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S. 3001

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

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 25, 2002

Mr. KENNEDY (for himself, Mr. GREGG, Mrs. CLINTON, Mr. ROBERTS, Mr. DODD, Mr. FRIST, Mr. JEFFORDS, Ms. COLLINS, and Mr. TORRICELLI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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—

8 (1) it is estimated that—

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

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

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

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

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

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

23 (B) nationally, the number of recalls because of
24 unlabeled allergens rose to 121 in 2000 from about
25 35 a decade earlier;

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

5 (5)(A) current regulations of the Food and
6 Drug Administration require that ingredients in
7 foods be listed by their “common or usual name”;

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

13 (C) current regulations of the Food and Drug
14 Administration exempt spices, flavorings, and cer-
15 tain colorings and additives from ingredient labeling
16 requirements that would allow consumers to avoid
17 those to which they are allergic; and

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

21 (B) the current recommended treatment is
22 avoidance of glutens in foods that are associated
23 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 is 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) has appeared pre-
6 viously in the ingredient list; and

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

10 “(2) The information required under this subsection
11 may appear in labeling other than the label only if the
12 Secretary finds that such other labeling is sufficient to
13 protect the public health. A finding by the Secretary under
14 this subparagraph is effective upon publication in the Fed-
15 eral Register as a notice (including any change in an ear-
16 lier 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 AMENDMENT.—Section 201 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)
16 is amended by adding at the end the following:

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

19 “(1) Milk, egg, fish, Crustacean shellfish, tree
20 nuts, wheat, peanuts, and soybeans.

21 “(2) A proteinaceous substance derived from a
22 food specified in paragraph (1) (unless the Secretary
23 determines that the substance does not cause an al-
24 lergic response that poses a risk to human health).”.

1 (d) EFFECTIVE DATE.—A food that is labeled on or
2 after January 1, 2006, and that is, or that intentionally
3 bears or contains, a major food allergen (as defined in the
4 amendment made by subsection (c)) shall be labeled in
5 compliance with the requirements of the amendment made
6 by subsection (a).

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

8 Not later than June 30, 2004, the Secretary of
9 Health and Human Services shall submit to the Com-
10 mittee on Health, Education, Labor, and Pensions of the
11 Senate and the Committee on Energy and Commerce of
12 the House of Representatives a report that—

13 (1)(A) analyzes—

14 (i) the ways in which foods, during manu-
15 facturing and processing, can be unintentionally
16 contaminated with major food allergens, includ-
17 ing contamination caused by the use by manu-
18 facturers of the same production line to produce
19 both products for which major food allergens
20 are intentional ingredients and products for
21 which major food allergens are not intentional
22 ingredients; and

23 (ii) the ways in which foods produced on
24 dedicated production lines might nonetheless

1 become unintentionally contaminated with
2 major food allergens; and

3 (B) estimates how common those practices are
4 in the food industry, with breakdowns by food type
5 as appropriate;

6 (2) recommends methods that can be used to
7 reduce or eliminate cross-contact of foods with the
8 major food allergens;

9 (3) describes—

10 (A) the various types of advisory labeling
11 (such as use of the words “may contain”) used
12 by food producers;

13 (B) the conditions of manufacture of food
14 that are associated with the various types of ad-
15 visory labeling; and

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

18 (4) determines how consumers with food aller-
19 gies or the caretakers of consumers would prefer in-
20 formation about the risk of cross-contact be commu-
21 nicated on food labels by using appropriate survey
22 mechanisms; and

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

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

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

8 (1) to ensure that the foods comply with prac-
9 tices to reduce or eliminate cross-contact of a food
10 with major food allergen residues that are not inten-
11 tional ingredients of the food; and

12 (2) to ensure that major food allergens are
13 properly labeled on foods.

