

106TH CONGRESS  
1ST SESSION

# S. 790

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

APRIL 13, 1999

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 1999”.

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) The Secretary shall—

2 “(A) not later than 6 months after the date of  
3 enactment of this paragraph identify contaminants  
4 for which—

5 “(i) the Administrator has established a  
6 national primary drinking water regulation  
7 under section 1412 of the Safe Drinking Water  
8 Act (42 U.S.C. 300g–1) and the Secretary has  
9 not established a standard of quality regulation  
10 for such contaminant or has established a  
11 standard of quality regulation or monitoring re-  
12 quirement that may be less protective of public  
13 health than the national primary drinking water  
14 regulation; or

15 “(ii) the Secretary has established a stand-  
16 ard of quality regulation for such contaminant  
17 that may be less protective of public health  
18 than the standard for such a contaminant  
19 issued by the World Health Organization, the  
20 European Union, or the State of California; and

21 “(B) not later than 12 months after that date  
22 of enactment, propose an interim standard of quality  
23 regulation, for each contaminant identified under  
24 subparagraph (A), that contains a standard or moni-

1       toring requirement that is at least as protective of  
2       public health as the more protective of—

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

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

8               “(C) not later than 24 months after that date  
9       of enactment, issue a final regulation of the stand-  
10      ard described in subparagraph (B), for each identi-  
11      fied contaminant.

12      “(6) The Secretary is authorized to award grants to  
13      the States for the enforcement of the regulations described  
14      in paragraph (5).

15      “(7)(A) Not later than 24 months after the date of  
16      enactment of this paragraph, the Secretary shall publish  
17      final regulations as described in paragraph (5) in the Fed-  
18      eral Register.

19      “(B) If the Secretary fails to publish the regulations  
20      described in subparagraph (A), then—

21              “(i) all functions that the Secretary of Health  
22      and Human Services exercised before the effective  
23      date of this subparagraph (including all related  
24      functions of any officer or employee of the Depart-  
25      ment of Health and Human Services) relating to in-

1       specions and enforcement concerning bottled water  
2       shall be transferred to the Environmental Protection  
3       Agency;

4           “(ii) all references to the Secretary in para-  
5       graph (5), notwithstanding the references in clause  
6       (i) and (ii) of subparagraph (A), and all references  
7       in paragraph (6) and subsections (c), (d), and (e)  
8       shall instead be to the Administrator;

9           “(iii) except as otherwise provided in this sub-  
10      paragraph, the assets, liabilities, grants, contracts,  
11      property, records, and unexpended balances of ap-  
12      propriations, authorizations, allocations, and other  
13      funds employed, used, held, arising from, available  
14      to, or to be made available in connection with the  
15      functions transferred under clause (i), subject to sec-  
16      tion 1531 of title 31, United States Code, shall be  
17      transferred to the Environmental Protection Agency,  
18      and unexpended funds transferred pursuant to this  
19      subparagraph shall be used only for the purposes for  
20      which the funds were originally authorized and ap-  
21      propriated;

22           “(iv) all orders, determinations, rules, regula-  
23      tions, permits, agreements, grants, contracts, certifi-  
24      cates, licenses, registrations, privileges, and other  
25      administrative actions—

1           “(I) that have been issued, made, granted,  
2           or allowed to become effective by the President,  
3           any Federal agency or official of a Federal  
4           agency, or by a court of competent jurisdiction,  
5           in the performance of functions that are trans-  
6           ferred under this subparagraph; and

7           “(II) that were in effect before the effec-  
8           tive date of this subparagraph, or were final be-  
9           fore the effective date of this subparagraph and  
10          are to become effective on or after the effective  
11          date of this subparagraph;

12          shall continue in effect according to their terms until  
13          modified, terminated, superseded, set aside, or re-  
14          voked in accordance with law by the President, the  
15          Administrator or other authorized official, a court of  
16          competent jurisdiction, or by operation of law;

17          “(v) this subparagraph shall not affect any pro-  
18          ceedings, including notices of proposed rulemaking,  
19          or any application for any license, permit, certificate,  
20          or financial assistance pending before the Secretary  
21          on the effective date of this subparagraph, with re-  
22          spect to functions transferred by this subparagraph;

23          “(vi) such proceedings and applications de-  
24          scribed in clause (v) shall be continued and orders  
25          shall be issued in such proceedings and appeals

1 taken from the orders, and payments shall be made  
2 pursuant to the orders, as if this subparagraph had  
3 not been enacted, and orders issued in any such pro-  
4 ceedings shall continue in effect until modified, ter-  
5 minated, superseded, set aside, or revoked by a duly  
6 authorized official, by a court of competent jurisdic-  
7 tion, or by operation of law;

