies with the provisions laid down in point 1 of the First Schedule.

2. Equipment for exploiting the water must be so installed so as to avoid any possibility of contamination and to preserve the properties, corresponding to those ascribed to it, which the water possesses at source.

To this end, in particular:

(a) the spring or outlet must be protected against the risks of pollution;

(b) the catchment, pipes and reservoirs must be of materials suitable for water and so built as to prevent any chemical, physico-chemical or microbiological alteration of the water;

(c) the conditions of exploitation, particularly the washing and bottling plant, must meet hygiene requirements. In particular, the containers must be so treated or manufactured as to avoid adverse effects on the microbiological and chemical characteristics of the water;

(d) the transport of natural mineral water in containers other than those authorised for distribution to the ultimate consumer is prohibited.

3. Where it is found, during exploitation, that the natural mineral water is polluted and no longer presents the microbiological characteristics laid down in paragraphs 5.6 to 5.8 of these regulations, the person exploiting the spring must forthwith suspend all operations, particularly the bottling process, until the cause of pollution is eradicated and the water complies with the provisions of those paragraphs.

4. The responsible authority in the country of origin shall carry out periodic checks to see whether:

(a) the natural mineral water in respect of which exploitation of the spring has been authorised complies with Section I of the First Schedule;

(b) the provisions of paragraphs 2 and 3 are being applied by the person exploiting the spring.

THIRD SCHEDULE

INDICATIONS AND CRITERIA LAID DOWN IN PARAGRAPH 10.9

Indications	***Criteria***
Low mineral content	Mineral salt content, calculated as a fixed residue, not greater than 500 mg/l
Very low mineral content	Mineral salt content, calculated as a fixed residue, not greater than 50 mg/l
Rich in mineral salts	Mineral salt content, calculated as a fixed residue, greater than 1,500 mg/l
Contains bicarbonate	Bicarbonate content greater than 600 mg/l
Contains sulphate	Sulphate content greater than 200 mg/l
Contains chloride	Chloride content greater than 200 mg/l
Contains calcium	Calcium content greater than 150 mg/l
Contains magnesium	Magnesium content greater than 50 mg/l
Contains fluoride	Fluoride content greater than 1 mg/l
Contains iron	Bivalent iron content greater than 1 mg/l
Acidic	Free carbon dioxide content greater than 250 mg/l
Suitable for the preparation of infant food	–
Suitable for a low-sodium diet	Sodium content less than 20 mg/l
May be laxative	–
May be diuretic	–