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NUEVA LEY DE ETIQUETADO DE ALERGENOS: "FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT "

Tanto el Senado como posteriormente el Presidente de los Estados Unidos han aprobado la nueva Ley de etiquetado de alergenos denominada Food Allergen Labeling and Consumer Protection Act. Esta nueva Ley entrará en vigor el 1 de Enero de 2006. Se trata de una enmienda de la Sección 403 del Acta Federal sobre Alimentos, Medicinas y Cosméticos 'Federal Food, Drug and Cosmetic Act' donde se añade al final los nuevos puntos que regulan el etiquetado de alergenos. En el Anexo 1 se adjunta esta nueva Ley y en el Anexo 2 se encuentra el Acta Federal sobre Alimentos, Medicinas y Cosméticos sin la nueva enmienda.

ANTECEDENTES

La nueva Ley de etiquetado de alergenos es un compromiso entre grupos del Congreso para dar mayor flexibilidad a la legislación original introducida en Mayo de 2002 por el Senador Ted Kennedy y la Republicana Nita Lowey. Esta legislación anterior incluía los siguientes requerimientos:

- Obligatoriedad de declarar en el etiquetado los alergenos más importantes que se encuentren dentro de los alimentos y con unos límites muy estrictos sobre la forma de listar estos alergenos en el etiquetado.
- mandatos más restrictivos sobre el mantenimiento de los registros y el acceso del Gobierno a los registros de las industrias.
- Listado obligatorio en el etiquetado de alimentos del número de teléfono, añadido al del nombre y ubicación de las compañías encargadas la elaboración de los productos alimenticios.
- Prohibir la terminología "may contain" (puede contener) en el etiquetado después de cuatro años.

Además, el Congreso de los Estados Unidos ha considerado importante introducir la nueva regulación de 2004 asándose en la siguiente información:

1. Se estima que:
   a. Aproximadamente el 2 por ciento de los adultos y en torno al 5 por ciento de los niños sufren alergias como consecuencia de la comida en Estados Unidos.
   b. Cada año, aproximadamente 30.000 personas requieren asistencia médica y 150 personas mueren por reacciones alérgicas de la comida.

2. a. Ocho tipos de alimentos o grupos de alimentos – leche, huevos, pescado, mariscos, frutos secos, cacahuetes, trigo y soja – provocan el 90 por ciento de las alergias.
   b. Actualmente, no hay cura en el caso de las alergias producidas por los alimentos.
   c. Un consumidor alérgico debe evitar los alimentos a los cuales es alérgico

3. a En una revisión de alimentos elegidos al azar, en el helado y los caramelos en Minnesota y Wisconsin en 1999, la FDA encontró que el 25 por ciento de las muestras no especificaban en el etiquetado el uso de cacahuetes y huevos como ingredientes.

b. A escala nacional, el número de productos retirados del mercado por no etiquetar los alergenos incrementó en 121 en el 2000 mientras que en la década anterior se encontraba en 35.

4. Un estudio reciente muestra que muchos padres con hijos con problemas de alergia fueron incapaces de identificar en los etiquetados los alergenos.

5. a Los ingredientes dentro de un producto alimentario deben listarse con un nombre común o usual.

b. En algunos casos, el uso común de algunos ingredientes no resulta familiar a los consumidores, y muchos consumidores no se dan cuenta que ese ingrediente deriva o contiene un alergeno.
c. En otros casos, los ingredientes pueden ser declarados como un tipo, este sería el caso de las especias, aderezos y ciertos colorantes, o están exentos de los requerimientos del etiquetado, como es el caso de algunos aditivos.

6. a la enfermedad celíaca causa daños gastrointestinales, en el sistema nervioso central y otros órganos

b. el tratamiento recomendado es evitar el gluten en los alimentos ya que está asociado con la enfermedad celíaca.
c. Se estima que la enfermedad celíaca se encuentra en un 0,5 –1 por ciento de la población de los Estados Unidos.

Por otro lado, con la nueva ley del 2004, se ha logrado que la IDFA, International Dairy Foods Association, esté más satisfecha ya que se han eliminado ciertas exigencias e incertidumbres que existían en la legislación anterior.

