

CHAPTER 53

(House Bill 214)

AN ACT concerning

Bottled Water – Standard of Identity and Labeling Requirements – Out-of-State Registration of Bottled Water and Soft Drinks

FOR the purpose of requiring bottled water to meet certain federal standards of identity; requiring certain labeling requirements to conform with certain federal regulations; requiring a certain representative of the bottler to renew a waiver of filtration and disinfection treatment by submitting a certain letter to the Department of Health and Mental Hygiene; requiring a certain representative of the bottler to give certain notice to the Department under certain circumstances; repealing the out-of-state registration requirements for bottled water; altering a certain definition; and generally relating to the sale of bottled water and soft drinks in the State.

BY repealing and reenacting, without amendments,
Article – Health – General
Section 21–301(a) and (k) and 21–336(b)
Annotated Code of Maryland
(2005 Replacement Volume and 2007 Supplement)

BY repealing and reenacting, with amendments,
Article – Health – General
Section 21–301(b) and (m), 21–336(a), (c), (e)(1), (g), (h), (i), and (k), and
21–336.1
Annotated Code of Maryland
(2005 Replacement Volume and 2007 Supplement)

BY repealing
Article – Health – General
Section 21–301(l), 21–331, and 21–336(d)
Annotated Code of Maryland
(2005 Replacement Volume and 2007 Supplement)

BY adding to
Article – Health – General
Section 21–336(c)
Annotated Code of Maryland
(2005 Replacement Volume and 2007 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

21–301.

(a) In this subtitle the following words have the meanings indicated.

(b) (1) “Bottled water” means any water that is sealed in bottles, **PACKAGES**, or other containers [for:

(i) Drinking;

(ii) Cooking; or

(iii) Other purposes making it likely that the water will be ingested by human beings.

(2) (i) “Bottled water” may:

1. Include natural or added carbonation; and

2. Be prepared with added flavors, extracts, or essences that are derived from a spice or fruit and that comprise less than 1 percent by weight of the final product; but

(ii) “Bottled water” may not contain any sweetener, acidulent, or additive other than the flavors, extracts, or essences authorized under subparagraph (i) of this paragraph] **AND OFFERED FOR SALE FOR HUMAN CONSUMPTION, INCLUDING BOTTLED MINERAL WATER.**

~~[(3)]~~**(2)** “Bottled water” does not include:

(i) Soft drinks; or

(ii) A beverage that is labeled “club soda” or “seltzer water”.

(k) (1) Except as provided under paragraph (2) of this subsection, “soft drink” means any nonalcoholic beverage.

(2) “Soft drink” does not include:

(i) Apple cider;

(ii) Soft drinks that are manufactured on the premises of a soda fountain and used at that soda fountain; or

(iii) Bottled water.

[(l) “Soft drink registration” means a registration issued by the Department to sell in this State a soft drink that is manufactured outside this State.]

[(m)] (L) “Surimi” means an intermediate manufactured seafood product derived from minced fish meat, washed to remove water-soluble protein and blood or other undesirable components and mixed with additives to enhance its frozen storage and functional characteristics.

[21-331.

(a) Except as otherwise provided in this subtitle, a soft drink that is manufactured outside this State shall be registered with the Department before any person may sell the soft drink in this State.

(b) To qualify for a soft drink registration, an applicant shall satisfy the Department that the soft drink for which the soft drink registration is bought is manufactured under standards substantially similar to those required of soft drinks manufactured in this State.

(c) To apply for a soft drink registration, the manufacturer of the soft drink or a dealer for the manufacturer shall:

(1) Submit an application to the Department on the form that the Department requires;

(2) List on the application form the flavors of soft drink that the applicant proposes to sell; and

(3) Pay to the Department an inspection fee established by the Secretary under § 2-104 of this article for each flavor.

(d) Before issuing a soft drink registration, the Department may analyze the soft drink identified in the application to determine whether that soft drink meets the requirements for registration.

(e) If the applicant and the soft drink for which the applicant seeks a soft drink registration meet the requirements of this subtitle, the Department shall:

(1) Register the soft drink; and

(2) Issue a soft drink registration certificate to the applicant.

(f) While it is effective, a soft drink registration authorizes the sale in this State of the soft drinks identified in the soft drink registration.]

21-336.

(a) (1) In this section [the following words have the meanings indicated.

(2) (i) “Approved], “**APPROVED** source” means a source of water that is:

[1.] (I) Sampled and found through laboratory analysis to comply with:

[A.] 1. The microbiological standards adopted by the Department, with testing on a monthly basis; and

[B.] 2. The chemical and radiological standards adopted by the Department, which shall meet or exceed the standards prescribed by the federal Food and Drug Administration, with testing annually for chemical analyses and once every 4 years for radiological analyses; and

[2.] (II) If applicable, constructed and inspected in accordance with regulations adopted by the Department of the Environment under §§ 9-204, 9-1305, and 9-1306 of the Environment Article.

