

111TH CONGRESS  
1ST SESSION

# S. 2848

To amend the Federal Food, Drug, and Cosmetic Act to require manufacturers of bottled water to submit annual reports, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

DECEMBER 8, 2009

Mr. LAUTENBERG introduced the following bill; which was read twice and referred to the Committee on Environment and Public Works

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require manufacturers of bottled water to submit annual reports, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Bottled Water Safety  
5       and Right to Know Act of 2009”.

6       **SEC. 2. CONSUMER CONFIDENCE REPORTS.**

7       Section 410 of the Federal Food, Drug, and Cosmetic  
8       Act (21 U.S.C. 349) is amended—

9               (1) in subsection (b), by adding at the end the  
10       following:

1           “(5) IDENTIFICATION OF CONTAMINANTS; IN-  
2       TERIM AND FINAL STANDARDS.—The Secretary  
3       shall—

4           “(A) not later than 180 days after the date  
5       of enactment of this paragraph identify each  
6       contaminant for which—

7           “(i) the Administrator of the Environ-  
8       mental Protection Agency has established  
9       a national primary drinking water regula-  
10      tion under section 1412 of the Safe Drink-  
11      ing Water Act (42 U.S.C. 300g–1) and the  
12      Secretary—

13           “(I) has not established a stand-  
14      ard of quality regulation; or

15           “(II) has established a standard  
16      of quality regulation or monitoring re-  
17      quirement that may be less protective  
18      of public health than the national pri-  
19      mary drinking water regulation; or

20           “(ii) the Secretary has established a  
21      standard of quality regulation that may be  
22      less protective of public health than the  
23      standard for the contaminant issued by the  
24      World Health Organization, the European  
25      Union, or the State of California;

“(B) not later than 1 year after the date of enactment of this paragraph, propose an interim standard of quality regulation for each contaminant identified under subparagraph (A) that contains a standard or monitoring requirement that is at least as protective of public health as the more protective of—

“(i) the national primary drinking water regulation described in subparagraph (A); or

“(ii) a standard issued by the World Health Organization, the European Union, or the State of California; and

“(C) not later than 2 years after the date of enactment of this paragraph, issue a final regulation establishing the standard described in subparagraph (B) for each contaminant identified under subparagraph (A).

“(6) GRANTS TO STATES.—The Secretary may award grants to the States for the enforcement of the regulations described in paragraph (5).

“(7) FINAL REGULATIONS.—

“(A) DEFINITION OF FEDERAL AGENCY.—

In this paragraph, the term ‘Federal agency’

1 has the meaning given the term ‘agency’ in sec-  
2 tion 551 of title 5, United States Code.

3 “(B) PUBLICATION.—Not later than 2  
4 years after the date of enactment of this para-  
5 graph, the Secretary shall publish in the Fed-  
6 eral Register the final regulation as described in  
7 paragraph (5)(C).

8 “(C) FAILURE TO PUBLISH.—If the Sec-  
9 retary fails to publish the regulation described  
10 in subparagraph (A)—

11 “(i) all functions of the Secretary be-  
12 fore date of enactment of this paragraph  
13 (including all related functions of any offi-  
14 cer or employee of the Department of  
15 Health and Human Services) relating to  
16 inspections and enforcement concerning  
17 bottled water shall be transferred to the  
18 Environmental Protection Agency;

19 “(ii) each reference to the Secretary  
20 contained in paragraph (5) (except for the  
21 references contained in clauses (i) and (ii)  
22 of paragraph (5)(A)), paragraph (6), and  
23 subsections (c), (d), and (e) shall be con-  
24 sidered to be a reference to the Adminis-

1           trator of the Environmental Protection  
2           Agency;

3           “(iii) except as otherwise provided in  
4           this subparagraph, the assets, liabilities,  
5           grants, contracts, property, records, and  
6           unexpended balances of appropriations, au-  
7           thorizations, allocations, and other funds  
8           employed, used, held, arising from, avail-  
9           able to, or to be made available in connec-  
10          tion with the functions transferred under  
11          clause (i), subject to section 1531 of title  
12          31, United States Code, shall be trans-  
13          ferred to the Environmental Protection  
14          Agency, and the unexpended funds trans-  
15          ferred pursuant to this subparagraph shall  
16          be used only for the purposes for which the  
17          funds were originally authorized and ap-  
18          propriated;