Los pasos que se siguieron para convertir la propuesta en Ley fueron, en primer lugar la aprobación del Senado el 9 de Marzo de 2004 y posteriormente, el 3 de Agosto, el Presidente George Bush firmó la nueva propuesta de ley llamada "Food Allergen Labeling and Consumer Protection Act of 2004" (Ley de Etiquetado de Productos Alergénicos y Protección del Consumidor) convirtiéndola en Ley.

OBJETO Y CONTENIDO ESENCIALES DE LA LEY APROBADA

Esencialmente, esta Ley requiere que los productores identifiquen en lenguaje corriente, la presencia de los ocho tipos de alergenos más importantes (leche, huevos, cacahuetes, frutos secos, marisco, pescado, trigo, soja) en la lista de ingredientes del etiquetado de los productos alimentarios. La norma requiere también que se identifique en el etiquetado la presencia de los alergenos utilizados en las especias, aderezos, aditivos y colorantes.

La regulación actual permite que las especias, aderezos y algunos colorantes utilizados en los alimentos sean declarados colectivamente sin especificar cada uno de sus ingredientes por separado. La Food and Drug Administration (FDA) ya venía aconsejando que los productores declarasen cualquier posible ingrediente alergénico contenido en las especias, aderezos o colorantes desde el año 2001. Más adelante, la FDA y el Food Safety and Inspection Service (FSIS) proporcionaron una guía a la industria alimentaria en la que informaban sobre el etiquetado de ingredientes alergénicos y sobre la prevención de la contaminación cruzada de los alimentos con alergenos durante su producción. Muchos productores declararon voluntariamente los alergenos en el etiquetado y tienen programas de control para reducir o eliminar la posible contaminación cruzada.

La Ley, que se puede encontrar en la sección 741 del título II del Code of Federal Regulation, tiene por objeto regular el etiquetado de productos agroalimentarios de manera que en el mismo figure la existencia en su caso de alguno de los principales productos alergénicos . Los elementos esenciales de la misma son:

- El 1 de Enero de 2006 entrará en vigor el nuevo etiquetado de alimentos que exige que aquellos productos que contengan alergenos como la leche, los huevos, el marisco, pescado, el trigo, los frutos secos, los cacahuetes y soja, deberán especificarlo en el etiquetado de los mismos. Si no se ha modificado el etiquetado de los referidos productos, al llegar esta fecha, la FDA retirará el producto del mercado.
- Obligatoriedad del marcado en el etiquetado de todos los ingredientes que contengan productos alergénicos incluyendo especias, aderezos, colorantes y aditivos.
- Se podrá optar por una de las opciones siguientes:
    - Incluir una descripción en inglés corriente como "albumen (huevo)"
    - Incluir la información sobre los alergenos en un apartado distinto como "contiene: soja, huevos" ("contains: soy, eggs")

La norma contiene dos excepciones en los requerimientos de etiquetado de los alergenos. No haría falta modificar el etiquetado en los dos casos siguientes:

- Si el producto alergénico ya está identificado de alguna manera en la lista de ingredientes. Por ejemplo, una etiqueta que incluya ya el termino "leche de chocolate" no hace falta que el ingrediente "leche" se vuelva a especificar en el etiquetado de alergenos.
- Si el alergeno ya ha aparecido anteriormente en la lista de ingredientes. Por ejemplo, helado producido a base de leche desnatada, nata, proteínas de trigo, calcio, caseinato, cacahuetes y huevos, en este caso no haría falta volver a incluir en la lista de alergenos ninguno de estos ingredientes ya que están todos identificados en un lenguaje común.

La nueva legislación también requiere que el Secretario de Salud y Servicios Humanos (US secretary of health and human services) de Estados Unidos publique datos nacionales sobre los efectos de los alergenos en las personas: enfermedades y muertes. Además, la norma requiere estudios acerca de temas como los avisos "may contain" (podría contener), las buenas prácticas en la producción, las incidencias de contaminación cruzada y las inspecciones de los establecimientos.