[(ii)] (2) “Approved source” includes:

[1.] (I) An artesian well;

[2.] (II) A drilled well;

[3.] (III) A glacier;

[4.] (IV) A public water supply;

[5.] (V) A spring; and

[6.] (VI) A source of mineral water that complies with the standards specified in [subparagraph (i)] **PARAGRAPH (1)** of this [paragraph] **SUBSECTION** but fails to meet the standards with respect to those properties of mineral water related to[

A. Limitations] **THE LIMITATIONS on CHLORIDE, IRON, MANGANESE, SULFATE, total dissolved solids, ZINC, OR ANY OTHER EXEMPTIONS LISTED UNDER 21 C.F.R. 165.110**]; and

B. Any maximum contaminant level or quality standard regulated by the United States Environmental Protection Agency only as a secondary standard].

[(iii)] (3) The Department may approve a source that does not meet standards regulated by the United States Environmental Protection Agency as a secondary standard if the bottler shows by analysis that a particular treatment used reduces the level of contaminants in the bottled water to a level below the maximum contaminant level.

(3) (i) “Artesian water” means bottled water from a well in which the static water level rises above the top of the aquifer from which the water is drawn.

(ii) “Artesian water” shall meet all the requirements of natural water.

(4) (i) “Mineral water” means bottled water that:

1. Is obtained from a natural spring or by tapping at least 1 borehole into an underground approved source that is geologically and physically protected; and

2. Is clearly distinguishable from other types of water by its specific content of minerals and trace elements that remain constant in the original state at the point of emergence.

(ii) “Mineral water” shall meet all the requirements of natural water.

(5) (i) “Natural water” means bottled water that is:

1. Derived from an aquifer or a glacier; and

2. Except as related to disinfection purposes, not modified by blending with another type of water or by the addition or deletion of dissolved solids.

(ii) “Natural water” includes:

1. Artesian water;

2. Mineral water;

3. Glacier water;
4. Spring water; and
5. Well water.

(iii) "Natural water" does not include water that is derived from a municipal system or public water supply.

(iv) "Natural water" may be collected by means of pipes, pumps, trucks, tunnels, or other devices.

(6) "Purified water" means bottled water that:

(i) Is produced by distillation, deionization, reverse osmosis, or any other means approved by the Department; and

(ii) Meets all the requirements of the United States Pharmacopoeia definition of purified water.

(7) (i) "Spring water" means bottled water derived from an underground aquifer from which water flows naturally to the surface of the earth.

(ii) "Spring water" shall be collected:

1. At the natural orifice; or

2. If the water retains all of the physical properties of, and the same composition as, water that flows naturally to the surface of the earth, from a borehole near a spring that intercepts the same source of water as the spring.

(iii) "Spring water" shall meet all the requirements of natural water.

(8) (i) "Well water" means bottled water from a hole drilled in the ground to tap the water of an aquifer.

(ii) "Well water" shall meet all the requirements of natural water.]

(b) The requirements of this section are in addition to any other provision of law.

(C) ARTESIAN WATER, MINERAL WATER, NATURAL WATER, PURIFIED WATER, SPRING WATER, WELL WATER, AND ANY OTHER TYPE OF BOTTLED

WATER SHALL MEET THE REQUIREMENTS OF THE STANDARD OF IDENTITY FOR BOTTLED WATER UNDER 21 C.F.R. 165.110(A).

~~[(c)]~~ **(D)** (1) ~~[Except as authorized under subsection (d) of this section, a]~~
A person may not bottle water unless the person is licensed by the Department under § 21–305 of this subtitle.

(2) The Department may not issue a license if the Department determines that the water is:

- (i) Not from an approved source; or
- (ii) In any way injurious to the public health.

(3) To apply for a license to bottle water, a bottler shall:

(i) Submit an application to the Department on the form that the Department requires;

(ii) List on the application form the types of bottled water that the applicant proposes to bottle; and

(iii) Pay to the Department an annual fee established by the Secretary under § 2–104 of this article.

(4) While it is effective, a license to bottle water authorizes a bottler to bottle and sell in the State the types of bottled water identified in the license.

~~[(d)]~~ (1) Subject to the requirements of subsection (e) of this section, a person may not sell water in this State that was bottled outside this State unless the person bottling the water has registered the water with the Department.

(2) In order to register with the Department, a person shall present to the Department:

(i) A statement of acceptability issued by the appropriate approving authority of the state in which the water is collected, demonstrating that:

1. The source of the water supply and the method of handling the water, as practiced in that state, are not prejudicial to the public health and the method is at least as stringent as those required under this section; and

2. The water is allowed to be sold in the state that issued the statement of acceptability; and

(ii) Any other documents related to public health and safety required of a person applying for a license to bottle water in this State.

