

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

# H. R. 5747

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

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 14, 2002

Mrs. LOWEY (for herself, Mr. WAXMAN, Mr. BROWN of Ohio, Ms. DELAURO, Mr. SMITH of Washington, Ms. LEE, Mr. HOLT, Mr. HINCHEY, Mr. DEFAZIO, Ms. ROYBAL-ALLARD, Mr. LANGEVIN, Ms. RIVERS, Mr. LEVIN, Ms. NORTON, Mr. PRICE of North Carolina, Mr. NADLER, Mr. FROST, Mr. PALLONE, Mr. ROTHMAN, Mr. RANGEL, and Mr. GEORGE MILLER of California) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 Label-  
5       ing and Consumer Protection Act”.

6       **SEC. 2. FINDINGS.**

7       Congress finds that—

1 (1) it is estimated that—

2 (A) approximately 2 percent of adults and  
3 about 5 percent of infants and young children  
4 in the United States suffer from food allergies;  
5 and

6 (B) each year, roughly 30,000 individuals  
7 require emergency room treatment and 150 in-  
8 dividuals die because of allergic reactions to  
9 food;

10 (2)(A) Eight major foods or food groups—milk,  
11 eggs, fish, Crustacean shellfish, tree nuts, peanuts,  
12 wheat, and soybeans—account for 90 percent of  
13 food allergies;

14 (B) at present, there is no cure for food aller-  
15 gies; and

16 (C) a food allergic consumer must avoid the  
17 food to which the consumer is allergic;

18 (3)(A) in a review of randomly selected manu-  
19 facturers of baked goods, ice cream, and candy in  
20 Minnesota and Wisconsin in 1999, the Food and  
21 Drug Administration found that 25 percent of sam-  
22 pled foods failed to list peanuts or eggs as ingredi-  
23 ents on the food labels; and

1 (B) nationally, the number of recalls because of  
2 unlabeled allergens rose to 121 in 2000 from about  
3 35 a decade earlier;

4 (4) a recent study shows that many parents of  
5 children with a food allergy were unable correctly to  
6 identify in each of several food labels the ingredients  
7 derived from major food allergens;

8 (5)(A) ingredients in foods must be listed by  
9 their “common or usual name”;

10 (B) in some cases, the common or usual name  
11 of an ingredient may be unfamiliar to consumers,  
12 and many consumers may not realize the ingredient  
13 is derived from, or contains, a major food allergen;  
14 and

15 (C) spices, flavorings, and certain colorings and  
16 incidental additives are exempt from ingredient la-  
17 beling requirements that would allow consumers to  
18 avoid those to which they are allergic; and

19 (6)(A) celiac disease is an immune-mediated  
20 disease that causes damage to the gastrointestinal  
21 tract, central nervous system, and other organs;

22 (B) the current recommended treatment is  
23 avoidance of glutens in foods that are associated  
24 with celiac disease; and

1 (C) a multicenter, multiyear study estimated  
2 that the prevalence of celiac disease in the United  
3 States is 0.5 to 1 percent of the general population.

4 **SEC. 3. FOOD LABELING; REQUIREMENT OF INFORMATION**  
5 **REGARDING ALLERGENIC SUBSTANCES.**

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

9 “(t)(1) If it is not a raw agricultural commodity and  
10 it is, or it intentionally bears or contains, a major food  
11 allergen, unless either—

12 “(A) ‘Contains’, which statement is followed by  
13 the name of the food source as described in section  
14 201(ll)(1) from which the major food allergen is de-  
15 rived, follows immediately after or is adjacent to (in  
16 a type size no smaller than the type size used in the  
17 list of ingredients) the list of ingredients required  
18 under subsections (g) and (i); or

19 “(B) the common or usual name of the major  
20 food allergen in the list of ingredients required  
21 under sections (g) and (i) is followed in parentheses  
22 by the name of the food source as described in sec-  
23 tion 201(ll)(1) from which the major food allergen is  
24 derived, except that the name of the food source is  
25 not required when—

1           “(i) the common or usual name of the in-  
2           gredient uses the term used to describe a major  
3           food allergen in section 201(ll)(1), or

4           “(ii) the name of the food source as de-  
5           scribed in section 201(ll)(1) appears elsewhere  
6           in the ingredient list; and

7           Provided all major food allergens are labeled in a  
8           consistent manner either as specified in clause (A)  
9           or as specified in clause (B).