Además, requerirá que el Gobierno federal:

- Mejore la recogida de datos sobre alimentos alergénicos.
- Convoque un panel de expertos y revise las investigaciones sobre alimentos alergénicos.
- Informe al Congreso del número de inspecciones realizadas en las fábricas en relación a los alergenos durante un periodo de dos años y de qué forma podría reducirse o eliminarse la contaminación cruzada.
- Considere revisiones del Código Alimentario (Food Code) y provea las directrices al sector hostelero y establecimientos de alimentación para reducir o eliminar la contaminación cruzada con alergenos.
- Analice las preferencias de los consumidores

TEXTO DE LA NUEVA REGULACIÓN EN MATERIA DE ETIQUETADO (traducción no oficial)

La nueva norma ha sido aprobada por una Ley que contiene dos Títulos, siendo el Titulo II el que hace referencia al Etiquetado de Productos Alergénicos y Protección del Consumidor ('Food Allergen Labeling and Consumer Protection Act') y al que nos referiremos.

A continuación, como orientación, se destacan los principales puntos de esta Ley, pero se aconseja la lectura de la misma por lo que se adjunta como Anexo 1 a esta nota.

Sección 202 del Título II ANTECEDENTES Y CONSIDERANDOS (no se reproducen aquí)

Sección 203. ETIQUETADO DE LOS ALIMENTOS: REQUERIMIENTOS INFORMATIVOS EN RELACIÓN A LAS SUSTANCIAS ALERGÉNICAS.

(a) EN GENERAL – la sección 403 de la LEY Federal sobre Alimentos, Medicinas y Cosméticos "Federal Food, Drug, and Cosmetic Act" se modifica añadiendo al final lo siguiente:

Un alimento podrá considerarse con un marcado falso/inadecuado:

(1) si no tratándose de un artículo agrícola crudo/natural es o contiene algún ingrediente que a su vez contenga un producto alergénico, salvo que:

a) La palabra "Contiene", seguida del nombre de la fuente alimentaria de la cual deriva el alergeno, esté impresa directamente después o cerca de la lista de ingredientes (escrito en el mismo formato al empleado en los ingredientes) requeridos bajo los subapartado (g) y (i); o
b) El nombre común o corriente del alérgeno (alérgeno alimentario principal) en la lista de ingredientes requerida conforme lo establecido en los subapartados (g) y (i) se encuentre en tre paréntesis después del ingrediente del cual deriva, con la excepción de que:

i) El nombre corriente o común del ingrediente ya está identificado en la fuente alimentaria de la cual el alergeno deriva.
ii) El nombre de la fuente de la cual el alergeno deriva aparece en la lista de ingredientes, a no ser que el nombre de la fuente forme parte del nombre del ingrediente y no sea un alergeno tal y como se especifica bajo la sección 201 (qq)(2)(A)o (B)

(2) La expresión "El nombre de la fuente de la cual el alergeno deriva" significa el nombre descrito en la sección 201 (qq)(1); en el caso de los frutos secos, el pescado y el marisco, este término significa el tipo específico de fruto seco o pescado o marisco.

(3) La información exigida en esta subsección podrá aparecer en el etiquetado/marcado (entendido como etiquetado de contenido) en lugar de aparecer en la etiqueta (entendida como la etiqueta principal) únicamente si el Secretario considerara que este etiquetado resulta suficiente para proteger la salud de los consumidores. Cualquier cambio realizado por el Secretario a la luz de este párrafo se hará efectivo tras su publicación en el Federal Register como aviso ("notice").

(4) A pesar de lo establecido en las subsecciones (g), (i) o (k), o en cualquier otra regulación; un aderezo, colorante o aditivo que sea, lleve o contenga un alergeno estará sujeto a los requerimientos de esta subsección.

(5) El Secretario podrá a través de una norma modificar o eliminar los requerimientos del subapartado (A) o (B) del párrafo (1) , si considerara que ello resulta necesario para asegurar la protección de la salud de los consumidores.

(6)(A) Cualquier persona podrá solicitar al Secretario que se exima un ingrediente alimentario descrito en la sección 201(qq)(2) del cumplimiento de los requisitos del etiquetado de alergenos de esta subsección.

