

110TH CONGRESS
2D SESSION

S. 3475

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

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 11, 2008

Mr. LAUTENBERG (for himself and Mrs. BOXER) introduced the following bill; which was read twice and referred to the Committee on Environment and Public Works

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 2008”.

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—

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

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

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

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

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

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

22 “(ii) the Secretary has established a
23 standard of quality regulation that may be
24 less protective of public health than the
25 standard for the contaminant issued by the

1 World Health Organization, the European
2 Union, or the State of California;

3 “(B) not later than 1 year after the date
4 of enactment of this paragraph, propose an in-
5 terim standard of quality regulation for each
6 contaminant identified under subparagraph (A)
7 that contains a standard or monitoring require-
8 ment that is at least as protective of public
9 health as the more protective of—

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

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

16 “(C) not later than 2 years after the date
17 of enactment of this paragraph, issue a final
18 regulation establishing the standard described
19 in subparagraph (B) for each contaminant iden-
20 tified under subparagraph (A).

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

24 “(7) FINAL REGULATIONS.—

1 “(A) DEFINITION OF FEDERAL AGENCY.—

2 In this paragraph, the term ‘Federal agency’
3 has the meaning given the term ‘agency’ by sec-
4 tion 551(1) of title 5, United States Code.

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

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

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

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

1 sidered to be a reference to the Adminis-
2 trator of the Environmental Protection
3 Agency;

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

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

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

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

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

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

1 subparagraph with respect to any function
2 transferred by this subparagraph; and

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

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

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

23 “(vii) this subparagraph shall not af-
24 fect any civil action commenced before the
25 date of enactment of this subparagraph,

1 and proceedings shall be had, appeals
2 taken, and judgments rendered regarding
3 such a civil action in the same manner and
4 with the same effect as if this subpara-
5 graph had not been enacted;

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

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

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

24 “(I) the Secretary, with regard to
25 a function transferred under this sub-

1 paragraph, shall be considered to be a
2 reference to the Administrator; and

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

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

10 “(c) CONSUMER CONFIDENCE REPORTS.—

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

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

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

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

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

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

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

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