amendment by the Food and Drug Administration to the National Shellfish Sanitation Program’s Model Ordinance, or the issuance of any guidance or regulation by the Food and Drug Administration relating to the Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration (parts 123 and 1240 of title 21, Code of Federal Regulations (or any successor regulations), where such guidance, regulation or suggested amendment relates to post harvest processing for raw oysters, the Secretary shall prepare and 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 which shall include—

(1) an assessment of how post harvest processing or set of equivalently controlled controls feasibly may be implemented in the fastest, safest, and most economical manner;

(2) the projected public health benefits of any proposed post harvest processing;

(3) the projected costs of compliance with such post harvest processing measures;

(4) the impact post harvest processing is expected to have on the sales, cost, and availability of raw oysters;

(5) criteria for ensuring post harvest processing standards will be applied equally to shellfish imported from all nations of origin;

(6) an evaluation of alternative measures to prevent, eliminate, or reduce to an acceptable level the occurrence of foodborne illness; and

(7) the extent to which the Food and Drug Administration has consulted with the States and other regulatory agencies, as appropriate, with regard to post harvest processing measures.

(b) LIMITATION.—Subsection (a) shall not apply to the guidance described in section 103(h) [section 103(h) of Pub. L. 111–353, set out as a note above].

(c) REVIEW AND EVALUATION.—Not later than 30 days after the Secretary issues a proposed regulation or guidance described in subsection (a), the Comptroller General of the United States shall—

(1) review and evaluate the report described in (a) and report to Congress on the findings of the estimates and analysis in the report;

(2) compare each proposed regulation or guidance to similar regulations or guidance with respect to other regulated foods, including a comparison of risks the Secretary may find associated with seafood and the instances of those risks in such other regulated foods; and

(3) evaluate the impact of post harvest processing on the competitiveness of the domestic oyster industry in the United States and in international markets.

(d) WAIVER.—The requirement of preparing a report under subsection (a) shall be waived if the Secretary issues a guidance that is adopted as a consensus agreement between Federal and State regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference.

(e) PUBLIC ACCESS.—Any report prepared under this section shall be made available to the public.

Domestic Fish or Fish Product Compliance With Food Safety Standards or Procedures Deemed to Have Met Requirements for Federal Commodity Purchase Programs

Pub. L. 104–180, title VII, §783, Aug. 6, 1996, 110 Stat. 1601, provided that: “Hereafter, notwithstanding any other provision of law, any domestic fish or fish product produced in compliance with food safety standards or procedures accepted by the Food and Drug Administration as satisfying the requirements of the ‘Procedures for the Safe and Sanitary Processing and Importing of Fish and Fish Products’ published by the Food and Drug Administration as a final regulation in the Federal Register of December 19, 1995, shall be deemed to have met any inspection requirements of the Department of Agriculture or other Federal agency for any Federal commodity purchase program, including the program authorized under section 32 of the Act of August 24, 1935 (7 U.S.C. 612c) except that the Department of Agriculture or other Federal agency may utilize lot inspection to establish a reasonable degree of certainty that fish or fish products purchased under a Federal commodity purchase program, including the program authorized under section 32 of the Act of August 24, 1935 (7 U.S.C. 612c), meet Federal product specifications.’’

§343. Misbranded food

A food shall be deemed to be misbranded—

(a) False or misleading label

If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.

(b) Offer for sale under another name

If it is offered for sale under the name of another food.

(c) Imitation of another food

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) Misleading container

If its container is so made, formed, or filled as to be misleading.

(e) Package form

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) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter 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) Representation as to definition and standard of identity

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 3(h) of this title, 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) Representation as to standards of quality and fill of container

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 341 of this title, 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;

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 341 of this title, 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; or

(3) a food that is pasteurized unless—

(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation promulgated under this chapter; or

(B)(i) such food has been subjected to a safe process or treatment that—

(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;

(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(iv) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

(ii) at least 120 days have passed after the date of receipt of such notification by the Secretary without the Secretary making a determination that the process or treatment involved has not been shown to meet the requirements of subclauses (I) through (III) of clause (i).