(B) El Secretario aprobará o denegará dicha petición dentro del plazo de 180 días desde la recepción de la petición, o transcurrido dicho plazo la petición se estimará denegada, salvo que de mutuo acuerdo se haya acordado una prórroga del plazo anterior.

(C) La carga de la prueba corresponderá a la persona que solicite un cambio en el etiquetado que tendrá que encargarse de probar científicamente (incluyendo los métodos analíticos empleados para dicha prueba) que el ingrediente no causa ninguna reacción alérgica que pueda poner en peligro la salud de los consumidores.

(D)La resolución recaída en relación a dicha petición pondrá fin a la vía administrativa y se considerará acto definitivo.

(E) El Secretario deberá, sin demora, hacer publicas todas las peticiones recibidas a la luz de este párrafo dentro del periodo de 14 días desde la recepción de la solicitud y tendrá el deber de responder a cada una de las peticiones.

(7)(A) Una persona no necesitará presentar una petición al amparo del párrafo (6) para eximir a un ingrediente descrito en la sección 201(qq)(2) de la obligación de lo dispuesto en el etiquetado de alergenos, si la referida persona presenta ante el Secretario una notificación que contenga:

(i) Evidencias científicas (incluyendo el método analítico empleado para ello) que demuestre que el ingrediente no tiene proteínas alergénicas o

(ii) Una resolución del Secretario argumentando que el ingrediente no causa una reacción alérgica que suponga un riesgo para la salud de los consumidores conforme lo establecido en el programa de notificación establecido en la sección 409.

(B) El ingrediente podrá ser introducido en el comercio interestatal como producto sin riesgo de provocar alergias, 90 días después de haber recibido la notificación del Secretario, y salvo que el Secretario determine dentro de los 90 días que la notificación no cumple con los requisitos de este párrafo, o no exista una suficiente evidencia científica para determinar que el producto no contiene proteínas alergénicas o que no causa reacciones alérgicas que puedan suponer un riesgo para la salud de los consumidores.

(C) El Secretario deberá responder públicamente a todas las notificaciones recibidas a la luz de este subpárrafo dentro de los 14 días siguientes a la recepción de las mismas.

(x) A pesar de lo establecido en las subsecciones (g), (i) o (k), o en cualquier otra regulación; un aderezo, colorante o aditivo que contenga un alergeno deberá estar sujeto a los requisitos establecidos en la regulación del Secretario.

(b) COMPETENCIAS DE OTRAS AUTORIDADES- Las enmiendas de esta sección que exigen el etiquetado de los alergenos principales no afectará a la autoridad del Secretario de Salud y Servicios Humanos establecida por la Ley “Federal Food, Drug

and Cosmetic Act" (21 U.S.C 301 et seq.) para exigir el etiquetado/marcado de otros alergenos.

(c) APLICACIÓN DE LAS MODIFICACIONES

(1) Sección 201 del Acta "Federal Food, Drug, and Cosmetic Act (21 U.S.C 301) se modifica añadiendo al final lo siguiente:

(qq) El término "alérgeno principal " significa:

(1) Leche, huevo, pescado, mariscos, frutos secos, trigo, cacahuetes y soja.
(2) Un ingrediente que contenga proteínas derivadas de algñun producto especificado en el párrafo (1) excepto:
   A. Cualquier aceite refinado derivado de los alimentos del párrafo (1) y cualquier ingrediente derivado de dicho aceite refinado.
   B. Ingredientes exentos bajo el párrafo (6) o (7) de la sección 403(w)

(2) Sección 403(a)(2) del Acta "Federal Food, Drug, and Cosmetic Act" (21 U.S.C. 343-1(a)(2)) se modifica añadiendo "or 403(i)(2)" e insertando "403(i)(2), 403(w), or(403(x)".

(d) FECHA DE ENTRADA EN VIGOR: Las enmiendas realizadas al amparo de esta sección serán de aplicación a cualquier alimento etiquetado a partir del 1 de Enero del 2006.

