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# FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT

OCTOBER 17, 2002.—Ordered to be printed

Mr. KENNEDY, from the Committee on Health, Education, Labor, and Pensions, submitted the following

## R E P O R T

[To accompany S. 2499]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 2499) to establish labeling requirements regarding allergenic substances in food, and for other purposes, reports favorably thereon with an amendment and recommends that the bill (as amended) do pass.

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## I. PURPOSE AND SUMMARY OF THE BILL

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires, with some exceptions, a complete listing of all the ingredients in a food on the food label. Currently, the FFDCA does not require the eight major food allergens to be identified, using plain English, on the food label when ingredients contain allergenic substances. The names of many ingredients do not clearly identify in plain English that the ingredient is the source of an allergen.

There are also two exemptions from the requirement that each ingredient be listed in the food ingredient label. One exemption al-

lows for collective naming of flavors, certain colors, and spices. These terms are not completely descriptive, however; in particular, they do not identify if any components of the flavors, colors, and spices are allergens. Under the second exemption, incidental additives, which are food substances that are used in insignificant amounts and that do not have any technical or functional affect in the food, need not be identified in the food label. Although additives that contain a major food allergen are not considered to be incidental, these ingredients are nonetheless sometimes inadvertently left off of the food label.

Food allergens also may inadvertently find their way into a food because of a firm's production practices; for example, rework addition, product carryover due to use of common equipment or production scheduling. Such practices present an unintentional opportunity for a product that contains an allergen to come into cross-contact with a product that does not intentionally contain that particular allergen. Some food manufacturers have added statements, such as "May contain (allergic ingredient)," to their product labels to alert consumers to the possibility that the product may contain an allergic substance.

The term "gluten-free" has not been defined by regulation. Persons with celiac disease must avoid certain types of gluten in foods associated with celiac disease. When gluten from certain cereal grains is ingested by individuals with celiac disease, damage to the gastrointestinal tract, central nervous system, and other organs may occur over time. Allowing the term "gluten-free" on food labels will assist consumers who have celiac disease avoid gluten.

The committee has approved this legislation to address these and other issues related to food allergens and glutens in foods that are associated with celiac disease.

### 1. THE LEGISLATION REQUIRES PLAIN ENGLISH INGREDIENT LABELING OF THE EIGHT MAJOR FOOD ALLERGENS

The legislation amends the FFDCA to require that food ingredient statements identify in plain English when the food contains a major food allergen. The legislation also provides that food ingredient statements will identify when a food allergen is contained in spices, flavorings, colorings, and incidental additives.

### 2. THE LEGISLATION PROVIDES FOR A REPORT ON FOOD ALLERGEN CROSS-CONTACT AND ADVISORY LABELING AND FOR BIENNIAL REPORTS ON FOOD ALLERGEN INSPECTIONS

The legislation requires the Secretary of Health and Human Services (Secretary) to issue a report to Congress about food allergen cross contact and advisory labeling. The legislation also requires the Secretary to give priority to increasing the number of food allergen inspections and it requires biennial reports to Congress about such inspections.

### 3. THE LEGISLATION PROVIDES FOR ENHANCED SURVEILLANCE AND FOR A RESEARCH PLAN RELATING TO FOOD ALLERGENS

The legislation requires the Centers for Disease Control and Prevention (CDC) to track food-allergic-related deaths and other clinically significant and serious adverse events. It also directs the Na-

tional Institutes of Health (NIH) to convene a panel of experts to develop a plan for research activities concerning food allergies.

4. THE LEGISLATION PROVIDES THAT THE FOOD CODE ADDRESS FOOD ALLERGENS AND FOR TECHNICAL ASSISTANCE TO STATES REGARDING EMERGENCY TREATMENT OF ALLERGIC RESPONSES TO FOOD

The legislation directs the Secretary to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments. It also directs the Secretary to provide technical assistance relating to emergency treatment of allergic responses to foods.