14 (b) REPORT.—On October 1, 2003, and biennially
15 thereafter, the Secretary shall submit to the Committee
16 on Health, Education, Labor, and Pensions of the Senate
17 and the Committee on Energy and Commerce of the
18 House of Representatives a report that—

19 (1) states the number of inspections conducted
20 in the previous year and the numbers of facilities
21 and food labels that were found to be in compliance
22 or out of compliance;

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

24 (3) includes the number of voluntary recalls,
25 and their classifications, requested by the Secretary
26 of foods with undeclared major food allergens;

1 (4) assesses the extent of use of advisory lan-
2 guage found and the appropriateness of that use;
3 and

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

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

8 (a) CONTRACT WITH INSTITUTE OF MEDICINE.—

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

12 (1) the conduct of a review of the science relat-
13 ing to—

14 (A) the glutens in food that are associated
15 with celiac disease;

16 (B) the means of preventing and treating
17 celiac disease; and

18 (C) the methodologies for detecting such
19 glutens in foods; and

20 (2) the submission to the Secretary, the Com-
21 mittee on Health, Education, Labor, and Pensions
22 of the Senate and the Committee on Energy and
23 Commerce of the House of Representatives, not later
24 than 2 years after the date of enactment of this Act,

1 of a report concerning the review conducted under
2 paragraph (1).

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

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

20 (d) REPORT.—Not later than 2 years after submis-
21 sion to the Secretary of the report under subsection (a)(2),
22 the Secretary shall submit to the Committee on Health,
23 Education, Labor, and Pensions of the Senate and the
24 Committee on Energy and Commerce of the House of
25 Representatives a report that assesses whether additional

1 requirements for the labeling of gluten are warranted and
2 necessary to better inform individuals with celiac disease,
3 and if other labeling is warranted and necessary, identifies
4 the types of such labeling.

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

6 (a) STUDY.—Not later than one year after the date
7 of the enactment of this Act, the Secretary of Health and
8 Human Services (in this section referred to as the “Sec-
9 retary”), in consultation with consumers, providers, State
10 governments, and other relevant parties, shall complete a
11 study for the purposes of—

12 (1) determining whether existing systems for
13 the reporting, collection and analysis of national
14 data accurately capture information on—

15 (A) the prevalence of food allergies;

16 (B) the incidence of clinically significant or
17 serious adverse events related to food allergies;
18 and

19 (C) the use of different modes of treatment
20 for and prevention of allergic responses to
21 foods; and

22 (2) identifying new or alternative systems or en-
23 hancements to existing systems (including by edu-
24 cating physicians and other health care providers),

1 for the reporting collection and analysis of national
2 data on—

3 (A) the prevalence of food allergies;

4 (B) the incidence of clinically significant or
5 serious adverse events related to food allergies;
6 and

7 (C) the use of different modes of treatment
8 for and prevention of allergic responses to
9 foods.

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

17 (1) the prevalence of food allergies;

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

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

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

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

4 **SEC. 8. FOOD ALLERGIES RESEARCH.**

5 (a) IN GENERAL.—The Secretary of Health and
6 Human Services, through the National Institutes of
7 Health, shall convene a panel of nationally recognized ex-
8 perts to review current basic and clinical research efforts
9 related to food allergies. The panel shall develop a plan
10 for expanding, intensifying, and coordinating research ac-
11 tivities concerning food allergies.

12 (b) REPORT TO CONGRESS.—Not later than 1 year
13 after the date of enactment of this Act, the Secretary of
14 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 **SEC. 9. FOOD ALLERGENS IN THE FOOD CODE.**

19 The Secretary of Health and Human Services shall,
20 in the Conference for Food Protection, as part of its coop-
21 erative activities between the States under section 311 of
22 the Public Health Service Act (42 U.S.C. 243), pursue
23 revision of the Food Code to provide guidelines for pre-
24 paring allergen-free foods in food establishments, includ-
25 ing in restaurants, grocery store delicatessens and bak-

1 eries, and elementary and secondary school cafeterias. The
2 Secretary shall consider public and private guidelines and
3 recommendations for preparing allergen-free foods in pur-
4 suing this revision.

5 **SEC. 10. RECOMMENDATIONS REGARDING RESPONDING TO**
6 **FOOD-RELATED ALLERGIC RESPONSES.**

7 The Secretary of Health and Human Services shall,
8 in providing technical assistance relating to trauma care
9 and emergency medical services to State and local agencies
10 under section 1202(b)(3) of the Public Health Service Act
11 (42 U.S.C. 300d–2(b)(3)), include technical assistance re-
12 lating to the use of different modes of treatment for and
13 prevention of allergic responses to foods.

○