Washington Septiembre 2004

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ANEXO1
(SE REPRODUCE TEXTO DE LA NORMA OBTENIDA DEL FEDERAL REGISTER)

TITLE II--FOOD : Food Allergen Labeling and Consumer Protection

Act of 2004.>> ALLERGEN LABELING AND CONSUMER PROTECTION

SEC. 201. SHORT TITLE.

This title may be cited as the ``Food Allergen Labeling and Consumer Protection Act of 2004".

SEC. 202. FINDINGS.

Congress finds that--

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(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;
(C)

(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 the foods 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

(D) 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 to correctly identify in each of several food labels the ingredients derived from major food allergens;

(5)(A) ingredients in foods must 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) in other cases, the ingredients may be declared as a class, including spices, flavorings, and certain colorings, or are exempt from the ingredient labeling requirements, such as incidental additives; 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

(E) 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. 203. 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:

``(w)(1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either--``(A) the word `Contains', followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in 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 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 name of the food source from which the major food allergen is derived; or ``(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen under section 201(qq)(2)(A) or (B).

``(2) As used in this subsection, the term `name of the food source from which the major food allergen is derived' means the name described in section 201(qq)(1); provided that in the case of a tree nut, fish, or Crustacean shellfish, the term `name of the food source from which the major food allergen is derived' means the name of the specific type of nut or species of fish or Crustacean shellfish.

``(3) 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. <<NOTE: Federal Register, publication.>> A finding by the Secretary under this paragraph (including any change in an earlier finding under this paragraph) is effective upon publication in the Federal Register as a notice.

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

``(5) 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 requirements of subparagraph (B) of paragraph (1), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A) or the requirements of subparagraph (B) is necessary to protect the public health.

``(6)(A) Any person may petition the Secretary to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection.

``(B) The Secretary shall approve or deny such petition within 180 days of receipt of the petition or the petition shall be deemed denied, unless an extension of time is mutually agreed upon by the Secretary and the petitioner.

``(C) The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that
poses a risk to human health.

``(D) A determination regarding a petition under this paragraph shall constitute final agency action.

``(E) The Secretary shall promptly post to a public site all petitions received under this paragraph within 14 days of receipt and the Secretary shall promptly post the Secretary's response to each.

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``(7)(A) A person need not file a petition under paragraph (6) to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection, if the person files with the Secretary a notification containing--``(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or ``(ii) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409.

``(B) The food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this paragraph, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergenic response that poses a risk to human health.

``(C) <<NOTE: Public information. Deadline.>> The Secretary shall promptly post to a public site all notifications received under this subparagraph within 14 days of receipt and promptly post any objections thereto by the Secretary.

``(x) Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that 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 <<NOTE: 21 USC 343 note.>> on Other Authority.--The amendments made by this section that require a label or labeling for major food allergens do 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 a label or labeling for other food allergens.

(c) Conforming Amendments.--

(1) Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) (as amended by section 102(b)) is amended by adding at the end the following:

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

``(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

``(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

``(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

``(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).".(2) Section 403A(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(2)) is amended by striking ``or 403(i)(2)'' and inserting ``403(i)(2), 403(w), or 403(x)".

(d) Effective Date.--The <<NOTE: Applicability. 21 USC 321

note.>> amendments made by this section shall apply to any food that is labeled on or after January 1, 2006.

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SEC. 204. REPORT ON FOOD ALLERGENS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as 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)(A) analyzes--

(i) the ways in which foods, during manufacturing and processing, are 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 are unintentionally contaminated with major food allergens; and

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

(2) advises whether good manufacturing practices or other methods 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 labeling that uses 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) describes how consumers with food allergies or the caretakers of consumers would prefer that information about the risk of cross-contact be communicated on food labels as determined by using appropriate survey mechanisms;

(5) states the number of inspections of food manufacturing and processing facilities conducted in the previous 2 years and describes--

(A) the number of facilities and food labels that were found to be in compliance or out of compliance with respect to cross-contact of foods with residues of major food allergens and the proper labeling of major food allergens;

(B) the nature of the violations found; and

(C) the number of voluntary recalls, and their classifications, of foods containing undeclared major food allergens; and

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

SEC. 205. INSPECTIONS RELATING TO FOOD ALLERGENS.