(3) The provisions of this subsection do not prevent the Department from prohibiting the use or sale of bottled water shipped from outside this State, if, in the judgment of the Department:

(i) The water is shown by analysis to be unfit for drinking;

(ii) The water has been misbranded under § 21–210 of this title;

or

(iii) Its quality in any way is injured by such handling as may be accorded to it after arriving in this State.

(4) The Secretary shall establish an annual out-of-state registration fee under this section in accordance with § 2–104 of this article.]

(e) (1) (i) A person who is licensed [or registered] under this section shall submit to the Department the results of:

1. Annual chemical and radiological analyses of a representative sample of the person's source water and bottled water; and

2. A monthly microbiological analysis of a representative sample of the source water and bottled water.

(ii) The analyses shall demonstrate that the source water and bottled water comply with the chemical, radiological, and microbiological standards adopted by the Department, which shall meet or exceed the standards prescribed by the federal Food and Drug Administration.

(iii) 1. Except as otherwise required by law, mineral water is not subject to[:

A. The limitation] **THE LIMITATIONS on CHLORIDE, IRON, MANGANESE, SULFATE, total dissolved solids, ZINC, OR ANY OTHER EXEMPTIONS LISTED** under 21 CFR [103.35; or

B. Any maximum contaminant level or quality standard that is not a primary standard for purposes of regulation by the United States Environmental Protection Agency under the Safe Water Drinking Act] **165.110**.

2. Bottled water may not exceed:

- A. 10 parts per billion of total trihalomethanes;
- B. 5 parts per billion of lead; or
- C. 100 parts per billion of chlorine.

(g) Labeling of the type of bottled water and any additional ingredients, as required under subsection (f) of this section, shall conform to the [following requirements:

(1) Artesian water may be labeled “artesian water” or “natural artesian water”;

(2) (i) 1. Mineral water may be labeled “mineral water” or “natural mineral water”; but

2. Bottled water to which minerals have been added:

A. Shall be labeled to disclose what minerals were added;

and

B. May not be labeled “mineral water”; and

(ii) The total dissolved solids contained in mineral water shall be:

1. Written on the label; and

2. Stated in milligrams per liter;

(3) Purified water shall be labeled “purified water” or by the method of preparation, and the method of preparation shall be stated on the label;

(4) Spring water may be labeled “spring water” or “natural spring water”;

(5) Well water may be labeled “well water” or “natural well water”;

(6) Bottled water:

(i) May be labeled “naturally carbonated” or “naturally sparkling” if:

1. It contains carbon dioxide that emerges from the source and the water is bottled directly with its entrapped gas; or

2. Carbon dioxide is mechanically separated from the water and is later reintroduced at the same or lower concentration as the concentration that naturally occurs; and

(ii) Shall be labeled “carbonated”, “carbonation added”, or “sparkling” if it contains carbon dioxide from a manufactured source;

(7) (i) Bottled water may be labeled “drinking water” or “bottled drinking water”;

(ii) Except for “purified drinking water”, as defined by the United States Pharmacopoeia, at any point during the bottling process, bottled water that is derived from a public drinking water supply, as defined under the Safe Drinking Water Act, shall be labeled “drinking water” or “bottled drinking water”, and its approved source shall be stated on the label in a factually accurate manner;

(8) (i) Except as provided under subparagraph (ii) of this paragraph, a licensee or registrant under this section may not label bottled water with a word or a derivative of a word that does not accurately describe the type of bottled water;

(ii) 1. The provisions of subparagraph (i) of this paragraph may not be construed to restrict a word or a derivative of a word that is part of a bottler’s trademark, trade name, or company name; but

2. If the word or derivative of a word that is part of the bottler’s trademark, trade name, or company name is reasonably construed to mean a type of bottled water, the type of water in the container shall be identified on the same label in typeface at least as large as the typeface used in the trademark, trade name, or company name;

(9) Bottled water that meets more than 1 definition under subsection (a) of this section may be labeled as any of its applicable types; and

(10) Any additional standards established by the Department] **LABELING REQUIREMENTS FOR BOTTLED WATER UNDER 21 C.F.R. 165.110(A).**

(h) In accordance with regulations adopted by the Department, a person licensed [or registered] under this section shall establish written procedures and implement those procedures to:

(1) Prevent contamination during the processing, packaging, transportation, or storage of bottled water; and

(2) Recall bottled water when the person, the Department, or any other government agency determines that a supply is injurious in any way to the public health.

(i) The Department may suspend or revoke a license [or registration] issued under this section if the licensee [or registrant]:

(1) Violates or fails to satisfy any requirement of this title or any regulation adopted under this title; or

(2) Fraudulently or deceptively obtains a license [or registration].