5. THE LEGISLATION PROVIDES FOR VOLUNTARY "GLUTEN-FREE" LABELING AND TWO REPORTS ON CELIAC DISEASE AND LABELING OF GLUTENS IN FOODS ASSOCIATED WITH CELIAC DISEASE

The legislation requires the Secretary to contract with the Institute of Medicine to provide a report to Congress and the Secretary about the glutens in foods that are associated with celiac disease. The legislation requires the Secretary to define the term "gluten-free" for voluntary use in food labeling. In addition, the legislation requires the Secretary to submit a report to Congress about the labeling of gluten in foods that are associated with celiac disease.

## II. Background and Need for the Legislation

Seven million Americans suffer from food allergies, approximately 2 percent of adults and 5 percent of infants and young children. Recent studies estimate that 150 Americans die each year and that 30,000 individuals require emergency room treatment because of allergic responses to food. Eight major foods or food groups—milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans—account for 90 percent of food allergies. There is currently no cure for food allergies. Instead, people with a food allergy must avoid the food to which they are allergic.

To avoid an allergen, food-allergic consumers must carefully read the labels for every food product they consume. This task is complicated because the names of many ingredients do not clearly identify that they are derived from an allergen. Currently, ingredients that may cause allergic reactions are listed on food labels using terms that do not identify the allergen in plain English. For example, whey and casein are foods derived from milk that cause allergic reactions in those allergic to milk. Currently, whey and casein are required to be identified in the food ingredient list only as whey and casein, however. A recent study showed that many parents of children with food allergy were unable to identify correctly several ingredients derived from major food allergens in each of several food labels. Use of plain English in food labels to identify the presence of the eight major food allergens will make the food label much more useful to consumers with food allergies.

In addition, currently spices, flavorings, and certain colorings and incidental additives are exempt from ingredient labeling requirements and need only be identified collectively as spices or flavorings, for example. Because some of these ingredients contain allergens, this exemption can pose a health threat to susceptible consumers, even though spices, flavorings, colorings, and incidental

additives are generally present in foods in only small quantities. Requiring the use of plain English to identify the presence of the eight major food allergens used in spices, flavors, and certain colors and incidental additives will also make the food label more useful to allergic consumers.

Food allergens sometimes inadvertently find their way into a food because of a firm's production practices; for example, rework addition, product carryover due to use of common equipment or production scheduling. Such practices present an unintentional opportunity for a product that contains an allergen to come into cross-contact with a product that does not intentionally contain that particular allergen. This problem of unintentional "cross-contact" deserves study and further action by both FDA and the food industry.

Although FDA and the industry must identify and implement practicable steps to eliminating the possibility of cross-contact, it may be that, in some instances, even such procedures will not be sufficient to eliminate the presence of an allergen. In such instances, it will be appropriate for food manufacturers to use advisory labeling (such as "may contain") to indicate the possible presence of food allergens in a food product. Many food manufacturers currently use such advisory language. Many do so appropriately, given the current state of knowledge about processes and technologies to reduce cross-contact. Yet there is concern among the food allergenic community that some members of the food industry use advisory labeling inappropriately, or not at all when they should. FDA and the food industry should carefully consider the use of advisory labeling, which can save the life of a consumer when it is appropriately used.

Although several studies have provided estimates, the prevalence of food allergies is uncertain. Currently, the CDC does not sufficiently track data on the prevalence of food allergies, incidence of clinically significant and serious adverse events related to food allergies, and the use of different modes of treatment for and prevention of allergic responses to foods. The CDC should improve the collection of this information to better determine the national significance of food allergies.

Research on food allergies is being conducted by public and private organizations. The NIH should conduct a comprehensive review of completed and ongoing studies on food allergies. Based on their findings, NIH should make recommendations identifying clinical research that should be conducted.