The Secretary of Health and Human Services shall conduct inspections consistent with the authority 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 entities operating the facilities comply with practices to reduce or eliminate cross-contact of a food

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with residues of major food allergens that are not intentional ingredients of the food; and
(2) to ensure that major food allergens are properly labeled
on foods.

SEC. 206. GLUTEN LABELING.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, shall issue a proposed rule to define, and permit use of, the term ``gluten-free'' on the labeling of foods. Not later than 4 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.

SEC. 207. IMPROVEMENT AND PUBLICATION OF DATA ON FOOD-RELATED ALLERGIC RESPONSES.

(a) In General.--The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Food and Drugs, shall improve (including by educating physicians and other health care providers) 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.

(b) Authorization of Appropriations.--For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 208. FOOD ALLERGIES RESEARCH.

(a) In General.--The <<NOTE: Government organization.>> Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene an ad hoc panel of nationally recognized experts in allergy and immunology to review current basic and clinical research efforts related to food allergies.

(b) Recommendations.--Not <<NOTE: Deadline. Public information.>> later than 1 year after the date of enactment of this Act, the panel shall make recommendations to the Secretary for enhancing and coordinating research activities concerning food allergies, which the Secretary shall make public.

SEC. 209. FOOD ALLERGENS IN THE FOOD CODE.

The Secretary of Health and Human Services shall, in the Conference for Food Protection, as part of its efforts to encourage cooperative activities between the States under section 311 of he 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 bakeries, and elementary and secondary school cafeterias. The Secretary shall consider guidelines and recommendations developed by public and private entities for public and private food establishments for preparing allergen-free foods in pursuing this revision.

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SEC. 210. 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.

Approved August 2, 2004.

LEGISLATIVE HISTORY--S. 741:

HOUSE REPORTS: No. 108-608 (Comm. on Energy and Commerce).
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ANEXO 2
(SE REPRODUCE TEXTO DE LA NORMA OBTENIDA DEL FEDERAL CODE **)**

CHAPTER IV - FOOD
DEFINITIONS AND STANDARDS FOR FOOD

MISBRANDED FOOD

SEC. 403. [343] A food shall be deemed to be misbranded -

- (a) If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2).

- (b) If it is offered for sale under the name of another food.

- (c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

- (d) If its container is so made, formed, or filled as to be misleading.

- (e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

- (f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

- (g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

- (h) If it purports to be or is represented as -

  (1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or
  (2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

- (i) Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 721(c) unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

- (j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

- (k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

- (l) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical, except that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

- (m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721.

- (n) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of The Poison Prevention Packaging Act of 1970.

- (o) (1) If it contains saccharin, unless, except as provided in subparagraph (2), its label and labeling bear the following statement: "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS". Such statement shall be located in a conspicuous place on such label and labeling as proximate as possible to the name of such food and shall appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on such label and labeling.

    - (2) The Secretary may by regulation review and revise or remove the requirement of subparagraph (1) if the Secretary determines such action is necessary to reflect the current state of knowledge concerning saccharin.

- (p) **Repealed by Public Law 104-124 April 1, 1996.**

- (q) (1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides -

    (A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or
    (ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,
    (B) the number of servings or other units of measure per container,
    (C) the total number of calories -

        (i) derived from any source, and
        (ii) derived from the total fat,

    in each serving size or other unit of measure of the food,

    (D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,
    (E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this Act before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

    The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary

determines that such highlighting will assist consumers in maintaining healthy dietary practices.

- (2)(A) If the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.

- (B) If the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

- (3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

- (4)(A) The Secretary shall provide for furnishing the nutrition information required by subparagraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by clause (B) or by issuing regulations that are mandatory as provided by clause (D).