(k) By [March 31, 1993] **OCTOBER 1, 2008**, the Department shall adopt regulations to implement the provisions of this section.

21-336.1.

(a) Except as permitted under subsection (b) of this section, bottled water shall:

(1) Be obtained from an approved source; and

(2) Undergo:

(i) Ozonation or an equivalent disinfection process approved by the Department; and

(ii) When required by the Department, filtration or any other treatment that is necessary for the water to comply with the standards adopted by the Department under § 21-336(e)(1)(ii) of this subtitle.

(b) The Department may grant to a bottler a waiver of the filtration and disinfection treatment required under subsection (a) of this section if the Department is satisfied that the filtration and disinfection treatment are not necessary to assure that a bottled water product will consistently comply with the microbiological standards under this subtitle.

(c) (1) Based on the bottler's demonstration of long-term baseline microbiological data that monitors the source and the product, the nature and extent of source monitoring, and source protection and bottling sanitation procedures instituted by the bottler, a waiver may be granted if:

(i) The product and source are in compliance with the Codex Alimentarius standard for natural mineral water, CAC/RS 108, as amended, and the requirements under § 21-336(a)(2) and (e) of this subtitle;

(ii) The product and source are in compliance with the Code of Hygienic Practice of the Codex Alimentarius, Alinorm 85/13A, as amended, for the collection, processing, and marketing of natural mineral water; and

(iii) The bottler has submitted a basic hydrogeological survey of the source, a hydrogeological assessment that demonstrates that the source is not under the direct influence of surface water, and an annual sanitary survey, all of which have been prepared by a professionally qualified hydrogeologist and which demonstrate the integrity of the source.

(2) The annual sanitary survey required under paragraph (1)(iii) of this subsection shall include:

(i) Watershed surveillance that includes an inspection of those portions of the drainage area necessary to identify and evaluate actual and probable sources of contamination;

(ii) Evaluation of source construction and protection, and, when appropriate, intake structures and transmission facilities; and

(iii) Evaluation of finished water storage facilities.

(d) Once a waiver has been granted under this section:

(1) A bottler shall [submit an annual report to the Department that demonstrates continued compliance of the source and the product with the Codex Alimentarius standards by:

(i) Testing and approval of the source and product at least once every 2 months by the appropriate authority;

(ii) Microbiological testing:

1. On a weekly basis, as described in the Code of Hygienic Practices of the Codex Alimentarius, Alinorm 85/13A, for the collection, processing, and marketing of natural mineral water; and

2. In accordance with the standards described in 21 CFR 103.35; and

(iii) An annual inspection by an independent organization acceptable to the Department that demonstrates compliance with the Code of Hygienic Practices of the Codex Alimentarius, Alinorm 85/13A, and with the requirements of 21 CFR Part 129 for the collection, processing, and marketing of natural mineral water; and] **RENEW THE WAIVER OF THE FILTRATION AND DISINFECTION TREATMENT PROVIDED UNDER SUBSECTION (B) OF THIS SECTION ON AN ANNUAL BASIS IF A**

CONTINUATION OF OPERATIONS IS DESIRED BY SUBMITTING A LETTER OF COMPLIANCE WITH SUBSECTION (C) OF THIS SECTION FROM A REPRESENTATIVE OF THE BOTTLER TO THE DEPARTMENT.

(2) THE REPRESENTATIVE OF THE BOTTLER SHALL CERTIFY UNDER PERSONAL KNOWLEDGE AND PENALTY OF PERJURY THAT THE CONDITIONS UNDER SUBSECTION (C) OF THIS SECTION ON WHICH THE WAIVER WAS GRANTED HAVE NOT CHANGED.

(3) THE REPRESENTATIVE OF THE BOTTLER SHALL HAVE A CONTINUING OBLIGATION TO NOTIFY THE DEPARTMENT OF ANY CHANGE OF A CONDITION UNDER SUBSECTION (C) OF THIS SECTION NOT LATER THAN 5 DAYS FROM THE DATE OF THE CHANGE.

[(2)] (4) The product shall be bottled:

(i) In an enclosed filling room or chamber that is under positive pressure of filtered purified air; and

(ii) At a facility and with good manufacturing practices that comply with the requirements of 21 CFR Part 129.

(e) If a bottled water product is not in compliance with any requirement under subsection (c) or (d) of this section:

(1) The Department shall revoke the waiver; and

(2) The product shall be subject to the filtration and disinfection treatment requirements under subsection (a) of this section.

(f) Except for filtration and disinfection treatment, this section may not be construed to waive any requirement that is applicable under this subtitle to a bottled water product.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2008.

Approved by the Governor, April 8, 2008.