

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4704

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling requirements regarding allergenic substances in food, and for other purposes.

---

## IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2002

Mrs. LOWEY (for herself, Mrs. JONES of Ohio, Ms. MCKINNEY, Mr. KILDEE, Mr. FRANK, Mr. KUCINICH, Mrs. MINK of Hawaii, Ms. RIVERS, Mr. OWENS, Mr. RANGEL, Mr. NADLER, Ms. LEE, Ms. VELÁZQUEZ, Mrs. MORELLA, and Mr. ISRAEL) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling requirements regarding allergenic substances in food, 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 “Food Allergen Con-  
5       sumer Protection Act”.

6       **SEC. 2. FINDINGS.**

7       The Congress finds as follows:

1           (1) Approximately 7,000,000 Americans suffer  
2 from food allergies. Every year roughly 30,000 peo-  
3 ple receive emergency room treatment due to the in-  
4 gestion of allergenic foods, and an estimated 150  
5 Americans die from anaphylactic shock caused by a  
6 food allergy.

7           (2) Eight major foods—milk, egg, fish,  
8 Crustacea, tree nuts, wheat, peanuts, and soy-  
9 beans—cause 90 percent of allergic reactions. At  
10 present, there is no cure for food allergies. A food  
11 allergic consumer depends on a product’s label to ob-  
12 tain accurate and reliable ingredient information so  
13 as to avoid food allergens.

14           (3) Current Food and Drug Administration reg-  
15 ulations exempt spices, flavorings, and certain color-  
16 ings and additives from ingredient labeling require-  
17 ments that would allow consumers to avoid those to  
18 which they are allergic. Such unlabeled food aller-  
19 gens may pose a serious health threat to those sus-  
20 ceptible to food allergies.

21           (4) A recent Food and Drug Administration  
22 study found that 25 percent of bakery products, ice  
23 creams, and candies that were inspected failed to list  
24 peanuts and eggs, which can cause potentially fatal

1 allergic reactions. The mislabeling of foods puts  
2 those with a food allergy at constant risk.

3 (5) In that study, the Food and Drug Adminis-  
4 tration found that only slightly more than half of in-  
5 spected manufacturers checked their products to en-  
6 sure that all ingredients were accurately reflected on  
7 the labels. Furthermore, the number of recalls be-  
8 cause of unlabeled allergens rose to 121 in 2000  
9 from about 35 a decade earlier. In part, mislabeling  
10 occurs because potentially fatal allergens are intro-  
11 duced into the manufacturing process when produc-  
12 tion lines and cooking utensils are shared or used to  
13 produce multiple products.

14 (6) Individuals who have food allergies may out-  
15 grow their allergy if they strictly avoid consuming  
16 the allergen. However, some scientists believe that  
17 because low levels of allergens are unintentionally  
18 present in foods, those with an allergy are unable to  
19 keep from being repeatedly exposed to the very foods  
20 they are allergic to. Good manufacturing practices  
21 can minimize the unintentional presence of food al-  
22 lergens. In addition, when good manufacturing prac-  
23 tices cannot eliminate the potential for cross-con-  
24 tamination, an advisory label on the product can  
25 provide additional consumer protection.

1           (7) The Food and Drug Administration is the  
2           Nation’s principal consumer protection agency,  
3           charged with protecting and promoting public health  
4           through premarket and postmarket regulation of  
5           food. The agency must have both the necessary au-  
6           thority to ensure that foods are properly labeled and  
7           produced using good manufacturing practices and  
8           the ability to penalize manufacturers who violate our  
9           food safety laws.

10           (8) Americans deserve to have confidence in the  
11           safety and labeling of the food on their tables.

12 **SEC. 3. FOOD LABELING; REQUIREMENT OF INFORMATION**  
13 **REGARDING ALLERGENIC SUBSTANCES.**

14           (a) IN GENERAL.—Section 403 of the Federal Food,  
15           Drug, and Cosmetic Act (21 U.S.C. 343) is amended by  
16           adding at the end the following:

17           “(t)(1) If it is not a raw agricultural commodity and  
18           it is, or it intentionally bears or contains, a known food  
19           allergen, unless its label bears, in bold face type, the com-  
20           mon or usual name of the known food allergen and the  
21           common or usual name of the food source described in  
22           subparagraph (3)(A) from which the known food allergen  
23           is derived, except that the name of the food source is not  
24           required when the common or usual name of the known  
25           food allergen plainly identifies the food source.

