DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 304, 316, 317, 318, 319, 320, 327, 362, 381, 412 and 413

[Docket No. FSIS–2014–0024]

RIN 0583–AD56

Revision of the Nutrition Facts Labels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: Consistent with the recent changes that the Food and Drug Administration (FDA) finalized, the Food Safety and Inspection Service (FSIS) is proposing to amend the nutrition labeling requirements for meat (including fish of the order Siluriformes) and poultry products to better reflect the most recent scientific research and dietary recommendations and to improve the presentation of nutrition information to assist consumers in maintaining healthy dietary practices. FSIS is proposing to update the list of nutrients that are required or permitted to be declared; provide updated Daily Reference Values (DRVs) and Reference Daily Intake (RDI) values that are based on current dietary recommendations from consensus reports; and amend the labeling requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant women and lactating women and establish nutrient reference values specifically for these population subgroups. FSIS is also proposing to revise the format and appearance of the Nutrition Facts label; amend the definition of a single-serving container; require dual-column labeling for certain containers; and update and modify several reference amounts customarily consumed (RACCs or reference amounts). Finally, FSIS is proposing to consolidate the nutrition labeling regulations for meat and poultry products into a new Code of Federal Regulations (CFR) part.

DATES: Comments must be received by March 20, 2017.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov*. Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163B, Washington, DC 20250–3700.
- *Hand- or Courier-Delivered Submittals:* Deliver to Patriots Plaza 3, 355 E Street SW., Room 8–163B, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2014–0024. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov*.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8–164, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeff Canavan, Deputy Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Stop Code 3784, Patriots Plaza 3, 8–161A, 1400 Independence Avenue SW., Washington, DC 20250–3700; Telephone (301) 504–0879; Fax (202) 245–4792.

SUPPLEMENTARY INFORMATION:

Executive Summary

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) direct the Secretary of Agriculture to maintain meat and poultry product inspection programs designed to assure consumers that meat and poultry products distributed to them (including imports) are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. The FMIA and PPIA (''the Acts'') also provide that the labels of meat and poultry products must be approved by the Secretary of Agriculture, who has delegated this authority to FSIS, before these products can enter commerce. The Acts prohibit the sale or offer for sale by any person, firm, or corporation of any article in commerce under any name or other marking or labeling that is false or misleading or in any container of a misleading form or size (21 U.S.C 607(d); 21 U.S.C 457(c)). The Acts also prohibit the distribution in-commerce of meat or poultry products that are adulterated or misbranded. The FMIA and PPIA give FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the provisions of the Acts (21 U.S.C. 621 and 463(b)).

To prevent meat and poultry products from being misbranded, the meat and poultry product inspection regulations require that the labels of meat and poultry products include specific information, and that such information be displayed as prescribed in the regulations (9 CFR part 317 and part 381). The nutrition labeling requirements for meat and meat food products are in 9 CFR 317.300–317.400, and the nutrition labeling requirements for poultry products are in 9 CFR 381.400–381.500. The nutrition labeling regulations for meat and poultry products include requirements regarding: Location of nutrition information; labeling with number of servings; nutrition label content; reference amounts customarily consumed per eating occasion; and nutrient content claims.

On March 3, 2014, the Food and Drug Administration (FDA) published two proposed rules, ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (the ''FDA Nutrition Labeling Proposed Rule'')(79 FR 11880) and ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments'' (the ''FDA Serving Size Proposed Rule'')(79 FR 11989). FDA proposed these rules to update the Nutrition Facts label to reflect newer nutrition and public health research and recent dietary recommendations from expert groups and to improve the presentation of nutrition information to help consumers make more informed choices and maintain healthy dietary practices. On July 27, 2015, FDA published a supplemental notice of proposed rulemaking ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Notice of Proposed Rulemaking'' (the ''FDA Nutrition Labeling Supplemental Proposed Rule'') (80 FR 44303) to revise certain provisions of the FDA Nutrition Labeling Proposed Rule. On May 27, 2016, FDA published two final rules, ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (the ''FDA Nutrition Labeling Final Rule'')(81 FR 33742) and ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments'' (the ''FDA Serving Size Final Rule'') (81 FR 34000).