For purposes of paragraph (3), a determination by the Secretary that a process or treatment has not been shown to meet the requirements of subclauses (I) through (III) of subparagraph (B)(i) shall constitute final agency action under such subclauses.

(i) Label where no representation as to definition and standard of identity

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 379e(c) of this title, 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) Representation for special dietary use

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) Artificial flavoring, artificial coloring, or chemical preservatives

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) Pesticide chemicals on raw agricultural commodities

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) Color additives

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 379e of this title.

(n) Packaging or labeling of drugs in violation of regulations

If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.


(q) Nutrition information

(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

1 So in original. Probably should be followed by a comma.
in a common household measure that is appro-

priate to the food, or

(ii) if the use of the food is not typically ex-

pressed in a serving size, the common house-

hold unit of measure that expresses the serv-

ing 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 con-
tained 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 chapter before October 1,

1990, if the Secretary determines that such in-

formation will assist consumers in maintain-
ing healthy dietary practices.

The Secretary may by regulation require any in-

formation 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 di-

terary practices.

(2)(A) If the Secretary determines that a nu-

trient other than a nutrient required by sub-

paragraph (1)(C), (1)(D), or (1)(E) should be in-

cluded in the label or labeling of food subject to

subparagraph (1) for purposes of providing in-

formation 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 in-

formation relating to a nutrient required by sub-

paragraph (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 con-

sumers in maintaining healthy dietary prac-
tices, 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 informa-

tion required by subparagraphs (1) and (2) be dis-

played at the location in the retail establish-
mant at which the food is offered for sale.

(4)(A) The Secretary shall provide for furnish-

ing the nutrition information required by sub-

paragraphs (1) and (2) with respect to raw agri-
cultural 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

November 8, 1990, the Secretary, after providing

an opportunity for comment, shall issue guide-

delines for food retailers offering raw agricultural

commodities or raw fish to provide nutrition in-

formation specified in subparagraphs (1) and (2).

Such guidelines shall take into account the ac-
tions taken by food retailers during such 12-
month period to provide consumers nutrition

information on raw agricultural commodities

and raw fish. Such guidelines shall only apply—

(I) in the case of raw agricultural commod-

ities, to the 20 varieties of vegetables most fre-

quently consumed during a year and the 20 va-

rieties of fruit most frequently consumed dur-

ing a year, and

(II) to the 20 varieties of raw fish most fre-

quently 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 No-

vember 8, 1990, the Secretary shall issue a final

regulation defining the circumstances that con-

stitute 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 guid-

elines. The size of the retailers and the por-
tion of the market served by retailers in compli-

ance 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

November 8, 1990, the Secretary shall issue a re-
oprt on actions taken by food retailers to pro-

vide 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 sub-

stantial compliance with the guidelines, the

Secretary shall issue a report and make a deter-

mination 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 pro-

posed 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 require-

ments 6 months after issuing the proposed regu-
lations. The final regulations shall become effec-
tive 6 months after the date of their promul-
gation.

(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 fre-

quently consumed. Such regulations shall per-
mit 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

that
(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 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 of food 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 subparagraph, the requirements of such subparagraphs shall not apply to any food product if—

(1) 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) 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 and fewer than 600,000 units of such product were sold in the United States,

(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 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 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 of food products 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 equivalent employees or food products sold during the 12 months preceding 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 350 of this title 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 the 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.

(H) RESTAURANTS, RETAIL FOOD ESTABLISHMENTS, AND VENDING MACHINES.—

(i) GENERAL REQUIREMENTS FOR RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS.—Except for food described in subclause (vii), in the case of food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items, the restaurant or similar retail food establishment shall disclose the information described in subclauses (ii) and (iii).

(ii) INFORMATION REQUIRED TO BE DISCLOSED BY RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—Except as provided in subclause (vii), the restaurant or similar retail food establishment shall disclose in a clear and conspicuous manner—

(1)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu listing the item for sale, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu and designed to enable the public to understand, in the context of a total daily diet, the significance of
the caloric information that is provided on the menu;

(II)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu board, including a drive-through menu board, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu board, designed to enable the public to understand, in the context of a total daily diet, the significance of the nutrition information that is provided on the menu board;

(III) in a written form, available on the premises of the restaurant or similar retail establishment and to the consumer upon request, the nutrition information required under clauses (C) and (D) of subparagraph (I); and

(IV) on the menu or menu board, a prominent, clear, and conspicuous statement regarding the availability of the information described in item (III).