1       “(2) The information required under this paragraph  
2 may appear in labeling other than the label only if the  
3 Secretary finds that such other labeling is sufficient to  
4 protect the public health. A finding by the Secretary under  
5 this subparagraph is effective upon publication in the Fed-  
6 eral Register as a notice (including any change in an ear-  
7 lier finding under this subparagraph).

8       “(3) For purposes of this Act, the term ‘known food  
9 allergen’ means any of the following:

10           “(A) Milk, egg, fish, Crustacea, tree nuts,  
11 wheat, peanuts, and soybeans.

12           “(B) A proteinaceous substance derived from a  
13 food specified in clause (A), unless the Secretary de-  
14 termines that the substance does not cause an aller-  
15 gic response that poses a risk to human health.

16           “(C) Other grains containing gluten (rye, bar-  
17 ley, oats, and triticale).

18           “(D) In addition, any food that the Secretary  
19 by regulation determines causes an allergic or other  
20 adverse response that poses a risk to human health.

21       “(4) Notwithstanding paragraph (g), (i), or (k), or  
22 any other law, the labeling requirement under this para-  
23 graph applies to spices, flavorings, colorings, or incidental  
24 additives that are, or that bear or contain, a known food  
25 allergen.

1       “(u) If it is a raw agricultural commodity that is,  
2 or bears or contains, a known food allergen, unless it has  
3 a label or other labeling that bears in bold face type the  
4 common or usual name of the known food allergen and  
5 the Secretary has found that the label or other labeling  
6 is sufficient to protect the public health. A finding by the  
7 Secretary under this paragraph is effective upon publica-  
8 tion in the Federal Register as a notice (including any  
9 change in an earlier finding under this paragraph).

10       “(w) If the labeling required under paragraphs (g),  
11 (i), (k), (t), (u), or (v)—

12               “(1) does not use a single, easy-to-read type  
13 style that is black on a white background, using  
14 upper and lower case letters and with no letters  
15 touching;

16               “(2) does not use at least 8 point type with at  
17 least one point leading (i.e., space between two lines  
18 of text), provided the total surface area of the food  
19 package available to bear labeling exceeds 12 square  
20 inches; or

21               “(3) does not comply with regulations issued by  
22 the Secretary to make it easy for consumers to read  
23 and use such labeling by requiring a format that is  
24 comparable to the format required for the disclosure  
25 of nutrition information in the food label under sec-

1       tion 101.9(d)(1) of title 21, Code of Federal Regula-  
2       tions.”.

3       (b) CIVIL PENALTIES.—Section 303(g)(2) of the  
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 333(g)(2)) is amended—

6           (1) in subparagraph (A), by striking “section  
7       402(a)(2)(B) shall be subject” and inserting the fol-  
8       lowing: “section 402(a)(2)(B) or regulations under  
9       this chapter to minimize the unintended presence of  
10      allergens in food, or that is misbranded within the  
11      meaning of section 403(t), 403(u), 403(v), or  
12      403(w), shall be subject”; and

13          (2) in subparagraph (B), by inserting “or mis-  
14      branded” after “adulterated” each place such term  
15      appears.

16      (c) CONFORMING AMENDMENT.—Section 201 of the  
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)  
18 is amended by adding at the end the following:

19          “(ll) The term ‘known food allergen’ has the meaning  
20      given such term in section 403(t)(3).”.

21      (d) EFFECTIVE DATE.—The amendments made by this  
22 section take effect upon the expiration of the 180-day pe-  
23 riod beginning on the date of the enactment of this Act.

1 **SEC. 4. UNINTENTIONAL PRESENCE OF KNOWN FOOD AL-**  
2 **LERGENS.**

3 (a) **FOOD LABELING OF SUCH FOOD ALLERGENS.—**  
4 Section 403 of the Federal Food, Drug, and Cosmetic Act,  
5 as amended by section 3(a) of this Act, is amended by  
6 inserting after paragraph (u) the following:

7 “(v) If the presence of a known food allergen in the  
8 food is unintentional and its labeling bears a statement  
9 that the food may bear or contain the known food allergen,  
10 or any similar statement, unless the statement is made  
11 in compliance with regulations issued by the Secretary to  
12 provide for advisory labeling of the known food allergen.”.

13 (b) **EFFECTIVE DATE.—**The amendment made by  
14 subsection (a) takes effect upon the expiration of the four-  
15 year period beginning on the date of the enactment of this  
16 Act, except with respect to the authority of the Secretary  
17 of Health and Human Services to engage in rulemaking  
18 in accordance with section 5.

