

HOUSE BILL 214

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By: **Chair, Health and Government Operations Committee (By Request -
Departmental - Health and Mental Hygiene)**

Introduced and read first time: January 23, 2008

Assigned to: Health and Government Operations

Committee Report: Favorable

House action: Adopted

Read second time: February 13, 2008

CHAPTER _____

1 AN ACT concerning

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

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

13 BY repealing and reenacting, without amendments,
14 Article – Health – General
15 Section 21–301(a) and (k) and 21–336(b)
16 Annotated Code of Maryland
17 (2005 Replacement Volume and 2007 Supplement)

18 BY repealing and reenacting, with amendments,
19 Article – Health – General
20 Section 21–301(b) and (m), 21–336(a), (c), (e)(1), (g), (h), (i), and (k), and
21 21–336.1
22 Annotated Code of Maryland
23 (2005 Replacement Volume and 2007 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike-out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 BY repealing
2 Article – Health – General
3 Section 21–301(l), 21–331, and 21–336(d)
4 Annotated Code of Maryland
5 (2005 Replacement Volume and 2007 Supplement)

6 BY adding to
7 Article – Health – General
8 Section 21–336(c)
9 Annotated Code of Maryland
10 (2005 Replacement Volume and 2007 Supplement)

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

13 **Article – Health – General**

14 21–301.

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

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

18 (i) Drinking;

19 (ii) Cooking; or

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

22 (2) (i) “Bottled water” may:

23 1. Include natural or added carbonation; and

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

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

31 [(3)](2) “Bottled water” does not include:

1 (i) Soft drinks; or

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

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

5 (2) “Soft drink” does not include:

6 (i) Apple cider;

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

9 (iii) Bottled water.

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

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

16 [21-331.

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

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

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

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

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

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

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

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

6 (1) Register the soft drink; and

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

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

10 21-336.

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

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

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

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

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

22 [2.] (II) If applicable, constructed and inspected in
23 accordance with regulations adopted by the Department of the Environment under §§
24 9-204, 9-1305, and 9-1306 of the Environment Article.

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

26 [1.] (I) An artesian well;

27 [2.] (II) A drilled well;

28 [3.] (III) A glacier;

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

1 [5.] (v) A spring; and

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

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

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

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

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

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

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

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

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

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

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

31 1. Derived from an aquifer or a glacier; and

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

1 (ii) "Natural water" includes:

- 2 1. Artesian water;
- 3 2. Mineral water;
- 4 3. Glacier water;
- 5 4. Spring water; and
- 6 5. Well water.

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

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

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

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

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

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

18 (ii) "Spring water" shall be collected:

19 1. At the natural orifice; or

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

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

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

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

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

3 (c) **ARTESIAN WATER, MINERAL WATER, NATURAL WATER, PURIFIED**
4 **WATER, SPRING WATER, WELL WATER, AND ANY OTHER TYPE OF BOTTLED**
5 **WATER SHALL MEET THE REQUIREMENTS OF THE STANDARD OF IDENTITY FOR**
6 **BOTTLED WATER UNDER 21 C.F.R. 165.110(A).**

7 [(c)] (D) (1) [Except as authorized under subsection (d) of this section, a]
8 A person may not bottle water unless the person is licensed by the Department under
9 § 21-305 of this subtitle.

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

12 (i) Not from an approved source; or

13 (ii) In any way injurious to the public health.

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

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

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

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

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

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

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

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

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

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

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

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

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

11 2. Bottled water to which minerals have been added:

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

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

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

17 1. Written on the label; and

18 2. Stated in milligrams per liter;

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

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

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

24 (6) Bottled water:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 21–336.1.

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

11 (1) Be obtained from an approved source; and

12 (2) Undergo:

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

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

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

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

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

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

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

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

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

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

13 (iii) Evaluation of finished water storage facilities.

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

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

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

20 (ii) Microbiological testing:

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

24 2. In accordance with the standards described in 21 CFR
25 103.35; and

26 (iii) An annual inspection by an independent organization
27 acceptable to the Department that demonstrates compliance with the Code of Hygienic
28 Practices of the Codex Alimentarius, Alinorm 85/13A, and with the requirements of 21
29 CFR Part 129 for the collection, processing, and marketing of natural mineral water;
30 and] **RENEW THE WAIVER OF THE FILTRATION AND DISINFECTION TREATMENT**
31 **PROVIDED UNDER SUBSECTION (B) OF THIS SECTION ON AN ANNUAL BASIS IF A**
32 **CONTINUATION OF OPERATIONS IS DESIRED BY SUBMITTING A LETTER OF**
33 **COMPLIANCE WITH SUBSECTION (C) OF THIS SECTION FROM A**
34 **REPRESENTATIVE OF THE BOTTLER TO THE DEPARTMENT.**

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

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

9 **[(2)] (4) The product shall be bottled:**

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

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

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

16 (1) The Department shall revoke the waiver; and

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

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

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.