(iii) SELF-SERVICE FOOD AND FOOD ON DISPLAY.—Except as provided in subclause (vii), in the case of food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers, a restaurant or similar retail food establishment shall place adjacent to each food offered a sign that lists calories per displayed food item or per serving.

(iv) REASONABLE BASIS.—For the purposes of this clause, a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of title 21, Code of Federal Regulations (or any successor regulation) or in a related guidance of the Food and Drug Administration.

(v) MENU VARIABILITY AND COMBINATION MEALS.—The Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children’s combination meals, through means determined by the Secretary, including ranges, averages, or other methods.

(vi) ADDITIONAL INFORMATION.—If the Secretary determines that a nutrient, other than a nutrient required under subclause (i)(III), should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, disclosure of such nutrient in the written form required under subclause (ii)(III).

(vii) NONAPPLICABILITY TO CERTAIN FOOD.—

(I) IN GENERAL.—Subclauses (i) through (vi) do not apply to—

(aa) items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use);

(bb) daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; or

(cc) such other food that is part of a customary market test appearing on the menu for less than 90 days, under terms and conditions established by the Secretary.

(II) WRITTEN FORMS.—Subparagraph (5)(C) shall apply to any regulations promulgated under subclauses (ii)(III) and (vi).

(viii) VENDING MACHINES.—

(I) IN GENERAL.—In the case of an article of food sold from a vending machine that—

(aa) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and

(bb) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines,

the vending machine operator shall provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.

(IX) VOLUNTARY PROVISION OF NUTRITION INFORMATION.—

(I) IN GENERAL.—An authorized official of any restaurant or similar retail food establishment or vending machine operator not subject to the requirements of this clause may elect to be subject to the requirements of such clause, by registering biannually the name and address of such restaurant or similar retail food establishment or vending machine operator with the Secretary, as specified by the Secretary by regulation.

(II) REGISTRATION.—Within 120 days of March 23, 2010, the Secretary shall publish a notice in the Federal Register specifying the terms and conditions for implementation of item (I), pending promulgation of regulations.

(III) RULE OF CONSTRUCTION.—Nothing in this subclause shall be construed to authorize the Secretary to require an application, review, or licensing process for any entity to register with the Secretary, as described in such item.

(X) REGULATIONS.—

(I) PROPOSED REGULATION.—Not later than 1 year after March 23, 2010, the Secretary shall promulgate proposed regulations to carry out this clause.

(II) CONTENTS.—In promulgating regulations, the Secretary shall—

(aa) consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training
of food service workers, variations in ingredients, and other factors, as the Secretary determines; and 

(bb) specify the format and manner of the nutrient content disclosure requirements under this subparagraph.

(III) REPORTING.—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 quarterly report that describes the Secretary’s progress toward promulgating final regulations under this subparagraph.

(xi) DEFINITION.—In this clause, the term “menu” or “menu board” means the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection.

(r) Nutrition levels and health-related claims

(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 cholesterol unless the label or labeling 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,

(iv) may not state the absence of a nutrient 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 la-
belonging 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 321(n) of this title; 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 subchapter III of this chapter 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 321(n) of this title; 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.

(B) 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 subchapter III of this chapter 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 a 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) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such reports.

(5)(A) This paragraph does not apply to infant formulas subject to section 350a(h) of this title and medical foods as defined in section 360ee(b) of this title.
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(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 341 of this title 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 (1)(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) Dietary supplements

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 321(ff) of this title; and

(ii) 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 321(ff)(1)(A) of this title, 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) 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.

(u) Ginseng

If it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus Panax.

(v) Failure to label; health threat

If—

(1) it fails to bear a label required by the Secretary under section 381(m)(1) of this title (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) upon or after notifying the owner or consignee involved that the label is required
(w) Major food allergen labeling requirements

(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) of this section; or
   (B) the common or usual name of the major food allergen in the list of ingredients required under subsections (g) and (i) of this section 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 321(qq)(2)(A) or (B) of this title.