19          “(iv) until modified, terminated, su-  
20          perseded, set aside, or revoked in accord-  
21          ance with applicable law by the President,  
22          the Administrator or other authorized offi-  
23          cial, or a court of competent jurisdiction,  
24          or by operation of law, each order, deter-  
25          mination, rule, regulation, permit, agree-

1           ment, grant, contract, certificate, license,  
2           registration, privilege, and other adminis-  
3           trative action shall continue in force and  
4           effect if the action—

5                   “(I) has been issued, made,  
6                   granted, or allowed to become effec-  
7                   tive by the President or any Federal  
8                   agency or official, or by a court of  
9                   competent jurisdiction, in the per-  
10                  formance of functions that are trans-  
11                  ferred under this subparagraph; and

12                   “(II) was in effect before the  
13                   date of enactment of this subpara-  
14                   graph, or was final before that date  
15                   and is scheduled to become effective  
16                   on or after the effective date of this  
17                   subparagraph;

18                   “(v)(I) this subparagraph shall not af-  
19                   fect any proceeding, including notices of  
20                   proposed rulemaking, or any application  
21                   for any license, permit, certificate, or fi-  
22                   nancial assistance pending before the Sec-  
23                   retary on the date of enactment of this  
24                   subparagraph with respect to any function  
25                   transferred by this subparagraph; and

1 “(II)(aa) a proceeding or application  
2 described in subclause (I) shall be contin-  
3 ued, orders shall be issued in such a pro-  
4 ceeding and appeals taken from the orders,  
5 and payments shall be made pursuant to  
6 such an order, as if this subparagraph had  
7 not been enacted; and

8 “(bb) orders issued in such a pro-  
9 ceeding shall continue in effect until modi-  
10 fied, terminated, superseded, set aside, or  
11 revoked by a duly authorized official, a  
12 court of competent jurisdiction, or oper-  
13 ation of law;

14 “(vi) nothing in this subparagraph  
15 prohibits the discontinuance or modifica-  
16 tion of any proceeding described in clause  
17 (v) under the same terms and conditions  
18 and to the same extent that the proceeding  
19 could have been discontinued or modified if  
20 this subparagraph had not been enacted;

21 “(vii) this subparagraph shall not af-  
22 fect any civil action commenced before the  
23 date of enactment of this subparagraph,  
24 and proceedings shall be had, appeals  
25 taken, and judgments rendered regarding

1 such a civil action in the same manner and  
2 with the same effect as if this subpara-  
3 graph had not been enacted;

4 “(viii) no civil action or other pro-  
5 ceeding commenced by or against the Sec-  
6 retary, or by or against any individual in  
7 the official capacity of the individual as an  
8 officer of the Secretary, shall abate by rea-  
9 son of the enactment of this subparagraph;

10 “(ix) any administrative action relat-  
11 ing to the preparation or promulgation of  
12 a regulation by the Secretary relating to a  
13 function transferred under this subpara-  
14 graph may be continued by the Adminis-  
15 trator of the Environmental Protection  
16 Agency with the same effect as if this sub-  
17 paragraph had not been enacted; and

18 “(x) a reference in any other Federal  
19 law, Executive order, rule, regulation, or  
20 delegation of authority, or any document of  
21 or relating to—

22 “(I) the Secretary, with regard to  
23 a function transferred under this sub-  
24 paragraph, shall be considered to be a  
25 reference to the Administrator; and



1 “(II) the Department of Health  
 2 and Human Services, with regard to  
 3 functions transferred under this sub-  
 4 paragraph, shall be considered to be a  
 5 reference to the Environmental Pro-  
 6 tection Agency.”; and

7 (2) by adding at the end the following:

8 “(c) CONSUMER CONFIDENCE REPORTS.—

9 “(1) IN GENERAL.—Not later than 18 months  
 10 after the date of enactment of this subsection, the  
 11 Secretary shall promulgate regulations that require  
 12 each manufacturer of bottled water to submit re-  
 13 ports and display information as required under  
 14 paragraph (2).