8 “(vii) nothing in this subparagraph shall be  
9 construed to prohibit the discontinuance or modifica-  
10 tion of any such proceeding described in clause (v)  
11 under the same terms and conditions and to the  
12 same extent that such proceeding could have been  
13 discontinued or modified if this subparagraph had  
14 not been enacted;

15 “(viii) this subparagraph shall not affect suits  
16 commenced before the effective date of this subpara-  
17 graph, and in all such suits, proceedings shall be  
18 had, appeals taken, and judgments rendered in the  
19 same manner and with the same effect as if this  
20 subparagraph had not been enacted;

21 “(ix) no suit, action, or other proceeding com-  
22 menced by or against the Secretary, or by or against  
23 any individual in the official capacity of such indi-  
24 vidual as an officer of the Secretary, shall abate by  
25 reason of the enactment of this subparagraph;

1           “(x) any administrative action relating to the  
 2           preparation or promulgation of a regulation by the  
 3           Secretary relating to a function transferred under  
 4           this subparagraph may be continued by the Adminis-  
 5           trator with the same effect as if this subparagraph  
 6           had not been enacted; and

7           “(xi) a reference in any other Federal law, Ex-  
 8           ecutive order, rule, regulation, or delegation of au-  
 9           thority, or any document of or relating to—

10           “(I) the Secretary with regard to functions  
 11           transferred under this subparagraph, shall be  
 12           deemed to refer to the Administrator; and

13           “(II) the Department of Health and  
 14           Human Services with regard to functions trans-  
 15           ferred under this subparagraph, shall be  
 16           deemed to refer to the Environmental Protec-  
 17           tion Agency.

18           “(C) As used in subparagraph (B), the term ‘Federal  
 19           agency’ has the meaning given the term ‘agency’ by sec-  
 20           tion 551(1) of title 5, United States Code.”; and

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

22           “(c)(1) Not later than 18 months after the date of  
 23           enactment of this subsection, the Secretary shall issue reg-  
 24           ulations that require each manufacturer of bottled water

1 to submit reports and display information as required  
2 under paragraph (2).

3 “(2) The regulations issued under paragraph (1)  
4 shall require that each manufacturer of bottled water  
5 shall—

6 “(A) not later than 36 months after the date of  
7 enactment of this subsection and annually there-  
8 after, prepare and submit in electronic form, on a  
9 form provided by the Secretary, an annual report to  
10 the Secretary that describes, at a minimum—

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

12 “(ii) the type of treatment to which the  
13 water has been subjected and whether such  
14 treatment meets the Secretary’s criteria for full  
15 protection of immuno-compromised individuals  
16 from cryptosporidium and other microbial  
17 pathogens;

18 “(iii) the amount and range of any regu-  
19 lated contaminant detected in the water during  
20 the reporting year, the maximum contaminant  
21 level goal for the contaminant, if any, and  
22 whether the goal was exceeded during the re-  
23 porting year; and

24 “(iv) the amount and range of any unregu-  
25 lated contaminant detected in the water during



1 the reporting year that is subject to unregu-  
 2 lated contaminant monitoring or notification re-  
 3 quirements under sections 1445 or 1414, re-  
 4 spectively, of the Safe Drinking Water Act (42  
 5 U.S.C. 300j-4; 300g-3), or that the Secretary  
 6 determines may present a threat to public  
 7 health; and

8 “(B) for the second and each subsequent re-  
 9 porting year, display on the labels of the bottled  
 10 water—

11 “(i) if the maximum contaminant level goal  
 12 or lowest health advisory level under the Safe  
 13 Drinking Water Act (whichever is lower) for a  
 14 regulated contaminant is exceeded during the  
 15 preceding reporting year—

16 “(I) the amount and range of the reg-  
 17 ulated contaminant in the bottled water;

18 “(II) the maximum contaminant level  
 19 goal for the contaminant; and

20 “(III) a plain definition of ‘maximum  
 21 contaminant level goal’ as determined by  
 22 the Administrator;

23 “(ii) the amount and range of any unregu-  
 24 lated contaminant detected in the water during  
 25 the preceding reporting year that is subject to

1 unregulated contaminant monitoring or notifi-  
2 cation requirements under sections 1445 or  
3 1414, respectively, of the Safe Drinking Water  
4 Act (42 U.S.C. 300j-4; 300g-3) or that the  
5 Secretary has determined may present a threat  
6 to public health;

7 “(iii) the source of the water;

8 “(iv) the type of treatment, if any, to  
9 which the water has been subjected and wheth-  
10 er such treatment meets the Secretary’s criteria  
11 for full protection of immuno-compromised indi-  
12 viduals for cryptosporidium and other microbial  
13 pathogens;

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

16 “(vi) the toll-free telephone number de-  
17 scribed in paragraph (3)(B).