Numerous food establishments, including restaurants, grocery store delicatessens and bakeries, and school cafeterias are working to better serve those consumers with food allergies. Private guidelines demonstrating and recommending ways to prepare allergen-free foods have helped to educate such food establishments. Revision of the Food Code to include similar recommendations, however, will help to better alert the food establishments to the problem food allergies pose to public health and make the distribution of such information more widespread.

Not all States and localities provide emergency medical technicians with adequate training to treat successfully a patient undergoing a food allergic response. The government should provide tech-

nical assistance to such States and localities to enhance their preparedness to address emergencies caused by food allergens.

Celiac disease is an immune-mediated disease. When gluten from certain cereal grains is ingested by individuals with celiac disease, damage to the gastrointestinal tract, central nervous system, and other organs may occur over time. The response to glutens by those with celiac disease is not an allergic response. A multicenter, multiyear study estimated the prevalence of celiac disease in the United States to be 0.5 to 1 percent of the general population. The current recommended treatment is avoidance of glutens in foods that are associated with celiac disease. Allowing a clearly defined "gluten-free" claim to appear on the labels of food products will assist individuals with celiac disease to avoid the glutens associated with the disease.

## III. Legislative History and Committee Action

On May 9, 2002, Senator Kennedy, for himself and Senator Clinton, introduced S. 2499, to amend the FFDCA to require plain English labeling of the eight major food allergens in food ingredient labeling.

On September 25, 2002, the committee held an executive session to consider S. 2499. Senator Kennedy, for himself and Senators Gregg, Clinton, Roberts, and Frist, offered a substitute amendment as modified that was considered as original text by the committee. The committee approved S. 2499, as amended, by unanimous voice vote.

## IV. Explanation of the Legislation and Committee Views

### *Requirement of Plain English Labeling of the Eight Major Food Allergens*

The legislation amends section 201 of the FFDCA to define the term "major food allergen." It is defined to mean the eight most significant food allergens—milk, egg, fish (e.g., bass, flounder, or tuna), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans—and any proteinaceous substance derived from one of these eight food allergens, unless the Secretary determines that the substance does not cause an allergic response that poses a risk to human health. Fish, Crustacean shellfish, and tree nuts are collective names that include a variety of different items. For example, the term "tree nuts" refers to a variety of individual nuts, including almonds, Brazil nuts, cashews, chestnuts, filberts/hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts. Similarly, the term "Crustacean shellfish" refers to crabs, crawfish/crayfish, lobster, prawns, and shrimp. The term "fish" refers to a variety of different fish. The committee intends that the Secretary will provide guidance to industry on the information that would be useful for making a determination that a proteinaceous substance derived from one of the eight major food allergens does not cause an allergic response that poses a risk to human health. The committee also intends that the Secretary provide an appropriate process for providing such information to the Secretary that minimizes the burden on the food manufacturer.

The legislation also amends section 403 of the FFDCA to provide two new misbranding provisions. The first of these, section 403(t), requires that the eight major food allergens be labeled on foods that are not raw agricultural products. Under section 403(t), manufacturers will have two options as to how they must label the eight major food allergens on such foods. Under either plain English allergen labeling option, the term for a major food allergen—milk, egg, wheat, peanuts, soybeans, or, in the case of the collective terms "fish," "Crustacean shellfish," or "tree nuts," the common or usual name for the relevant specific members of the class, such as "tuna," "shrimp," or "almond"—will appear in the food label if the food is, or intentionally bears or contains, a major food allergen as defined in section 201(ll). These plain English allergen labeling requirements apply only to foods for which an ingredient list is required in a label or labeling under the FFDCA.

Manufacturers may choose to summarize the allergen information using the terms for the major food allergens from which any ingredients in the food are derived in a statement at the end of, or immediately adjacent to, the ingredient list. This information must appear in a type size no smaller than the type size used in the ingredient list.