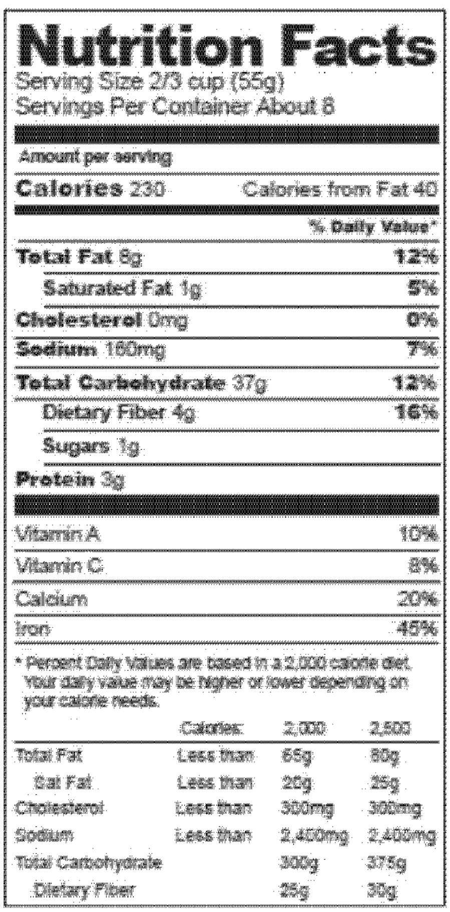
FSIS has reviewed FDA's analysis, and to ensure that there is consistency in how nutrition information is presented across the food supply, FSIS is proposing to amend the nutrition labeling regulations for meat and poultry products to parallel, to the extent possible, FDA's final regulations. This approach will clarify information for consumers and improve efficiency in the marketplace.

FSIS is proposing to consolidate the nutrition labeling regulations that currently are presented separately for meat and for poultry products (in 9 CFR 317.300–317.400 and 381.400–381.500, respectively) into a single part, 9 CFR part 413. Consistent with FDA's final regulations, FSIS is also proposing to update the list of nutrients that are required or permitted to be declared and to provide updated DRVs and RDIs that are based on current dietary recommendations from consensus reports. For example, FSIS is proposing to remove the requirement to declare ''Calories from Fat;'' require the declaration of ''Added Sugars,'' vitamin D, and potassium; permit the voluntary declaration of vitamins A and C; and update the reference value for the declaration of percent Daily Value (DV) for sodium from the current value of 2,400 mg (milligrams) to 2,300 mg. FSIS is also proposing to amend the requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant women and lactating women and establish nutrient reference values specifically for these population subgroups.

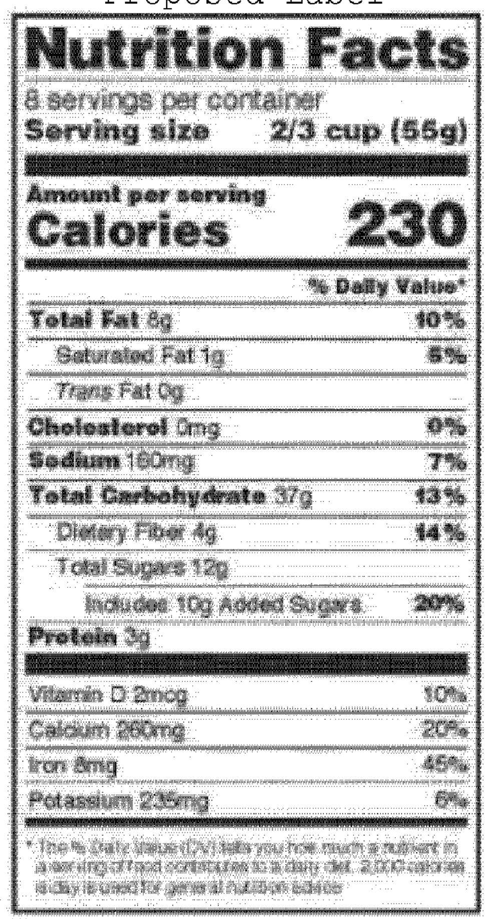
FSIS is also proposing to revise the format and appearance of the Nutrition Facts label. Some of the proposed changes include increasing the type size for ''Calories,'' ''servings per container,'' and the ''Serving size'' declarations, and bolding the number of calories and the ''Serving size'' declaration to highlight this information.

FSIS is also proposing to amend the definition of a single-serving container; require dual-column labeling for certain containers; and update and modify several RACCs. These proposed changes will provide consumers information to assist them in maintaining healthy dietary practices.

Current Label



Proposed Label



Summary of Costs and Benefits

Quantitative costs for the proposed rule include relabeling, recordkeeping, and reformulation. Quantitative benefits are a measure of expected health improvements experienced from increased label-use by overweight and hypertensive adults. The summary of cost and benefits in Table 1 are annualized at a 3 percent discount rate over 20 years with a compliance period of 24 months for large manufacturers and 36 months for small.