15 “(2) REQUIREMENTS.—The regulations promul-  
 16 gated under paragraph (1) shall require that each  
 17 manufacturer of bottled water shall—

18 “(A) not later than 3 years after the date  
 19 of enactment of this subsection and annually  
 20 thereafter, prepare and submit in electronic  
 21 form, on a form provided by the Secretary, an  
 22 annual report to the Secretary that describes,  
 23 at a minimum—

24 “(i) the source of the water purveyed;

1 “(ii) the type of treatment to which  
2 the water has been subjected and whether  
3 such treatment meets the criteria of the  
4 Secretary for full protection of  
5 immunocompromised individuals from  
6 cryptosporidium and other microbial patho-  
7 gens;

8 “(iii) the quantity and range of any  
9 regulated contaminant detected in the  
10 water during the reporting year, the max-  
11 imum contaminant level goal for the con-  
12 taminant, if any, and whether the goal was  
13 exceeded during the reporting year; and

14 “(iv) the quantity and range of any  
15 unregulated contaminant detected in the  
16 water during the reporting year that is  
17 subject to unregulated contaminant moni-  
18 toring or notification requirements under  
19 sections 1445 or 1414, respectively, of the  
20 Safe Drinking Water Act (42 U.S.C. 300j-  
21 4; 300g-3), or that the Secretary deter-  
22 mines may present a threat to public  
23 health; and

1 “(B) for the second and each subsequent  
2 reporting year, display on the labels of the bot-  
3 tled water—

4 “(i) if the maximum contaminant level  
5 goal or lowest health advisory level under  
6 the Safe Drinking Water Act (whichever is  
7 lower) for a regulated contaminant is ex-  
8 ceeded during the preceding reporting  
9 year—

10 “(I) the quantity and range of  
11 the regulated contaminant in the bot-  
12 tled water;

13 “(II) the maximum contaminant  
14 level goal for the contaminant; and

15 “(III) a plain definition of the  
16 term ‘maximum contaminant level  
17 goal’ as determined by the Adminis-  
18 trator;

19 “(ii) the quantity and range of any  
20 unregulated contaminant detected in the  
21 water during the preceding reporting year  
22 that is subject to unregulated contaminant  
23 monitoring or notification requirements  
24 under sections 1445 or 1414, respectively,  
25 of the Safe Drinking Water Act (42 U.S.C.

1                   300j–4; 300g–3) or that the Secretary has  
2                   determined may present a threat to public  
3                   health;

4                   “(iii) the source of the water;

5                   “(iv) the type of treatment, if any, to  
6                   which the water has been subjected and  
7                   whether such treatment meets the criteria  
8                   of the Secretary for full protection of  
9                   immunocompromised individuals for  
10                  cryptosporidium and other microbial patho-  
11                  gens;

12                  “(v) the address for the Internet  
13                  website described in paragraph (3)(A); and

14                  “(vi) the toll-free telephone number  
15                  described in paragraph (3)(B).

16                  “(3) PUBLIC AVAILABILITY.—Not later than  
17                  180 days after the date on which an annual report  
18                  referred to in paragraph (2) is submitted to the Sec-  
19                  retary, the Secretary shall make the report available  
20                  to the public—

21                  “(A) on an Internet website maintained by  
22                  the Secretary; and

23                  “(B) in paper form, in English, Spanish,  
24                  and in any other language determined to be ap-  
25                  propriate by the Secretary, upon request made

1 through use of a toll-free telephone number  
2 maintained by the Secretary.

3 “(4) SUPPLEMENT.—

4 “(A) IN GENERAL.—In addition to submit-  
5 ting an annual report under paragraph (2), the  
6 manufacturer may submit to the Secretary a  
7 supplement that contains additional information  
8 that the manufacturer determines to be appro-  
9 priate for public education.

10 “(B) PUBLIC AVAILABILITY.—The Sec-  
11 retary may make the supplement available to  
12 the public in the same manner as the annual  
13 report is made available to the public under  
14 paragraph (3).

15 “(5) ADDITIONAL INFORMATION.—In the same  
16 manner as the annual report is made available to the  
17 public under paragraph (3), the Secretary shall  
18 make the following information available to the pub-  
19 lic:

20 “(A) The definitions of the terms ‘max-  
21 imum contaminant level goal’ and ‘maximum  
22 contaminant level’.