Alternatively, manufacturers may place the term for the appropriate major food allergen in parentheses within the ingredient list after the common or usual name of the ingredient derived from that major food allergen. There are two exceptions to this requirement. First, the listing of the term for the food allergen is not required to appear in parentheses after an ingredient name if the ingredient name uses the term for the major food allergen (for example, "milk" need not appear in parentheses after "milk" or "milk byproduct," nor need "almond" appear after "almond"). Second, the term for a food allergen need not be placed after an ingredient if the term for that food allergen appears elsewhere in the ingredient list; the food allergen term need only appear once in the ingredient statement.

These two options can be illustrated by an example. If a food were to have as ingredients semolina, rice flour, rolled oats, pine nuts, tomato juice, whey, sodium caseinate, and natural flavoring, with the natural flavoring including peanuts as a constituent, the major food allergens in the food could be labeled in two ways. First, the following statement could appear at the end of, or immediately adjacent to, the list of ingredients: "Contains wheat, milk, pine nuts, and peanuts." Second, the ingredient list could read: "Ingredients: semolina (wheat), rice flour, rolled oats, pine nuts, tomato juice, whey (milk), sodium caseinate, and natural flavoring (peanuts)."

These two examples illustrate several aspects of the allergen labeling requirements. In the second example, "milk" does not appear in parentheses after "sodium caseinate" because it has already appeared after "whey." In the examples, the natural flavoring includes peanuts as a constituent and so peanuts is labeled as an allergen in the food. In other words, the food allergen labeling requirement applies to spices, flavorings, colorings, and incidental additives. Only the peanut constituent of the natural flavoring ingredient is identified, however; the other constituents of the flavoring—or indeed of any spice, coloring, or incidental additive—are

not required to be listed under either plain English labeling option permitted under the legislation.

The term "pine nuts" is in the summary of allergy information in the first example, but it need not appear after "pine nut" in the ingredient list in the second example because the repetition is unnecessary. The first example illustrates the committee's intent that the term for the relevant specific member of the class "fish" or "Crustacean shellfish" or "tree nuts" is required to be used whenever an ingredient is, or is derived from, an example from one of these food categories. The second example illustrates the committee's intent that an ingredient whose common or usual name uses the term for the major food allergen—in the example, "pine nuts" clearly uses the term for pine nuts—need not be followed by a parenthetical repeating the term. Finally, all major food allergens are required to be labeled consistently: either in the summary of allergen information at the end of, or immediately adjacent to, the ingredient list, or using parentheses after ingredients.

The committee intends that the use of the term "milk" in either of these examples does not violate the standard of identity for milk established under FDA regulations. Used in this context, the term "milk" is used to identify a major food allergen and not the identity of the ingredient or the food.

The legislation gives FDA the authority to modify or eliminate these requirements by regulation. This authority is limited in a few respects, however. First, FDA may modify one or both labeling options. Second, FDA may not eliminate all major food allergen labeling by eliminating both labeling options; rather, FDA may eliminate only one of the approaches. Third, and most significantly, FDA must demonstrate in the regulation that modification or elimination of an allergen labeling requirement is necessary to protect public health. The committee considers this standard to impose a high burden on the Secretary to justify changing these requirements of the legislation.

Section 403(t) is limited to foods that are not raw agricultural products. Accordingly, this legislation does not change the applicability of current misbranding and adulteration provisions to foods that are raw agricultural products. In particular, raw agricultural products into which major food allergens have been introduced by any means would be considered to be misbranded by FDA if not appropriately labeled under sections 201(n) and 403(a)(1) of the FFDCA, and even so may be considered to be adulterated by FDA under section 402(a)(1).

In addition, the legislation amends section 403A of the FFDCA to give the modification to the ingredient label required by section 403(t) the same preemptive effect over State and local ingredient labeling that the current ingredient labeling has.

The labeling requirements of section 403(t) become effective for foods labeled on or after January 1, 2006. This effective date gives the food industry time to provide this essential public health information on the labels of their foods. Importantly, this requirement does not require the relabeling of food products that are in the marketplace before the effective date. In other words, this legislation does not require food products to be pulled from the marketplace and relabeled in conformance with the requirements of this legislation if they were labeled before January 1, 2006.