18 “(3) Not later than 6 months after the date on which  
19 an annual report referred to in paragraph (2) is submitted  
20 to the Secretary, the Secretary shall make the report avail-  
21 able to the public—

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

24 “(B) in paper form, in English, Spanish, and in  
25 any other language determined to be appropriate by

1 the Secretary, upon request made through use of a  
2 toll-free telephone number maintained by the Sec-  
3 retary.

4 “(4) In addition to submitting an annual report  
5 under paragraph (2), the manufacturer may also submit  
6 a supplement to the Secretary that contains additional in-  
7 formation that the manufacturer determines to be appro-  
8 priate for public education. The Secretary may make the  
9 supplement available to the public in the same manner as  
10 the annual report is made available to the public under  
11 paragraph (3).

12 “(5) In the same manner as the annual report is  
13 made available to the public under paragraph (3), the Sec-  
14 retary shall make the following information available to  
15 the public:

16 “(A) The definitions of the terms ‘maximum  
17 contaminant level goal’ and ‘maximum contaminant  
18 level’.

19 “(B) For any regulated contaminant described  
20 in paragraph (2)(A), a statement setting forth—

21 “(i) the maximum contaminant level goal;

22 “(ii) the maximum contaminant level; and

23 “(iii) if a violation of the maximum con-  
24 taminant level has occurred during the report-

1           ing year, the potential health concerns associ-  
2           ated with such a violation.

3           “(C) For any unregulated contaminant de-  
4           scribed in paragraph (2)(A), a statement describing  
5           the health advisory or explaining the reasons for de-  
6           termination by the Secretary that the contaminant  
7           may present a threat to public health.

8           “(D) A statement explaining that the presence  
9           of contaminants in bottled drinking water does not  
10          necessarily create a health risk.

11          “(E) The date of the last Federal and State in-  
12          spections of the bottled water facilities relating to  
13          the safety of the water.

14          “(F) A statement describing any violations dis-  
15          covered at the facilities during the inspections de-  
16          scribed in subparagraph (E) and any enforcement  
17          actions that were taken as a consequence of the vio-  
18          lations.

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

21          “(d) Every manufacturer of bottled water who is sub-  
22          ject to any requirement of this section shall maintain such  
23          records, make such reports, conduct such monitoring, and  
24          provide such information as the Secretary may reasonably  
25          require by regulation in order to assist the Secretary in

1 establishing regulations under this section, in determining  
 2 whether the manufacturer has acted or is acting in compli-  
 3 ance with this section, in evaluating the health risks of  
 4 unregulated contaminants, or in advising the public of  
 5 such risks.

6 “(e) Not later than 12 months after the date of en-  
 7 actment of this subsection, and annually thereafter, the  
 8 Secretary shall make available to the public, in the same  
 9 manner as the annual report is made available under sub-  
 10 section (c)(3), information regarding violations of bottled  
 11 water regulations relating to inspections, and any enforce-  
 12 ment actions taken in regards to such violations. The Sec-  
 13 retary shall establish and administer a grant program to  
 14 fund the gathering of such information.

15 “(f) In this section:

16 “(1) The term ‘bottled water’ means all water  
 17 sold in the United States that—

18 “(A) is intended for human consumption;

19 “(B) is sealed in bottles or other con-  
 20 tainers; and

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

1           “(2) The term ‘contaminant’ means any phys-  
 2           ical, chemical, biological, or radiological substance or  
 3           matter in water.

4           “(3) The term ‘maximum contaminant level’  
 5           has the meaning given the term in section 1401 of  
 6           the Safe Drinking Water Act (42 U.S.C. 300f).

7           “(4) The term ‘maximum contaminant level  
 8           goal’ means a goal established by the Administrator  
 9           under section 1412 of the Safe Drinking Water Act  
 10          (42 U.S.C. 300g–1).

11          “(5) The term ‘regulated contaminant’ means a  
 12          contaminant that is regulated under section 1412 of  
 13          the Safe Drinking Water Act (42 U.S.C. 300g–1).

14          “(6) The term ‘unregulated contaminant’  
 15          means a contaminant that is not regulated under  
 16          section 1412 of the Safe Drinking Water Act (42  
 17          U.S.C. 300g–1).”.

18 **SEC. 3. PROHIBITED ACTS.**

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

22          “(aa) The failure by a manufacturer of bottled water  
 23          to submit an annual report or display the required infor-

1 mation on labels of bottled water in accordance with sec-  
2 tion 410(c).”.

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