(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 321(qq)(1) of this title; 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. 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) of this section, 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.

(x) Nonmajor food allergen labeling requirements

Notwithstanding subsection (g), (i), or (k) of this section, 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.

(y) Dietary supplements

If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes a domestic address or domestic phone number through which the responsible person (as described in section 379aa–1
of this title) may receive a report of a serious adverse event with such dietary supplement.


AMENDMENTS

2010—Par. (q)(5)(A)(ii). Pub. L. 111–148, §1203(a)(1), inserted “except as provided in clause (H)(i)(III), before ‘which is served’.”

Par. (q)(5)(A)(i). Pub. L. 111–148, §1205(a)(2), inserted “except as provided in clause (H)(ii)(III), before ‘which is processed’.”


2004—Par. (w), (x). Pub. L. 108–282 added pars. (w) and (x).


1997—Par. (r)(2)(B). Pub. L. 105–115, §305, amended cl. (B) generally. Prior to amendment, cl. (B) read as follows: “If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, the label or labeling shall contain, prominently and in immediate proximity to such claim, the following statement: ‘See nutrition information.’”


Par. (r)(3)(C), (D). Pub. L. 105–115, §303, added cl. (C) and (D).
1976—Par. (a). Pub. L. 94–271 inserted "(1)" after "1F" and inserted ", or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title" after "any particular".
1969—Par. (k). Pub. L. 86–537, §111, exempted pesticidal chemicals when used in or on a raw agricultural commodity which is the produce of the soil.
Par. (m). Pub. L. 86–618 added par. (m).
CHANGE OF NAME
Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.
Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

EFFECTIVE DATE OF 2006 AMENDMENT
"(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section [enacting section 379aa–1 of this title and amending this section and section 331 of this title] shall take effect 1 year after the date of enactment of this Act [Dec. 22, 2006]."
"(2) MISBRANDING.—Section 403(y) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(y)] (as added by this section) shall apply to any dietary supplement labeled on or after the date that is 1 year after the date of enactment of this Act [Dec. 22, 2006]."

EFFECTIVE DATE OF 2004 AMENDMENT
Amendment by Pub. L. 108–282 applicable to any food that is labeled on or after Jan. 1, 2006, see section 203(d) of Pub. L. 108–282, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

EFFECTIVE DATE OF 1994 AMENDMENT
Section 7(e) of Pub. L. 103–417 provided that: “ Dietary supplements—

"(1) may be labeled after the date of the enactment of this Act [Oct. 25, 1994] in accordance with the amendments made by this section [amending this section and section 350 of this title], and

"(2) shall be labeled after December 31, 1996, in accordance with such amendments.”

EFFECTIVE DATE OF 1990 AMENDMENT
“(1) Except as provided in paragraphs (2) and (3), the amendments made by section 7 [amending this section] shall take effect one year after the date of the enactment of this Act [Nov. 8, 1990].

“(2) If a food described in subparagraph (A)—

"(i) bears a label which was printed after July 1, 1991, and which is attached to the food before May 8, 1993, such food shall not be subject to the amendments made by this section [see
such food shall not be subject to the amendments made by section 7(a) and section 7(c) [amending this section].

“(3) A food purported to be a beverage containing a vegetable or fruit juice which bears a label attached to the food before May 8, 1993, shall not be subject to the amendments made by section 7(d) [amending this section].”

**CONSTRUCTION OF AMENDMENT BY PUB. L. 101–555**


**FINDINGS**


“(1) it is estimated that—

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

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

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

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

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

“(3)(A) in a review of 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

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

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

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

“(B) the current standard of treatment is avoidance of gluten in foods that are associated with celiac disease; and
"(C) a multicenter, multiyear study estimated that the prevalence of celiac disease in the United States is 0.5 to 1 percent of the general population."