The committee understands that many foods are already labeled in conformity with one of the plain English allergen labeling options, and it expects that most foods will be labeled in compliance with these requirements before January 1, 2006. In any case, all foods that intentionally bear or contain major food allergens must be labeled by January 1, 2006. This fixed date by which all affected foods must be relabeled will give consumers greater certainty that they will be able to rely on food labels as of that date.

The committee intends the requirements of section 403(t) to be self-implementing. FDA will not be required, nor is it necessary for FDA, to issue regulations to implement section 403(t). FDA may issue guidance, should the agency find that guidance would assist manufacturers or distributors, particularly small businesses, to comply with the requirements in this legislation.

The legislation also adds a second misbranding provision to account for other food allergens. In particular, section 403(u) provides that FDA has the authority to require by regulation appropriate labeling of any spice, flavoring, coloring, or incidental additive that is, or includes as a constituent, a food allergen that is not a major food allergen. In addition, the legislation provides that the amendments made by it do not otherwise alter FDA's authority to require the labeling of other food allergens that are not major food allergens. Finally, the legislation amends section 403A of the FFDCA to give requirements under section 403(u)—which provides for an exception to a current labeling exemption for spices, flavorings, colorings, and incidental additives that has preemptive effect over State and local labeling requirements—the same preemptive effect over State and local labeling requirements that the current exemption has.

*Food Allergy Surveillance, Research, and Response*

The committee is concerned that the prevalence of food allergies is uncertain and the incidence of clinically significant and serious adverse events is not being systematically monitored. In response to these concerns, the legislation requires the Centers for Disease Control and Prevention to better capture information on the prevalence of food allergies, the incidence of clinically significant or serious adverse events related to food allergies, and the use of different modes of treatment for and prevention of allergic responses to foods. In addition, the legislation requires the National Institutes of Health to convene a panel of nationally recognized experts to review current clinical research efforts and develop a plan for expanding research activities concerning food allergies.

The legislation directs the Secretary, in the Conference for Food Protection, to pursue revision of the Food Code to provide recommendations and guidance on preparing allergen-free foods in food establishments. The Secretary should refer to private guidelines, including the Food Allergy and Anaphylaxis Network and Food Allergy Initiative's document entitled: Food Allergy Training Guide for Restaurants and Food Services, as a model during development.

Finally, the legislation directs the Secretary to provide technical assistance to States and localities about treatment of food allergic responses by trauma care and emergency medical services. Currently, the preferred treatment for anaphylaxis from food allergy is

an auto-injector epinephrine device. The legislation does not specify this treatment, however, so that the Secretary will continue to provide such technical assistance as new treatments are developed.

*Celiac Disease and Gluten Labeling*

The legislation directs the Secretary to contract with the Institute of Medicine to conduct a review of the science relating to the glutens in food that are associated with celiac disease, the means of preventing and treating celiac disease, and the methodologies for detecting such glutens in food. This research should include information on both the sensitivity of individuals with celiac disease to gluten from different cereal grain sources and on gluten threshold levels (the amount of a gluten necessary to elicit the symptoms of celiac disease). The Institute of Medicine will provide a report to the Secretary and to Congress on this review not later than 2 years after the date of enactment of the legislation.

The committee expects this report to inform a rule making required by the legislation, by which the Secretary is to define and permit the use of the term "gluten-free" as a voluntary claim on the food label. The committee intends that this "gluten-free" claim not be a claim for special dietary use, a nutrient content claim, or a health claim. Further, the committee intends that, under the regulation, foods that are ordinarily gluten-free may be appropriately identified as a gluten-free food in food labeling. The legislation requires that the proposed rule allowing this claim be issued not later than 4 years after the date of enactment of the legislation, and that the final rule be issued not later than 6 years after the date of enactment of the legislation.