10          “(2) The information required under this subsection  
11          may appear in labeling in lieu of appearing on the label  
12          only if the Secretary finds that such other labeling is suffi-  
13          cient to protect the public health. A finding by the Sec-  
14          retary under this subparagraph is effective upon publica-  
15          tion in the Federal Register as a notice (including any  
16          change in an earlier finding under this subparagraph).

17          “(3) Notwithstanding subsection (g), (i), or (k), or  
18          any other law, a spice, flavoring, coloring, or incidental  
19          additive that is, or that intentionally bears or contains,  
20          a major food allergen shall be subject to the labeling re-  
21          quirements of this subsection.

22          “(4) The Secretary may by regulation modify the re-  
23          quirements of subparagraph (A) or (B) of paragraph (1),  
24          or eliminate either the requirement of subparagraph (A)  
25          or the requirement of subparagraph (B), if the Secretary

1 determines that the modification or elimination of the re-  
2 quirement is necessary to protect the public health.

3 “(u) Notwithstanding subsection (g), (i), or (k), or  
4 any other law, a spice, flavoring, coloring, or incidental  
5 additive that is, or that intentionally bears or contains,  
6 a food allergen (other than a major food allergen), as de-  
7 termined by the Secretary by regulation, shall be disclosed  
8 in a manner specified by the Secretary by regulation.”.

9 (b) EFFECT ON OTHER AUTHORITY.—This section  
10 does not alter the authority of the Secretary of Health  
11 and Human Services under the Federal Food, Drug, and  
12 Cosmetic Act (21 U.S.C. 301 et seq.) to require the label-  
13 ing of other food allergens.

14 (c) CONFORMING AMENDMENTS.—

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

18 “(ll) The term ‘major food allergen’ means any of the  
19 following:

20 “(1) Milk, egg, fish (e.g. bass, flounder, or  
21 tuna), Crustacean shellfish (e.g. crab, lobster, or  
22 shrimp), tree nuts (e.g. almonds, pecans, or wal-  
23 nuts), wheat, peanuts, and soybeans.

24 “(2) A proteinaceous substance derived from a  
25 food specified in paragraph (1) (unless the Secretary

1 determines that the substance does not cause an al-  
2 lergic response that poses a risk to human health).”.

3 (2) Section 403A(a)(2) of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 343–1(a)(2)) is  
5 amended by striking “or 403(i)(2)” and inserting  
6 “403(i)(2), 403(t), or 403(u)”.

7 (d) EFFECTIVE DATE.—A food that is labeled on or  
8 after January 1, 2006, and that is, or that intentionally  
9 bears or contains, a major food allergen (as defined in the  
10 amendment made by subsection (c)) shall be labeled in  
11 compliance with the requirements of the amendment made  
12 by subsection (a).

13 **SEC. 4. REPORT ON FOOD ALLERGENS.**

14 Not later than June 30, 2004, the Secretary of  
15 Health and Human Services shall submit to the Com-  
16 mittee on Health, Education, Labor, and Pensions of the  
17 Senate and the Committee on Energy and Commerce of  
18 the House of Representatives a report that—

19 (1)(A) analyzes—

20 (i) the ways in which foods, during manu-  
21 facturing and processing, can be unintentionally  
22 contaminated with major food allergens, includ-  
23 ing contamination caused by the use by manu-  
24 facturers of the same production line to produce  
25 both products for which major food allergens

1 are intentional ingredients and products for  
2 which major food allergens are not intentional  
3 ingredients; and

4 (ii) the ways in which foods produced on  
5 dedicated production lines might nonetheless  
6 become unintentionally contaminated with  
7 major food allergens; and

8 (B) estimates how common those practices are  
9 in the food industry, with breakdowns by food type  
10 as appropriate;

11 (2) recommends good manufacturing practices  
12 or other methods that can be used to reduce or  
13 eliminate cross-contact of foods with the major food  
14 allergens;

15 (3) describes—

16 (A) the various types of advisory labeling  
17 (such as use of the words “may contain”) used  
18 by food producers;

19 (B) the conditions of manufacture of food  
20 that are associated with the various types of ad-  
21 visory labeling; and

22 (C) the extent to which advisory labels are  
23 being used on food products;

24 (4) determines how consumers with food aller-  
25 gies or the caretakers of consumers would prefer in-



1 formation about the risk of cross-contact be commu-  
2 nicated on food labels by using appropriate survey  
3 mechanisms; and

4 (5) identifies the circumstances, if any, under  
5 which advisory labeling could appropriately be used.

