

GOVERNMENT NOTICES GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. R. 718

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FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT NO. 54 OF 1972)

REGULATIONS RELATING TO ALL BOTTLED WATERS

The Minister of Health has, in terms of section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), made regulations in the Schedule.

SCHEDULE

Definitions

1. In these regulations any expression to which a meaning has been assigned in the Act shall bear that meaning and, unless the context otherwise indicates –

"bottled water" means water that is packed in sealed containers of various forms and capacities, and which is offered for sale as a foodstuff for human consumption, but does not contain sugars, sweeteners, flavourings or any other foodstuffs;

"bulk" means non-bottled water in direct contact with the surface of the transportation vessel and the atmosphere;

"carbonated natural water" means natural water which, after possible treatment and packaging, has been made effervescent by the addition of carbon dioxide from an origin other than that of the natural water;

"decarbonated natural water" means natural water which, after possible treatment and packaging, has a lower carbon dioxide content than that at emergence and does not visibly and spontaneously give off carbon dioxide under

normal conditions of temperature and pressure;

"free carbon dioxide" means carbon dioxide that is not chemically bound to other elements or compounds;

"limit of quantification" means the lowest level at which a substance can be enumerated;

"naturally-carbonated natural water" means natural water which, after possible treatment and reincorporation of gas from the same source and packaged, taking into consideration normal technical tolerance, has the same content of carbon dioxide as it would if carbon dioxide were spontaneously and visibly given off under normal conditions of temperature and pressure;

"natural mineral water" means bottled natural water which contains mineral salts in various proportions and which is characterised by the presence of trace elements and other substances such as calcium, magnesium, sodium, and potassium;

"natural water" means bottled water derived from an underground formation which has not been modified and has not undergone treatment further than that stipulated in regulation 3;

"natural water with added carbon dioxide" means natural water which, after possible treatment and packaging, has more carbon dioxide content than such natural water had at its source;

"non-carbonated natural water" means natural water which, by nature and after possible treatment and packaging, taking into consideration usual technical tolerance, does not contain free carbon dioxide in amounts larger than are necessary to keep the hydrogen carbonate salts present in the water dissolved;

"normal technical tolerance" means the natural variation in the carbon dioxide content of natural mineral water;

"perimeter" means the outer boundary of the natural source of water;

"prepared water" means bottled water that has undergone any treatment acceptable for bottled waters and may originate from any type of water supply, e.g. distilled tap water, tap water with added minerals;

"spring water" means bottled water sourced from an underground formation from which water flows naturally to the surface of the earth, and which is collected from the spring or a borehole tapping the underground formation, and which may be classified as a 'natural water' or as 'water defined by origin';

"the Act" means the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972);

"water defined by origin" means bottled water originating from an underground or surface water system, which flows naturally from its source, e.g. artesian water.

PART I Natural waters

This part applies to natural mineral water, natural borehole water and natural spring water.

General requirements

2. Natural water shall –

- (1) be obtained directly from natural or drilled sources from the underground water-bearing strata for which all precautions shall be taken within the protected perimeters to avoid any pollution of, or any external effect on, the chemical and physical qualities of its natural condition;

- (2) be constant in its composition and have a stable discharge rate and temperature taking into account cycles of minor natural fluctuations, while it is still at the source;
- (3) be collected under conditions which guarantee the original bacteriological purity and chemical composition of essential components;
- (4) be packaged at or in close proximity to the point of emergence of the source with particular hygienic precautions;
- (5) be subjected to treatment only as prescribed in regulation 3 below:
Provided that the mineral content of the natural water and its essential constituents are not modified;
- (6) comply with all the general requirements for bottled waters stipulated in the Annexure to these regulations.

Treatment

3. Natural water may be subjected only to –

- (1) separation from unstable constituents by decantation or filtration, which can be accelerated by previous aeration;
- (2) removal of carbon dioxide from the natural water;
- (3) addition of carbon dioxide to the natural water, either direct or after initially removing carbon dioxide as referred to in subregulation (2).

Transportation

4. Natural water shall not be transported in bulk from the source to another facility

for treatment, packaging or any other process.

Labelling

5. For natural water, the following information shall appear on the label:

- (1) The name of the product, which shall be "natural mineral water" or "natural spring water" or any appropriate name indicating the natural condition of the water;
- (2) the physical address and the name of the source;
- (3) the analytical composition in milligrams per litre (mg/l);
- (4) the specification of the kind of natural water by the use of the expression "naturally-carbonated natural water", "non-carbonated natural water", "decarbonated natural water", "natural water with added carbon dioxide from source" or "carbonated natural water", which may be accompanied by further descriptive expressions such as "still" and "sparkling".

PART II Waters defined by origin

This part applies to iceberg water, snow water, stream water, rain water, river water, mist water, spring water, glacier water and sea water.

General requirements

6. Waters defined by origin shall –

- (1) originate from any specific environmental water source without passing through a community water system;
- (2) be extracted with precaution within the vulnerability perimeters to avoid

any contamination, pollution or external influence on the chemical, microbiological and physical quality of water at the origin;

- (3) be subjected only to treatments stipulated in regulation 7 below;
- (4) comply with all the general requirements for bottled waters stipulated in the Annexure to these regulations.

Treatment

7. Waters defined by origin shall be subjected to the following treatments: Provided that these modifications or treatments and the processes used to achieve them do not compromise the chemical, radiological and microbiological safety of these waters:

- (1) Reduction or elimination of dissolved gases and unstable constituents such as iron, manganese, sulphur, excess carbonates under normal pressure and temperature conditions.
- (2) Addition of carbon dioxide or reincorporation of original carbon dioxide present at the emergence.
- (3) Addition of air, oxygen or ozone on condition that the by-products due to ozone treatment do not affect the maximum levels for elements stipulated in the general requirements for bottled waters as set out in the Annexure to these regulations.
- (4) Decrease or increase in temperature.
- (5) Reduction or separation of elements originally present in excess of acceptable levels as stipulated in the general requirements for bottled waters in the Annexure to these regulations.