The committee also expects the Institute of Medicine report to inform a report by the Secretary to Congress on whether additional requirements for the labeling of gluten in food associated with celiac disease are warranted and necessary to better inform individuals with celiac disease. If the Secretary finds that other labeling of gluten in food associated with celiac disease is warranted and necessary, the report is to identify the types of such labeling and should describe why the different types of labeling are warranted and necessary.

## V. Cost Estimate

Due to time constraints the Congressional Budget Office estimate was not included in the report. When received by the committee, it will appear in the Congressional Record at a later time.

## VI. Application of Law to the Legislative Branch

S. 2499 adds two misbranding provisions to section 403 the FFDCA to provide, first, that food labels include plain English labeling of the eight major food allergens and second, that food allergens other than the eight major food allergens can be identified when they are contained in spices, flavorings, colorings, or other incidental additives. It also requires reports to the Congress by the Department of Health and Human Services and the Institute of Medicine about various issues relating to food allergens, celiac disease, and gluten, and requires certain other actions by the Depart-

ment relating to food allergens and gluten. As such, it has no application to the legislative branch.

## VII. Regulatory Impact Statement

The legislation requires foods that contain one or more of the eight major food allergens to be labeled so as to disclose the presence of those allergens in plain English. Because many in the food industry have already begun the process of labeling their products to disclose these allergens, and because the legislation requires food manufacturers to comply with this requirement by January 1, 2006, by which time most in the food industry may be expected to produce new labels for their foods notwithstanding the requirements of this legislation, the costs to most members of the food industry and to the food industry in aggregate of this requirement will be minimized. Accordingly, S. 2499 is not expected to increase costs to government.

## VIII. Section-by-Section Analysis

*Sec. 1. Short Title*

*Sec. 2. Findings*

*Sec. 3. Food Labeling; Requirement of Information Regarding Allergenic Substances*

Section 3 amends the FFDCA to define the term "major food allergen" to mean one of the eight major food allergens (milk, egg, fish (e.g., bass, flounder, or tuna), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans) and any proteinaceous substance derived from one of these eight food allergens, unless the Secretary determines that the substance does not cause an allergic response that poses a risk to human health. Section 3 amends the FFDCA to require that food ingredient statements identify in plain English when a food that is not a raw agricultural product is, or intentionally bears or contains, a major food allergen. Section 3 requires that this information appear consistently within each such food's label in one of two ways, either within the ingredient list in parentheses after the first ingredient that is derived from the allergen, or in summary form at the end of, or immediately adjacent to, the ingredient list. Section 3 requires that food ingredient statements identify in one of these ways when a major food allergen is used in spices, flavorings, colorings, and incidental additives. Section 3 requires all foods that are not raw agricultural products and that are, or that intentionally bear or contain, major food allergens to be so labeled by January 1, 2006. Section 3 also amends the FFDCA to give the plain English allergen labeling the same preemptive effect over State and local ingredient labeling as current ingredient labeling.

Section 3 provides that the FDA has the authority to require by regulation appropriate labeling of any spice, flavoring, coloring, or incidental additive that is, or intentionally includes as a constituent, a food allergen that is not a major food allergen. Section 3 also provides that this regulatory exception to the current labeling exemption for spices, flavorings, colorings, and incidental additives has the same preemptive effect over State and local labeling

requirements as the current exemption. In addition, section 3 provides that the amendments made by it do not otherwise alter FDA's authority to require the labeling of other food allergens that are not major food allergens.

*Section 4. Report on Food Allergens*

Section 4 requires the Secretary to issue a report to Congress by June 30, 2004, analyzing the ways in which foods, during manufacturing and processing, can be unintentionally contaminated with major food allergens (cross-contact); estimating how common these practices are; recommending methods that can be used to reduce or eliminate cross-contact of foods with the major food allergens; describing the types of advisory labeling used by the food industry, the conditions of manufacture associated with use of advisory labeling, and the extent of use of advisory labeling; determining how consumers with food allergies or the caretakers of consumers would prefer information about the risk of cross-contact be communicated on food labels; and identifying the circumstances, if any, under which advisory labeling could appropriately be used.