6 **SEC. 5. INSPECTIONS RELATING TO FOOD ALLERGENS.**

7 (a) IN GENERAL.—The Secretary of Health and  
8 Human Services shall give priority to increasing the num-  
9 ber of inspections under section 704 of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 374) of facilities in  
11 which foods are manufactured, processed, packed, or  
12 held—

13 (1) to ensure that the foods comply with prac-  
14 tices to reduce or eliminate cross-contact of a food  
15 with major food allergen residues that are not inten-  
16 tional ingredients of the food; and

17 (2) to ensure that major food allergens are  
18 properly labeled on foods.

19 (b) REPORTS.—On October 1, 2003, and biennially  
20 thereafter, the Secretary shall submit to the Committee  
21 on Health, Education, Labor, and Pensions of the Senate  
22 and the Committee on Energy and Commerce of the  
23 House of Representatives a report that—

24 (1) states the number of inspections conducted  
25 in the previous 2 years and the numbers of facilities

1 and food labels that were found to be in compliance  
2 or out of compliance;

3 (2) describes the nature of the violations found;

4 (3) includes the number of voluntary recalls,  
5 and their classifications, of foods with undeclared  
6 major food allergens;

7 (4) assesses the extent of use of advisory lan-  
8 guage found and the appropriateness of that use;  
9 and

10 (5) assesses the extent to which the Secretary  
11 and the food industry have effectively addressed  
12 cross-contact issues.

13 **SEC. 6. LABELING OF GLUTENS AND CELIAC DISEASE.**

14 (a) CONTRACT WITH INSTITUTE OF MEDICINE.—

15 The Secretary of Health and Human Services (in this sec-  
16 tion, the “Secretary”) shall enter into a contract with the  
17 Institute of Medicine for—

18 (1) the conduct of a review of the science relat-  
19 ing to—

20 (A) the glutens in food that are associated  
21 with celiac disease;

22 (B) the means of preventing and treating  
23 celiac disease; and

24 (C) the methodologies for detecting such  
25 glutens in foods; and

1           (2) the submission to the Secretary, the Com-  
2       mittee on Health, Education, Labor, and Pensions  
3       of the Senate and the Committee on Energy and  
4       Commerce of the House of Representatives, not later  
5       than 2 years after the date of enactment of this Act,  
6       of a report concerning the review conducted under  
7       paragraph (1).

8       (b) REQUIREMENTS OF EXPERTISE.—The Institute  
9       of Medicine shall conduct the review under subsection  
10      (a)(1) and make the report under subsection (a)(2) in con-  
11     junction with experts in celiac disease, including experts  
12     in the pathogenesis, epidemiology, and biochemistry of ce-  
13     liac disease, the sensitivity to, and tolerance of, the glutens  
14     in food that are associated with celiac disease, and the  
15     clinical aspects of celiac disease, including prevention and  
16     treatment.

17      (c) GLUTEN LABELING.—Considering the review con-  
18     ducted under paragraph (a)(1), the Secretary shall, not  
19     later than 4 years after the date of enactment of this Act,  
20     issue a proposed rule to define, and permit use of, the  
21     term “gluten-free” on the labeling of foods. Not later than  
22     6 years after the date of enactment of this Act, the Sec-  
23     retary shall issue a final rule to define, and permit use  
24     of, the term “gluten-free” on the labeling of foods.

1 (d) REPORT.—Not later than 2 years after submis-  
2 sion to the Secretary of the report under subsection (a)(2),  
3 the Secretary shall submit to the Committee on Health,  
4 Education, Labor, and Pensions of the Senate and the  
5 Committee on Energy and Commerce of the House of  
6 Representatives a report that assesses whether additional  
7 requirements for the labeling of gluten are warranted and  
8 necessary to better inform individuals with celiac disease,  
9 and if other labeling is warranted and necessary, identifies  
10 the types of such labeling.