- (6) Antimicrobial treatments shall be used in order to conserve the microbiological fitness for human consumption, original purity and safety of these waters.

Labelling

8. For waters defined by origin, the following information shall appear on the label:

- (1) The name of the product, indicating its environmental source;
- (2) further descriptive expressions such as "naturally carbonated" or "naturally sparkling" or "with added carbon dioxide" or "non carbonated" or "non sparkling" or "still";
- (3) the physical address and the name of the source;
- (4) the method of sanitisation;
- (5) the chemical composition of the water in milligrams per litre (mg/l).

PART III Prepared waters

This part applies to waters that are sourced from any acceptable water supply and do not comply with the provisions of the other sections in these regulations.

General requirements

9. Prepared waters can be collected from any source of water supply and should comply with all provisions under general requirements for bottled waters stipulated in the Annexure to these regulations.

Treatment

10. Prepared waters may be subjected to any antimicrobial treatment and any treatments that modify the physicochemical characteristics of the original water: Provided that such treatments result in prepared waters that comply with all provisions under the general requirements for bottled waters stipulated in the Annexure to these regulations.

Labelling

11. For prepared waters the following shall appear on the label:
- (1) The name of the product, which shall be "prepared water";
 - (2) further descriptive expressions such as "carbonated" or "sparkling";
 - (3) the disinfection or treatment method used, e.g. re-mineralised, ozonated, pasteurised, reverse osmosis;
 - (4) the chemical composition of the prepared water;
 - (5) the phrase "from a public or private distribution system" if the prepared water was supplied by a public or private tap-water distribution system.

Commencement

12. These regulations shall come into effect twelve months from the date of publication of this notice.



ME TSHABALALA-MSIMANG
MINISTER OF HEALTH

ANNEXURE

GENERAL REQUIREMENTS FOR BOTTLED WATERS

- (a) No bottled water shall contain substances or emit radioactivity in quantities that may be injurious to the health of the consumer.
- (b) Bottled water shall not contain the elements listed in column I in quantities greater than those indicated in column II, but for enforcement purposes in accordance with these regulations, bottled water containing elements in column I in quantities greater than the acceptable range in column III of the table below shall be deemed contaminated or injurious to health when tested in accordance with the methods prescribed in *Methods of Analysis and Sampling* (Volume 13) of the Codex Alimentarius Commission or corresponding methods as prescribed in SANS 1862:2003 and SANS 1657:2003.

TABLE: Maximum levels for elements that may be present in bottled water

I Substance	II Maximum level (mg/l)	III Acceptable range (mg/l)
Antimony	0,005	0,005 - 0,01
Arsenic	0,01 (as total arsenic)	0,01 - 0,05
Barium	0,7	-
Borate	5,0 (as total boron)	-
Bromate	0,01	-
Cadmium	0,003	0,003 - 0,005
Chromium	0,05 (as total chromium)	0,05 - 0,1
Copper	0,5	0,5 - 1,0
Cyanide	0,07	0,07 - 0,2

I Substance	II Maximum level (mg/l)	III Acceptable range (mg/l)
Fluoride	See item (f)	
Lead	0,01	0,01 - 0,05
Manganese	0,5	0,05 - 0,1
Mercury	0,001	0,001 - 0,002
Nickel	0,02	0,02 - 0,15
Nitrate	50 (calculated as nitrate)	-
Organophosphate pesticides	Below the limit of quantification	-
Organochlorine pesticides and polychlorinated biphenyls	Below the limit of quantification	-
Selenium	0,01	0,01 - 0,02
Surface active agents	Below the limit of quantification	-

- (c) At all stages of production, from the source through to marketing, bottled water shall conform to the microbiological requirements for bottled water as set out in the Regulations Governing Microbiological Standards for Foodstuffs and Related Matters promulgated under the Act.
- (d) Prior to use, bottled water shall be packed in hermetically sealed, sanitised containers suitable for preventing any adulteration or contamination.
- (e) Notwithstanding regulations 5, 8 and 11, the following constituents and chemical characteristics should be declared (in mg/l) on the label in the order provided below;

Calcium	as Ca
Magnesium	as Mg

Sodium	as Na
Potassium	as K
Chloride	as Cl
Sulphate	as SO ₄
Alkalinity	as CaCO ₃
Nitrate	as N
Fluoride	as F

In addition, the amount of total dissolved solids and the pH should be declared.

For prepared waters -

Iron	as Fe, and
Aluminium	as Al, should also be declared.

- (f) Notwithstanding the provisions stipulated in (e) above, bottled water shall be labelled in accordance with the provisions of the Regulations Governing the Labelling and Advertising of Foodstuffs promulgated under the Act.
- (g) Notwithstanding the provisions under (f), bottled water containing more than 1 mg/l fluoride shall have the expression "contains fluoride" affixed in close proximity to the name of the water or in a prominent place on the label. If it contains more than 2 mg/l fluoride, the expression "this product is not suitable for infants and children under the age of seven years" shall be affixed in close proximity to the name of the water or in a prominent place on the label.
- (h) No claims concerning medicinal effects (e.g. preventative, alleviate or curative) shall be made in respect of the properties of the bottled waters covered in these regulations.
- (i) Notwithstanding the provisions of paragraph (f), these regulations prohibit the use of any statement or any pictorial device that may create confusion in the minds of the public about the nature, origin, composition and properties of bottled waters put on sale in South Africa.