TABLE 1—SUMMARY OF COSTS AND BENEFITS

	Costs	Benefits	Net benefits
Annualized (3% Discount Rate, 20 Years)	$10,802,809	$36,894,007	$26,091,198
Annualized (7% Discount Rate, 20 Years)	14,603,562	22,541,264	7,937,702

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I. Background

The Nutrition Labeling and Education Act (NLEA) of 1990 required the nutrition labeling of most foods regulated by the FDA. Because FSIS is committed to providing consumers with the most informative labeling system possible, FSIS published regulations establishing comparable nutrition labeling requirements for meat and poultry products on January 6, 1993 (58 FR 632). These regulations required nutrition labels on the packages of all multi-ingredient and heat-processed meat and poultry products, unless an exemption applied. The required nutrition labeling provisions were referred to as ''the mandatory nutrition labeling program.'' The Agency's 1993 regulations also established guidelines for voluntary nutrition labeling of single-ingredient, raw meat and poultry products, including single-ingredient, raw ground or chopped products.

FSIS published technical amendments to the 1993 final rule (August 18, 1993, 58 FR 43787; September 10, 1993, 58 FR 47624; and March 16, 1994, 59 FR 12157), a final rule on the placement of nutrition labeling on meat and poultry products (August 8, 1994), a final rule with additional technical amendments to the nutrition labeling regulations (September 1, 1994; 59 FR 45189), and a final rule to provide codified language for provisions that previously cross-referenced FDA's nutrition labeling regulations on January 3, 1995 (60 FR 174). FSIS also published a final rule to require nutrition labeling of the major cuts of single-ingredient raw meat and poultry products and ground or chopped meat and poultry products on December 29, 2010 (75 FR 82164).

Currently, FSIS requires nutrition labels on the packages of all multi-ingredient and heat-processed meat and poultry products, and all ground or chopped products, unless an exemption applies (9 CFR 317.300; 317.301; 381.400; 381.401). FSIS also requires that nutrition information be provided on the label or at the point-of-purchase for the major cuts of single-ingredient, raw meat and poultry products identified in 9 CFR 317.344 and 381.444 that are not ground or chopped, except for certain exemptions. The following exemptions in 9 CFR 317.400 and 381.500 from the nutrition labeling requirements apply to the major cuts of single-ingredient, raw meat and poultry products and ground or chopped meat and poultry products:

- Products intended for further processing, provided that the labels for these products bear no nutrition claims or nutrition information;
- Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information;
- Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information;
- Products that are custom slaughtered or prepared; and
- Products intended for export.

FSIS also provides the following additional exemptions in 9 CFR 317.400 and 381.500 for ground or chopped products:

- Ground or chopped products that qualify for the small business exemption in 9 CFR 317.400(a)(1) or 381.500(a)(1);
- Products that are ground or chopped at an individual customer's request and that are prepared and served at retail, provided that the labels or labeling of these products bears no nutrition claims or nutrition information;
- Ground or chopped products in packages that have a total surface area for labeling of less than 12 square inches, provided that the product's labeling includes no nutrition claims or nutrition information and provided that an address or telephone number that a consumer can use to obtain the required information is included on the label; and
- Ground products produced by small businesses that use statements of percent fat and percent lean on the label or in labeling of ground products, provided they include no other nutrition claims or nutrition information on the product labels or labeling.

Generally, ready-to-eat products that are packaged and portioned at a retail store or similar retail-type establishment and multi-ingredient products (*e.g.,* sausage) processed at a retail store or similar retail-type establishment are exempt from nutrition labeling, provided that this exemption does not apply to ready-to-eat or multi-ingredient ground or chopped products described in 9 CFR 317.301 or 381.401. Restaurant menus also do not generally fall within the scope of FSIS's current nutrition labeling regulations (9 CFR 317.400 and 381.500). However, FDA requires that restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items disclose certain nutrition information for standard menu items (*see* ''Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments''; December 1, 2014; 79 FR 71155). FDA also requires that operators who own or operate 20 or more vending machines disclose calorie information for food sold from vending machines, subject to certain exemptions (*see* ''Food Labeling; Calorie Labeling of Articles of Food in Vending Machines''; December 1, 2014; 79 FR 71259).

FSIS does not require nutrition information for single-ingredient, raw meat and poultry products that are not major cuts and that are not ground or chopped. But, if nutrition information is provided for these products, it must be provided in accordance with the nutrition labeling requirements for the major cuts (9 CFR 317.300 and 381.400).