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

12 (a) STUDY.—Not later than one year after the date  
13 of the enactment of this Act, the Secretary of Health and  
14 Human Services (in this section referred to as the  
15 “Secretary”), in consultation with consumers, providers,  
16 State governments, and other relevant parties, shall com-  
17 plete a study for the purposes of—

18 (1) determining whether existing systems for  
19 the reporting, collection and analysis of national  
20 data accurately capture information on—

21 (A) the prevalence of food allergies;

22 (B) the incidence of clinically significant or  
23 serious adverse events related to food allergies;

24 and

1 (C) the use of different modes of treatment  
2 for and prevention of allergic responses to  
3 foods; and

4 (2) identifying new or alternative systems or en-  
5 hancements to existing systems (including by edu-  
6 cating physicians and other health care providers),  
7 for the reporting collection and analysis of national  
8 data on—

9 (A) the prevalence of food allergies;

10 (B) the incidence of clinically significant or  
11 serious adverse events related to food allergies;  
12 and

13 (C) the use of different modes of treatment  
14 for and prevention of allergic responses to  
15 foods.

16 (b) IMPROVEMENT AND PUBLICATION OF DATA.—On  
17 completion of, and consistent with the findings of, the  
18 study conducted under subsection (a), the Secretary, act-  
19 ing through the Director of the Centers for Disease Con-  
20 trol and Prevention and in consultation with the Commis-  
21 sioner of Foods and Drugs, shall improve the collection  
22 of, and publish as it becomes available, national data on—

23 (1) the prevalence of food allergies;

24 (2) the incidence of clinically significant or seri-  
25 ous adverse events related to food allergies; and

1           (3) the use of different modes of treatment for  
2           and prevention of allergic responses to foods.

3           (c) REPORT TO CONGRESS.—Not later than 30  
4 months after the date of the enactment of this Act, the  
5 Secretary shall submit to the Congress a report on the  
6 progress made with respect to subsections (a) and (b).

7           (d) AUTHORIZATION OF APPROPRIATIONS.—For the  
8 purpose of carrying out this section, there are authorized  
9 to be appropriated such sums as may be necessary.

10 **SEC. 8. FOOD ALLERGIES RESEARCH.**

11           (a) IN GENERAL.—The Secretary of Health and  
12 Human Services, through the National Institutes of  
13 Health, shall convene a panel of nationally recognized ex-  
14 perts to review current basic and clinical research efforts  
15 related to food allergies. The panel shall develop a plan  
16 for expanding, intensifying, and coordinating research ac-  
17 tivities concerning food allergies.

18           (b) REPORT TO CONGRESS.—Not later than 1 year  
19 after the date of enactment of this Act, the Secretary of  
20 Health and Human Services shall submit a plan under  
21 subsection (a) to the Committee on Energy and Commerce  
22 in the House of Representatives and the Committee on  
23 Health, Education, Labor, and Pensions in the Senate.

1 **SEC. 9. FOOD ALLERGENS IN THE FOOD CODE.**

2       The Secretary of Health and Human Services shall,  
3 in the Conference for Food Protection, as part of its coop-  
4 erative activities between the States under section 311 of  
5 the Public Health Service Act (42 U.S.C. 243), pursue  
6 revision of the Food Code to provide guidelines for pre-  
7 paring allergen-free foods in food establishments, includ-  
8 ing in restaurants, grocery store delicatessens and bak-  
9 eries, and elementary and secondary school cafeterias. The  
10 Secretary shall consider public and private guidelines and  
11 recommendations for preparing allergen-free foods in pur-  
12 suing this revision.

13 **SEC. 10. RECOMMENDATIONS REGARDING RESPONDING TO**  
14 **FOOD-RELATED ALLERGIC RESPONSES.**

15       The Secretary of Health and Human Services shall,  
16 in providing technical assistance relating to trauma care  
17 and emergency medical services to State and local agencies  
18 under section 1202(b)(3) of the Public Health Service Act  
19 (42 U.S.C. 300d–2(b)(3)), include technical assistance re-  
20 lating to the use of different modes of treatment for and  
21 prevention of allergic responses to foods.

○