23 “(B) For any regulated contaminant de-  
24 scribed in paragraph (2)(A), a statement set-  
25 ting forth—

1 “(i) the maximum contaminant level  
2 goal;

3 “(ii) the maximum contaminant level;  
4 and

5 “(iii) if a violation of the maximum  
6 contaminant level has occurred during the  
7 reporting year, the potential health con-  
8 cerns associated with such a violation.

9 “(C) For any unregulated contaminant de-  
10 scribed in paragraph (2)(A), a statement de-  
11 scribing the health advisory or explaining the  
12 reasons for determination by the Secretary that  
13 the contaminant may present a threat to public  
14 health.

15 “(D) A statement explaining that the pres-  
16 ence of contaminants in bottled drinking water  
17 does not necessarily create a health risk.

18 “(E) The date of the last Federal and  
19 State inspections of the bottled water facilities  
20 relating to the safety of the water.

21 “(F) A statement describing any violations  
22 discovered at the facilities during the inspec-  
23 tions described in subparagraph (E) and any  
24 enforcement actions that were taken as a con-  
25 sequence of the violations.

1                   “(G) The date of recall of any bottled  
2                   water and the reasons for the recall.

3           “(d) RECORDS, REPORTS, AND MONITORING.—Every  
4 manufacturer of bottled water who is subject to any re-  
5 quirement of this section shall maintain such records,  
6 make such reports, conduct such monitoring, and provide  
7 such information as the Secretary may reasonably require  
8 by regulation in order to assist the Secretary in promul-  
9 gating regulations under this section, in determining  
10 whether the manufacturer has acted or is acting in compli-  
11 ance with this section, in evaluating the health risks of  
12 unregulated contaminants, or in advising the public of  
13 those risks.

14           “(e) INFORMATION ON VIOLATIONS.—

15                   “(1) IN GENERAL.—Not later than 1 year after  
16 the date of enactment of this subsection, and annu-  
17 ally thereafter, the Secretary shall make available to  
18 the public, in the same manner as the annual report  
19 is made available under subsection (c)(3), informa-  
20 tion regarding violations of bottled water regulations  
21 relating to inspections, and any enforcement actions  
22 taken in regards to such violations.

23                   “(2) GRANT PROGRAM.—The Secretary shall es-  
24 tablish and administer a grant program to fund the  
25 gathering of information described in paragraph (1).

1 “(f) DEFINITIONS.—In this section:

2 “(1) BOTTLED WATER.—The term ‘bottled  
3 water’ means all water sold in the United States  
4 that—

5 “(A) is intended for human consumption;

6 “(B) is sealed in bottles or other con-  
7 tainers; and

8 “(C) may be still or carbonated, but has no  
9 sweeteners or juices added to the water, except  
10 for trace levels of flavorings.

11 “(2) CONTAMINANT.—The term ‘contaminant’  
12 means any physical, chemical, biological, or radio-  
13 logical substance or matter in water.

14 “(3) MAXIMUM CONTAMINANT LEVEL.—The  
15 term ‘maximum contaminant level’ has the meaning  
16 given the term in section 1401 of the Safe Drinking  
17 Water Act (42 U.S.C. 300f).

18 “(4) MAXIMUM CONTAMINANT LEVEL GOAL.—  
19 The term ‘maximum contaminant level goal’ means  
20 a goal established by the Administrator of the Envi-  
21 ronmental Protection Agency under section 1412 of  
22 the Safe Drinking Water Act (42 U.S.C. 300g–1).

23 “(5) REGULATED CONTAMINANT.—The term  
24 ‘regulated contaminant’ means a contaminant that is



1 regulated under section 1412 of the Safe Drinking  
2 Water Act (42 U.S.C. 300g-1).

3 “(6) UNREGULATED CONTAMINANT.—The term  
4 ‘unregulated contaminant’ means a contaminant  
5 that is not regulated under section 1412 of the Safe  
6 Drinking Water Act (42 U.S.C. 300g-1).”.

7 **SEC. 3. PROHIBITED ACTS.**

8 Section 301 of the Federal Food, Drug, and Cosmetic  
9 Act (21 U.S.C. 331) is amended by adding at the end the  
10 following:

11 “(uu) The failure by a manufacturer of bottled water  
12 to submit an annual report or display the required infor-  
13 mation on labels of bottled water in accordance with sec-  
14 tion 410(c).”.

○