(B)(i) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990[1], the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in subparagraphs (1) and (2). Such guidelines shall take into account the actions taken by food retailers during such 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply -

(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and
(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

(ii) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990[1], the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subclause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.
(C)(i) Upon the expiration of 30 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990[2], the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under clause (A). Such report shall include a determination of whether there is substantial compliance with the guidelines.
(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subclause (i) every two years.
(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under clause (A), the Secretary shall at the time such determination is made issue proposed regulations requiring that any person who offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by subparagraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.
(ii) Regulations issued under subclause (i) may require that the nutrition information required by subparagraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by subparagraphs (1) and (2).
(iii) Regulations issued under subclause (i) shall

permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.
(E) For purposes of this subparagraph, the term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.
(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

- (5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food -

  (i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,
  (ii) which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,
  (iii) which is an infant formula subject to section 412,
  (iv) which is a medical food as defined in section 5(b) of the Orphan Drug Act (21 USC 360ee(b)), or
  (v) which is described in section 405(2).
  (B) Subparagraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such subparagraphs is impracticable because the package of such food is too small to comply with the requirements of such subparagraphs and if the label of such food does not contain any nutrition information.
  (C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more

than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary. (D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000, the requirements of subparagraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim. (E)(i) During the 12-month period for which an exemption from subparagraphs (1) and (2) is claimed pursuant to this subclause, the requirements of such subparagraphs shall not apply to any food product if -

(I) the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r),
(II) the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 100 full-time equivalent employees,
(III) such person provided the notice described in subclause (iii), and
(IV) in the case of a food product which was sold in the 12-month period preceding the period for which an exemption was claimed, fewer than 100,000 units of such product were sold in the United States during such preceding period, or in the case of a food product which was not sold in the 12-month period preceding the period for which such exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which such exemption is claimed.

(ii) During the 12-month period after the applicable date referred to in this sentence, the requirements of subparagraphs (1) and (2) shall not apply to any food product which was first introduced into interstate commerce before May 8, 1994, if the labeling for such product does not provide nutrition

information or make a claim subject to paragraph (r), if such person provided the notice described in subclause (iii), and if -

(I) during the 12-month period preceding May 8, 1994, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 600,000 units of such product were sold in the United States,
(II) during the 12-month period preceding May 8, 1995, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 400,000 units of such product were sold in the United States, or
(III) during the 12-month period preceding May 8, 1996, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 200 full-time equivalent employees and fewer than 200,000 units of such product were sold in the United States.

(iii) The notice referred to in subclauses (i) and (ii) shall be given to the Secretary prior to the beginning of the period during which the exemption under subclause (i) or (ii) is to be in effect, shall state that the person claiming such exemption for a food product has complied with the applicable requirements of subclause (i) or (ii), and shall -

(I) state the average number of full-time equivalent employees such person employed during the 12 months preceding the date such person claims such exemption,
(II) state the approximate number of units the person claiming the exemption sold in the United States,
(III) if the exemption is claimed for a food product which was sold in the 12-month period preceding the period for which the exemption was claimed, state the approximate number of units of such product which were sold in the United States during such preceding

period, and, if the exemption is claimed for a food product which was not sold in such preceding period, state the number of units of such product which such person reasonably anticipates will be sold in the United States during the period for which the exemption was claimed, and
(IV) contain such information as the Secretary may require to verify the information required by the preceding provisions of this subclause if the Secretary has questioned the validity of such information.

If a person is not an importer, has fewer than 10 full-time equivalent employees, and sells fewer than 10,000 units of any food product in any year, such person is not required to file a notice for such product under this subclause for such year.
(iv) In the case of a person who claimed an exemption under subclause (i) or (ii), if, during the period of such exemption, the number of full-time equivalent employees of such person exceeds the number in such subclause or if the number of food products sold in the United States exceeds the number in such subclause, such exemption shall extend to the expiration of 18 months after the date the number of full-time equivalent employees or food products sold exceeded the applicable number.
(v) For any food product first introduced into interstate commerce after May 8, 2002, the Secretary may by regulation lower the employee or units of food products requirement of subclause (i) if the Secretary determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to such lower requirement.
(vi) For purposes of subclauses (i), (ii), (iii), (iv), and (v) -

(I) the term ''unit'' means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers,
(II) the term ''food product'' means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and which has similar preparation methods, and
(III) the term ''person'' in the case of

a corporation includes all domestic and foreign affiliates of the corporation.