19 **SEC. 5. REGULATIONS.**

20 (a) **IN GENERAL.—**

21 (1) **REGULATIONS.—**Not later than one year  
22 after the date of the enactment of this Act, the Sec-  
23 retary of Health and Human Services (in this sec-  
24 tion referred to as the “Secretary”) shall issue a  
25 proposed rule under sections 402, 403, and 701(a)  
26 of the Federal Food, Drug, and Cosmetic Act to im-



1       plement the amendments made by this Act. Not  
2       later than two years after such date of enactment,  
3       the Secretary shall promulgate a final rule under  
4       such sections.

5               (2) EFFECTIVE DATE.—The final rule promul-  
6       gated under paragraph (1) takes effect upon the ex-  
7       piration of the four-year period beginning on the  
8       date of the enactment of this Act. If a final rule  
9       under such paragraph has not been promulgated as  
10      of the expiration of such period, then upon such ex-  
11      piration the proposed rule under such paragraph  
12      takes effect as if the proposed rule were a final rule.

13      (b) UNINTENTIONAL PRESENCE OF KNOWN FOOD  
14 ALLERGENS.—

15              (1) GOOD MANUFACTURING PRACTICES;  
16      RECORDS.—Regulations under subsection (a) shall  
17      require the use of good manufacturing practices to  
18      minimize, to the extent practicable, the unintentional  
19      presence of allergens in food. Such regulations shall  
20      include appropriate record keeping and record in-  
21      spection requirements.

22              (2) ADVISORY LABELING.—In the regulations  
23      under subsection (a), the Secretary shall authorize  
24      the use of advisory labeling for a known food aller-  
25      gen when the Secretary has determined that good

1 manufacturing practices required under the regula-  
2 tions will not eliminate the unintentional presence of  
3 the known food allergen and its presence in the food  
4 poses a risk to human health, and the regulations  
5 shall otherwise prohibit the use of such labeling.

6 (c) **INGREDIENT LABELING GENERALLY.**—In regula-  
7 tions under subsection (a), the Secretary shall prescribe  
8 a format for labeling, as provided for under section  
9 403(w)(3) of the Federal, Food, Drug, and Cosmetic Act.

10 (d) **REVIEW BY OFFICE OF MANAGEMENT AND**  
11 **BUDGET.**—If the Office of Management and Budget (in  
12 this section referred to as “OMB”) is to review proposed  
13 or final rules under this Act, OMB shall complete its re-  
14 view in 10 working days, after which the rule shall be pub-  
15 lished immediately in the Federal Register. If OMB fails  
16 to complete its review of either the proposed rule or the  
17 final rule in 10 working days, the Secretary shall provide  
18 the rule to the Office of the Federal Register, which shall  
19 publish the rule, and it shall have full effect (subject to  
20 applicable effective dates specified in this Act) without re-  
21 view by OMB. If the Secretary does not complete the pro-  
22 posed or final rule so as to provide OMB with 10 working  
23 days to review the rule and have it published in the Fed-  
24 eral Register within the time frames for publication of the

1 rule specified in this section, the rule shall be published  
2 without review by OMB.

3 **SEC. 6. FOOD LABELING; INCLUSION OF TELEPHONE NUM-**  
4 **BER.**

5 (a) IN GENERAL.—Section 403(e) of the Federal  
6 Food, Drug, and Cosmetic Act (21 U.S.C. 343(e)) is  
7 amended—

8 (1) by striking “and (2)” and inserting the fol-  
9 lowing: “(2) in the case of a manufacturer, packer,  
10 or distributor whose annual gross sales made or  
11 business done in sales to consumers equals or ex-  
12 ceeds \$500,000, a toll-free telephone number  
13 (staffed during reasonable business hours) for the  
14 manufacturer, packer, or distributor (including one  
15 to accommodate telecommunications devices for deaf  
16 persons, commonly known as TDDs); or in the case  
17 of a manufacturer, packer, or distributor whose an-  
18 nual gross sales made or business done in sales are  
19 less than \$500,000, the mailing address or the ad-  
20 dress of the Internet site for the manufacturer,  
21 packer, or distributor; and (3)”; and

22 (2) by striking “clause (2)” and inserting  
23 “clause (3)”.

24 (b) EFFECTIVE DATE.—The amendments made by  
25 subsection (a) take effect upon the expiration of the 180-

1 day period beginning on the date of the enactment of this  
2 Act.

