

# 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

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## A BILL ENTITLED

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)

24 BY repealing  
25 Article – Health – General  
26 Section 21–301(l), 21–331, and 21–336(d)  
27 Annotated Code of Maryland

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 (2005 Replacement Volume and 2007 Supplement)

2 BY adding to

3 Article – Health – General

4 Section 21–336(c)

5 Annotated Code of Maryland

6 (2005 Replacement Volume and 2007 Supplement)

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

9 **Article – Health – General**

10 21–301.

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

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

14 (i) Drinking;

15 (ii) Cooking; or

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

18 (2) (i) “Bottled water” may:

19 1. Include natural or added carbonation; and

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

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

27 [(3)](2) “Bottled water” does not include:

28 (i) Soft drinks; or

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

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

3 (2) “Soft drink” does not include:

4 (i) Apple cider;

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

7 (iii) Bottled water.

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

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

14 [21-331.

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

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

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

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

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

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

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

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

3 (1) Register the soft drink; and

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

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

7 21–336.

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

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

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

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

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

19 [2.] (II) If applicable, constructed and inspected in  
20 accordance with regulations adopted by the Department of the Environment under §§  
21 9–204, 9–1305, and 9–1306 of the Environment Article.

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

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

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

25 [3.] (III) A glacier;

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

27 [5.] (V) A spring; and

28 [6.] (VI) A source of mineral water that complies with  
29 the standards specified in [subparagraph (i)] **PARAGRAPH (1)** of this [paragraph]

1 **SUBSECTION** but fails to meet the standards with respect to those properties of  
2 mineral water related to[:

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

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

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

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

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

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

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

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

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

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

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

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

32 (ii) “Natural water” includes:

33 1. Artesian water;



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

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

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

10                           (i)    Not from an approved source; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

31 2. Bottled water may not exceed:

32 A. 10 parts per billion of total trihalomethanes;



1 B. 5 parts per billion of lead; or

2 C. 100 parts per billion of chlorine.

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

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

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

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

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

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

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

16 1. Written on the label; and

17 2. Stated in milligrams per liter;

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

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

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

23 (6) Bottled water:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 21-336.1.

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

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

10 (2) Undergo:

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

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

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

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

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

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

31 (iii) The bottler has submitted a basic hydrogeological survey of  
32 the source, a hydrogeological assessment that demonstrates that the source is not  
33 under the direct influence of surface water, and an annual sanitary survey, all of

1 which have been prepared by a professionally qualified hydrogeologist and which  
2 demonstrate the integrity of the source.

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

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

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

10 (iii) Evaluation of finished water storage facilities.

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

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

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

17 (ii) Microbiological testing:

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

21 2. In accordance with the standards described in 21 CFR  
22 103.35; and

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

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

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

5           [(2)] (4)     The product shall be bottled:

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

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

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

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

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

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

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