(F) A dietary supplement product (including a food to which section 411 applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that -

(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;
(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;
(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and
(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.

(G) Subparagraphs (1), (2), (3), and (4) shall not apply to food which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

- (r) (1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication -

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2),

or
(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A) -

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,
(ii) may not state the absence of a nutrient unless -

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or
(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food,

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless -

(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and a requirement that the statement disclose that cholesterol is not usually present in the food, and
(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate

proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,
(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and
(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health- related condition that is diet related, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: "See nutrition information for ____ content." The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.
(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).
(D) Subparagraph (2) does not apply to a claim described in subparagraph (1)(A) which uses the term "diet" and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25,

1989, and (iii) the use of the term "diet" was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to paragraph (a).
(E) Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.
(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.
(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if-

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;
(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that, such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause

(i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;
(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and
(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee. (H) A claim submitted under the requirements of clause (G) may be made until--

(i) such time as the Secretary issues a regulation--

(I) prohibiting or modifying the claim and the regulation has become effective, or
(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.

(3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made -

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and
(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.
(ii) A regulation described in subclause (i) shall describe -

(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health-related condition, and
(II) the significance of each such nutrient in affecting such disease or health-related condition.

(iii) A regulation described in subclause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the

matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.
(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if-

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers; (ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers; (iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with

paragraph (a) and section 201(n); and
(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(D) A claim submitted under the requirements of clause (C) may be made until--

(i) such time as the Secretary issues a regulation under the standard in clause (B)(i)

(I) prohibiting or modifying the claim and the regulation has become effective, or
(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary

and the petitioner. If the Secretary denies the petition or the petition is deemed to be denied, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision. If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this paragraph and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This paragraph does not apply to infant formulas subject to section 412(h) and medical foods as defined in section 5(b) of the Orphan Drug

Act.
(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments
(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 401 shall not be subject to subparagraph (2)(A)(i) or (2)(B).
(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if -

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,
(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and
(C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after

the first marketing of the dietary supplement with such statement that such a statement is being made.

(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary--

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to-

(i) enable consumers to develop and maintain healthy dietary practices;
(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or
(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.

- (s) If -

(1) it is a dietary supplement; and
(2)(A) the label or labeling of the supplement fails to list -

(i) the name of each ingredient of the supplement that is described in section 201(ff); and
(ii)(I) the quantity of each such ingredient; or
(II) with respect to a proprietary blend of such ingredients, the total

quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to identify the product by using the term "dietary supplement", which term may be modified with the name of such an ingredient;
(C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;
(D) the supplement -

(i) is covered by the specifications of an official compendium;
(ii) is represented as conforming to the specifications of an official compendium; and
(iii) fails to so conform; or

(E) the supplement -

(i) is not covered by the specifications of an official compendium; and
(ii)(I) fails to have the identity and strength that the supplement is represented to have; or
(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.

A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.

SEC. 403A. [343-1] (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) 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) of this title and that is applicable to maple syrup,
(3) any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) 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(h)(1) and that is applicable to maple syrup,
(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q), except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A), or
(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r), except a requirement respecting a claim made in the label or labeling of food which is exempt under section 403(r)(5)(B) .

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.
(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that -

(3) would not cause any food to be in violation of any applicable requirement under Federal law,
(2) would not unduly burden interstate commerce, and
(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

DIETARY SUPPLEMENT LABLING EXEMPTIONS

SEC 403B. [343-2] (a) IN GENERAL. -- A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it -

(1) is not false or misleading;
(2) does not promote a particular manufacturer or brand of a dietary supplement;
(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;
(4) if displayed in an establishment, is physically separate from the dietary supplements; and

(5) does not have appended to it any information by sticker or any other method.

(b) APPLICATION -- Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.
(c) BURDEN OF PROOF -- In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.

DISCLOSURE

SEC. 403C. [343-3] (a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).
(b) In this section, the term "radiation disclosure statement" means a written statement that discloses that a food has been intentionally subject to radiation.