REGULATIONS

Section 2(b) of Pub. L. 101-535, as amended by Pub. L. 102-571, title II, §202(a)(2)(A), (B), Oct. 29, 1992, 106 Stat. 4500, 4501, provided that:

"(I) The Secretary of Health and Human Services shall issue proposed regulations to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)] within 12 months after the date of the enactment of this Act [Nov. 8, 1990], except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section. Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement such section, except that the Secretary makes a finding that there has been no claim, or labeling of a food to remain the same or permit the label or labeling of food to include nutritional information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

(ii) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act,

(iii) shall, in defining terms used to characterize the level of any nutrient in food under section 403(r)(2)(A)(i) of such Act, define—

(1) free,

(II) low,

(III) light or lite,

(IV) reduced,

(V) less, and

(VI) high,

unless the Secretary finds that the use of any such term would be misleading, or the Secretary shall issue final regulations—

(A) require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet,

(B) include regulations which establish standards, in accordance with paragraph (1)(A), to define serving size or other unit of measure for food,

(C) permit the label or labeling of food to include nutritional information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

(D) permit the nutrition information on the label or labeling of a food to remain the same or permit the label or labeling of food to include nutritional information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

(E) permit the label or labeling of food to remain the same or permit the label or labeling of food to include nutritional information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

(F) permit the label or labeling of food to remain the same or permit the label or labeling of food to include nutritional information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

(G) shall not be required to be made for butter,

(H) shall not be required to be made for margarine,

(i) may, in defining terms under section 403(r)(2)(A)(i), include similar terms which are commonly understood to have the same meaning, and

(ii) may, in defining terms under section 403(r)(5)(D), the procedure and standard respecting the validation of claims made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances and shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(3) of such Act: Calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease,

(vii) shall not require a person who proposes to make a claim described in section 403(r)(1)(B) of such Act which is in compliance with such regulations to secure the approval of the Secretary before making such claim.

(viii) may permit a claim described in section 403(r)(2)(A)(i) of such Act to be made for butter,

(ix) may, in defining terms under section 403(r)(2)(A)(i), include similar terms which are commonly understood to have the same meaning, and

(x) may, in defining terms under section 403(r)(5)(D), the procedure and standard respecting the validation of claims made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances and shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(5)(D) of such Act: folic acid and neural tube defects, antioxidant [sic] vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease.

(B) Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section. Such regulations—
tional substances shall not be considered to be final
regulations until December 31, 1993. There shall be
promptly published in the Federal Register notice of
the new status of the proposed regulations [see 57 F.R.
56347]."

"For construction of amendment made by section
202(a)(2)(B) of Pub. L. 102–571 to section 3(b) of Pub. L.
101–535 set out above, see section 202(a)(2)(C) of Pub. L.
102–571 set out above following section 2(b) of Pub. L.
101–535."

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Adminis-
trator to Secretary of Health, Education, and Welfare
[now Health and Human Services], and of Food and
Drug Administration in the Department of Agriculture
to Federal Security Agency, see notes set out under
section 321 of this title.

RULEMAKING ON LABELING

910, provided that: "Not later than 2 years after the
date of enactment of this Act [Aug. 2, 2004], the Sec-
retary 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 Sec-
retary shall issue a final rule to define, as appropriate,
the current regulation governing the labeling of foods
that have been treated to reduce pest infestation or
diseases by irradiation using radioactive isotopes, elec-
tronic beam, or x-ray. Pending promulgation of the final
rule required by this subsection [probably should be
'this section'], any person may petition the Secretary
for approval of labeling of foods which have been treated
by irradiation using radioactive isotopes, electronic beam,
or x-ray. The Secretary shall approve or deny such a
petition within 180 days of receipt of the petition, or the
petition shall be deemed denied, except to the extent addi-
tional agency review is mutually agreed upon by the
Secretary and the petitioner. Any denial of a petition
under this subsection shall constitute final agency ac-
dion subject to judicial review by the United States
Court of Appeals for the District of Columbia Circuit.
Any labeling approved through the foregoing petition
process shall be subject to the provisions of the final
rule referred to in the first sentence of the subpara-
graph on the effective date of such final rule."

COMMISSION ON DIETARY SUPPLEMENT LABELS

910, provided that: "(a) Establishment.—There shall be established as
an independent agency within the executive branch a
commission to be known as the Commission on Dietary
Supplement Labels (hereafter in this section referred to as the 'Commission').