*Section 5. Inspections Relating to Food Allergens*

Section 5 requires the Secretary to give priority to increasing the number of inspections to ensure that foods comply with practices to reduce or eliminate cross-contact of a food with major food allergen residues and that food allergens are properly labeled. Section 5 also requires biennial reports to Congress to include information on the number of inspections conducted in the previous year and the number of facilities and food labels that were found to be in compliance or out of compliance; the nature of the violations found; the number and classification of voluntary recalls of foods with undeclared major food allergens; the extent of use of advisory labeling and the appropriateness of that use; and the extent to which the Secretary and the food industry have effectively addressed cross-contact issues.

*Sec. 6. Labeling of Glutens and Celiac Disease*

Section 6 requires the Secretary to contract with the Institute of Medicine, in conjunction with celiac disease experts, for a report, to be issued not later than 2 years after the date of enactment of the legislation to the Secretary and Congress, reviewing the science relating to glutens in foods that are associated with celiac disease, the means of preventing and treating celiac disease, and the methodologies for detecting such glutens in foods. Section 6 requires the Secretary, after reviewing the Institute of Medicine report, to issue a rule not later than 6 years after the date of enactment of the legislation defining and permitting voluntary use of the term "gluten-free" on food labeling. In addition, section 6 requires the Secretary to submit a report to Congress 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, that identifies the types of such labeling.

*Sec. 7. Data on Food-Related Allergic Responses*

Section 7 requires the Secretary, not later than 1 year after the date of enactment of the legislation, to complete a study to determine whether existing systems of reporting, collecting, and analyzing national data accurately capture information about the prevalence of food allergies, the incidence of clinically significant or serious adverse events related to food allergies, and the use of different modes of treatment for and prevention of allergic responses to foods, and to identify new or alternative systems or enhancements of current systems to better collect such information. On completion of this study, section 7 requires the CDC to improve the collection of such information, and publish it as it becomes available. Not later than 30 months after the date of enactment of the legislation, the Secretary must submit a report on the progress made in conducting the study and enhancing food allergy surveillance. Section 7 authorizes the appropriation of such sums as may be necessary to carry out its purposes.

*Sec. 8. Food Allergies Research*

Section 8 directs the NIH to convene a panel of nationally recognized experts to review current basic and clinical research efforts related to food allergies and to develop a plan for expanding, intensifying, and coordinating research activities concerning food allergies. Section 8 requires the Secretary to submit the plan to Congress not later than 1 year after the date of enactment of the legislation.

*Sec. 9. Food Allergens in the Food Code*

Section 9 directs the Secretary, in the Conference for Food Protection, as part of its cooperative activities between the States under section 311 of the Public Health Service Act, to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries, and elementary and secondary school cafeterias.

*Sec. 10. Recommendations Regarding Responding to Food-Related Allergic Responses*

Section 10 directs the Secretary to provide technical assistance relating to the use of different modes of treatment for and prevention of allergic responses to foods when it provides technical assistance relating to trauma care and emergency medical services under Section 1202(b)(3) of the Public Health Service Act.

## IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

### FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

SEC. 201. For the purposes of this Act—
(a)(1) * * *

* * * * * * *

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

*(1) Milk, egg, fish (e.g. bass, founder, or tuna), Crustacean shellfish (e.g. crab, lobster, or shrimp), tree nuts (e.g. almonds, pecans, or walnuts), 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).*

* * * * * * *

SEC. 403. A food shall be deemed to be misbranded—
(a) * * *

* * * * * * *

*(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 subsections (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 uses 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) appears elsewhere 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 in lieu of appearing on 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.*

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Sec. 403A. (a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g), except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 401 and 403(g).

(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), or **[**403(i)(2)**]**, *403(i)(2), 403(t), or 403(u)* that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(c) and that is applicable to maple syrup.

(3) * * *

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