3 **SEC. 7. DATA ON FOOD-RELATED ALLERGIC RESPONSES.**

4 (a) IN GENERAL.—Consistent with the findings of  
5 the study conducted under subsection (b), the Secretary  
6 of Health and Human Services (in this section referred  
7 to as the “Secretary”), acting through the Director of the  
8 Centers for Disease Control and Prevention and in con-  
9 sultation with the Commissioner of Foods and Drugs,  
10 shall improve the collection of, and (beginning 18 months  
11 after the date of the enactment of this Act) annually pub-  
12 lish, national data on—

13 (1) the prevalence of food allergies, and

14 (2) the incidence of deaths, injuries, including  
15 anaphylactic shock, hospitalizations, and physician  
16 visits, and the utilization of drugs, associated with  
17 allergic responses to foods.

18 (b) STUDY.—Not later than one year after the date  
19 of the enactment of this Act, the Secretary, in consultation  
20 with consumers, providers, State governments, and other  
21 relevant parties, shall complete a study for the purposes  
22 of—

23 (1) determining whether existing systems for  
24 the reporting, collection and analysis of national

1 data accurately capture information on the subjects  
2 specified in subsection (a); and

3 (2) identifying new or alternative systems, or  
4 enhancements to existing systems, for the reporting  
5 collection and analysis of national data necessary to  
6 fulfill the purpose of subsection (a).

7 (c) PUBLIC AND PROVIDER EDUCATION.—The Sec-  
8 retary shall, directly or through contracts with public or  
9 private entities, educate physicians and other health pro-  
10 viders to improve the reporting, collection, and analysis  
11 of data on the subjects specified in subsection (a).

12 (d) CHILD FATALITY REVIEW TEAMS.—Insofar as is  
13 practicable, activities developed or expanded under this  
14 section shall include utilization of child fatality review  
15 teams in identifying and assessing child deaths associated  
16 with allergic responses to foods.

17 (e) REPORTS TO CONGRESS.—Not later than 18  
18 months after the date of the enactment of this Act, the  
19 Secretary shall submit to the Congress a report on the  
20 progress made with respect to subsections (a) through (d).

21 (f) AUTHORIZATION OF APPROPRIATIONS.—For the  
22 purpose of carrying out this section, there are authorized  
23 to be appropriated \$10,000,000 for fiscal year 2003, and  
24 such sums as may be necessary for each subsequent fiscal  
25 year.

1 (g) EFFECTIVE DATE.—This section takes effect on  
2 the date of the enactment of this Act.

3 **SEC. 8. FOOD ALLERGIES RESEARCH.**

4 (a) IN GENERAL.—The Secretary of Health and  
5 Human Services, through the National Institutes of  
6 Health, shall convene a panel of nationally recognized ex-  
7 perts to review current basic and clinical research efforts  
8 related to food allergies. The panel shall develop a plan,  
9 including recommendations for expenditures, for expand-  
10 ing, intensifying, and coordinating research activities con-  
11 cerning food allergies.

12 (b) REPORT TO CONGRESS.—Not later than 180 days  
13 after the date of the enactment of this Act, the Secretary  
14 of Health and Human Services shall submit a plan under  
15 subsection (a) to the Committee on Energy and Commerce  
16 in the House of Representatives and the Committee on  
17 Health, Education, Labor, and Pensions in the Senate.

18 (c) EFFECTIVE DATE.—This section takes effect on  
19 the date of the enactment of this Act.

20 **SEC. 9. CERTAIN FEDERAL RECOMMENDATIONS REGARD-**  
21 **ING AVOIDING AND RESPONDING TO FOOD-**  
22 **RELATED ALLERGIC RESPONSES.**

23 The Secretary of Health and Human Services shall  
24 carry out the following:

1           (1) Develop and appropriately disseminate rec-  
2           ommendations on—

3                   (A) training emergency medical technicians  
4                   with respect to administering epinephrine auto-  
5                   injector devices; and

6                   (B) the need for emergency vehicles to  
7                   maintain supplies of such devices.

8           (2) Activities to increase the awareness by the  
9           restaurant industry of public or private guidelines  
10           and recommendations for training in preparing aller-  
11           gen-free foods, including the Food Allergy and Ana-  
12           phylaxis Network and Food Allergy Initiative’s docu-  
13           ment entitled “Food Allergy Training Guide for Res-  
14           taurants and Good Services”.

15           (3) With respect to food prepared for students  
16           by elementary and secondary schools, develop and  
17           appropriately disseminate recommendations for the  
18           preparation of allergen-free foods, with priority given  
19           to the issue of life-threatening food allergies.

○