107TH CONGRESS
2D SESSION

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food Allergen Labeling and Consumer Protection Act''.

SEC. 2. FINDINGS.

Congress finds that—

(1) it is estimated that—

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

(B) each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food;

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

(B) at present, there is no cure for food allergies; and

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

(3)(A) in a review of randomly selected manufacturers of baked goods, ice cream, and candy in Minnesota and Wisconsin in 1999, the Food and Drug Administration found that 25 percent of sampled foods failed to list peanuts or eggs as ingredients on the food labels; and

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

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

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

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

(C) current regulations of the Food and Drug Administration exempt spices, flavorings, and certain colorings and additives from ingredient labeling requirements that would allow consumers to avoid those to which they are allergic; and

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

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

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

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

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

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

''(A) 'Contains', which statement is followed by the name of the food source as described in section 201(ll)(1) from which the major food allergen is derived, follows immediately after or is adjacent to (in a type size no smaller than the type size used in the list of ingredients) the list of ingredients required under subsections (g) and (i); or

''(B) the common or usual name of the major food allergen in the list of ingredients required under sections (g) and (i) is followed in parentheses by the name of the food source as described in section 201(ll)(1) from which the major food allergen is derived, except that the name of the food source is not required when—

''(i) the common or usual name of the ingredient is the term used to describe a major food allergen in section 201(ll)(1), or

''(ii) the name of the food source as described in section 201(ll)(1) has appeared previously in the ingredient list; and

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

''(2) The information required under this subsection may appear in labeling other than the label only if the Secretary finds that such other labeling is sufficient to protect the public health. A finding by the Secretary under this subparagraph is effective upon publication in the Federal Register as a notice (including any change in an earlier finding under this subparagraph).

''(3) Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that intentionally bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection.

''(4) The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of paragraph (1), or eliminate either the requirement of subparagraph (A) or the requirement of subparagraph (B), if the Secretary

determines that the modification or elimination of the requirement is necessary to protect the public health.

''(u) Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that intentionally bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.''.

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

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

''(ll) The term 'major food allergen' means any of the following:

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

''(2) A proteinaceous substance derived from a food specified in paragraph (1) (unless the Secretary determines that the substance does not cause an allergic response that poses a risk to human health).''.

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

SEC. 4. REPORT ON FOOD ALLERGENS.

Not later than June 30, 2004, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that—

(1)(A) analyzes—

(i) the ways in which foods, during manufacturing and processing, can be unintentionally contaminated with major food allergens, including contamination caused by the use by manufacturers of the same production line to produce both products for which major food allergens are intentional ingredients and products for which major food allergens are not intentional ingredients; and

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

become unintentionally contaminated with major food allergens; and

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

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

(3) describes—

(A) the various types of advisory labeling (such as use of the words ''may contain'') used by food producers;

(B) the conditions of manufacture of food that are associated with the various types of advisory labeling; and

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

(4) determines how consumers with food allergies or the caretakers of consumers would prefer information about the risk of cross-contact be communicated on food labels by using appropriate survey mechanisms; and

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

SEC. 5. INSPECTIONS RELATING TO FOOD ALLERGENS.

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

(1) to ensure that the foods comply with practices to reduce or eliminate cross-contact of a food with major food allergen residues that are not intentional ingredients of the food; and

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

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

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

(2) describes the nature of the violations found;

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

(4) assesses the extent of use of advisory language found and the appropriateness of that use; and

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

SEC. 6. LABELING OF GLUTENS AND CELIAC DISEASE.

(a) CONTRACT WITH INSTITUTE OF MEDICINE.—The Secretary of Health and Human Services (in this section, the ''Secretary'') shall enter into a contract with the Institute of Medicine for—

(1) the conduct of a review of the science relating to—

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

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

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

(2) the submission to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, not later than 2 years after the date of enactment of this Act,

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

(b) REQUIREMENTS OF EXPERTISE.—The Institute of Medicine shall conduct the review under subsection (a)(1) and make the report under subsection (a)(2) in conjunction with experts in celiac disease, including experts in the pathogenesis, epidemiology, and biochemistry of celiac disease, the sensitivity to, and tolerance of, the glutens in food that are associated with celiac disease, and the clinical aspects of celiac disease, including prevention and treatment.

(c) GLUTEN LABELING.—Considering the review conducted under paragraph (a)(1), the Secretary shall, not later than 4 years after the date of enactment of this Act, issue a proposed rule to define, and permit use of, the term ''gluten-free'' on the labeling of foods. Not later than 6 years after the date of enactment of this Act, the Secretary shall issue a final rule to define, and permit use of, the term ''gluten-free'' on the labeling of foods.

(d) REPORT.—Not later than 2 years after submission to the Secretary of the report under subsection (a)(2), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that assesses whether additional

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

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

(a) STUDY.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary''), in consultation with consumers, providers, State governments, and other relevant parties, shall complete a study for the purposes of—

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

(A) the prevalence of food allergies;

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

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

(2) identifying new or alternative systems or enhancements to existing systems (including by educating physicians and other health care providers),

for the reporting collection and analysis of national data on—

(A) the prevalence of food allergies;

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

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

(b) IMPROVEMENT AND PUBLICATION OF DATA.—On completion of, and consistent with the findings of, the study conducted under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Foods and Drugs, shall improve the collection of, and publish as it becomes available, national data on—

(1) the prevalence of food allergies;

(2) the incidence of clinically significant or serious adverse events related to food allergies; and

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

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

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

SEC. 8. FOOD ALLERGIES RESEARCH.

(a) IN GENERAL.—The Secretary of Health and Human Services, through the National Institutes of Health, shall convene a panel of nationally recognized experts to review current basic and clinical research efforts related to food allergies. The panel shall develop a plan for expanding, intensifying, and coordinating research activities concerning food allergies.

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

SEC. 9. FOOD ALLERGENS IN THE FOOD CODE.

The Secretary of Health and Human Services shall, in the Conference for Food Protection, as part of its cooperative activities between the States under section 311 of the Public Health Service Act (42 U.S.C. 243), pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bak-

eries, and elementary and secondary school cafeterias. The Secretary shall consider public and private guidelines and recommendations for preparing allergen-free foods in pursuing this revision.

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

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

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