"(b) Membership.—

"(1) Composition.—The Commission shall be com-
posed of 7 members who shall be appointed by the
President.

"(2) Expertise Requirement.—The members of the
Commission shall consist of individuals with expert-
ise and experience in dietary supplements and in the
manufacture, regulation, distribution, and use of
such supplements. At least three of the members of
the Commission shall be qualified by scientific train-
ing and experience to evaluate the benefits to health
of the use of dietary supplements and one of such
three members shall have experience in pharmaco-
gnozy, medical botany, traditional herbal medicine, or
other related sciences. Members and staff of the Com-
mission shall be without bias on the issue of dietary
supplements.

"(c) Functions of the Commission.—The Commission
shall conduct a study on, and provide recommendations
for, the regulation of label claims and statements for
dietary supplements, including the use of literature in
connection with the sale or distribution of dietary supple-
ments and procedures for the evaluation of such claims. In mak-
ing such recommendations, the Commission shall
evaluate how best to provide truthful, scientifically
valid, and not misleading information to consumers so
that such consumers may make informed and appro-
priate health care choices for themselves and their
families.

"(d) Administrative Powers of the Commission.—

"(1) Hearings.—The Commission may hold hear-
ings, sit and act at such times and places, take such
testimony, and receive such evidence as the Commissi-
on considers advisable to carry out the purposes of
this section.

"(2) Information from Federal Agencies.—The Commissi-
on may secure directly from any Federal
department or agency such information as the Commissi-
on considers necessary to carry out the provi-
sions of this section.

"(3) Authorization of Appropriations.—There are
authorized to be appropriated such sums as may be
necessary to carry out this section.

"(e) Reports and Recommendations.—

"(1) Final report required.—Not later than 24
months after the date of enactment of this Act [Oct.
25, 1994], the Commission shall prepare and submit
its report to the President and to the Congress a final report on
the study required by this section.

"(2) Recommendations.—The report described in
paragraph (1) shall contain such recommendations,
including recommendations for legislation, as the
Commission deems appropriate.

"(3) Action on Recommendations.—Within 90 days
of the issuance of the report under paragraph (1), the
Secretary of Health and Human Services shall pub-
lish in the Federal Register a notice of any recom-
mendation of Commission for changes in regulations
of the Secretary for the regulation of dietary supple-
ments and shall include in such notice a notice of
proposed rulemaking on such changes together with
an opportunity to present views on such changes. Such
rulemaking shall be completed not later than 2
years after the date of the issuance of such report. If
such rulemaking is not completed on or before the
expiration of such 2 years, regulations of the Secretary
published in 50 FR 395–426 on January 4, 1994, shall
not be in effect."

EXTENSION OF COMPLIANCE DEADLINE FOR CERTAIN
FOOD PRODUCTS PACKAGED PRIOR TO AUGUST 8, 1994

"That before August 8, 1994, sections 403(q) and 403(r)(2)
343(q), (r)(2)] and the provision of section 403(1) of such
Act added by section 7(2) of the Nutrition Labeling and
Education Act of 1990 [Pub. L. 101–535], shall not apply
with respect to a food product which is contained in a
package for which the label was printed before May 8,
1994 (or before August 8, 1994, in the case of a juice or
milk food product if the person responsible for the la-
beling of such food product exercised due diligence in
obtaining before such date labels which are in compli-
ance with such sections 403(q) and 403(r)(2) and such
provision of section 403(1), if, before June 15, 1994, the
person who introduces or delivers for introduction such
food product into interstate commerce submits to the
Secretary of Health and Human Services a certification
that such person will comply with this section and will
comply with such sections 403(q) and 403(r)(2) and such
provision of section 403(1) after August 8, 1994."

LIMITATIONS ON APPLICATION OF SMALL BUSINESS
EXEMPTION

Section 2(a) of Pub. L. 103–80 provided that:
§ 343–1. National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, 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 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, 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 341 and 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title 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 343(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 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title 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 343(h)(1) of this title and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 343(q)(5)(H)(ix) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.