II. The Proposed Rule

Nutrition labeling continues to be an integral part of USDA's efforts to educate consumers about nutrition and diet. Since 1980, USDA and the Department of Health and Human Services (HHS) have jointly published the Dietary Guidelines for Americans (DGA) every five years. The 2015–2020 DGA provides advice on food choices that promote overall health, reduce the risk of chronic disease, and help individuals attain and maintain a healthy weight.[1] The nutrition labeling information that FSIS is proposing to require in this rule would assist consumers in maintaining healthy dietary practices. The information should also help consumers follow the advice in the 2015–2020 DGA.

For example, the 2015–2020 DGA concluded that some Americans do not consume enough vitamin D or potassium, and inadequate intake of these nutrients presents public health concerns (pages 60). Vitamin D is important for bone health, and potassium helps to reduce the effects of excess sodium on blood pressure. This proposed rule would require vitamin D and potassium to be declared on nutrition labels, to assist consumers in maintaining healthy dietary practices. Moreover, consistent with the 2015–2020 DGA, the information should help consumers follow the 2015–2020 DGA's

[1] U.S. Department of Agriculture and U.S. Department of Health and Human Services, 2015—2020 Dietary Guidelines for Americans, 8th edition, Washington, DC: U.S. Government Printing Office, December 2015. Available at *http://www.health.gov/dietaryguidelines/2015.asp.*

advice to select foods that provide more of these nutrients (page 60). Additionally, the 2015–2020 DGA does not consider low intake of vitamins A and C to be a major public health concern (page 60). Currently, vitamins A and C must be declared on the Nutrition Facts label, but this proposed rule would make their declaration voluntary.

This proposed rule also proposes changes to the Daily Values for certain nutrients, consistent with the more recent scientific evidence from the 2015–2020 DGA. For example, FSIS is proposing to amend the current DV for sodium of 2,400 to 2,300 mg, which is consistent with the scientific evidence reflected in the 2015–2020 DGA's recommendation to limit intake of sodium to less than 2,300 mg per day and is the upper limit for individuals ages 14 years and older set by the Institute of Medicine. (page 15). Revising DVs to reflect the most current science on nutrient requirements will help consumers choose a better overall diet.

The 2015–2020 DGA also supports listing added sugars on nutrition labels. It affirms that poor diet and physical inactivity are primary factors contributing to overweight, obesity, and chronic illness (pages 2–3). Calories from added sugars, solid fats (including saturated and *trans* fats), and refined grains replace nutrient-dense foods and make it difficult to consume sufficient nutrients while controlling caloric intake (page 14). FSIS is proposing to require that added sugars be listed on nutrition labels to assist consumers in selecting a more nutrient-dense diet while controlling the total number of calories consumed (see section II.E.3 for discussion of the rationale for the proposed changes).

Section 403(q)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q)(1)(A)) defines serving size as an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food. FSIS, consistent with FDA, is proposing to update, modify, and establish certain RACCs and require that packages which contain more than 150 percent and less than 200 percent of a given RACC be labeled as containing one serving, regardless of the RACC of the product. Certain packages that contain at least 200 percent and up to and including 300 percent of a given RACC would be required to include dual column labels that provide nutrition information per serving or per package, as applicable. These changes will ensure that serving sizes are based on current consumption data and will provide consumers with information on the Nutrition Facts label related to the serving size that will assist them in maintaining healthy dietary practices.

Finally, FSIS is proposing several updates to the design of the current Nutrition Facts labels, including making the caloric content and serving size declarations more prominent. These and other changes aim to address current public health problems such as obesity, chronic disease, and nutrient deficiency by emphasizing important nutritional information and providing additional information to consumers.

A. Consolidating the Nutrition Labeling Requirements Into 9 CFR Part 413

Currently, the nutrition labeling regulations for meat and poultry products are presented separately (in 9 CFR 317.300–317.400 and 381.400–381.500, respectively). FSIS believes that the public would be better served by consolidating these regulations in one part of title 9. Rather than searching through two separate parts of title 9–CFR parts 317 and 381— to find the nutrition labeling regulations, interested parties would only have to read part 413. Therefore, FSIS is proposing to consolidate the nutrition labeling regulations for meat and poultry products into a single part, 9 CFR part 413.

B. Calories

FSIS requires the total number of calories per serving of a meat or poultry product to be declared on the Nutrition Facts label (9 CFR 317.309(c)(1); 9 CFR 381.409(c)(1); and proposed 9 CFR 413.309(c)(1)). FSIS is not proposing to change this requirement but is proposing changes to the requirements related to ''Calories from fat'' and ''Calories for saturated fat.''

1. Calories from Fat

FSIS currently requires that ''Calories from Fat'' be declared on Nutrition Facts labels (9 CFR 317.309(c)(1)(ii); 9 CFR 381.409(c)(1)(ii)). FSIS is proposing to no longer require, and to not allow voluntarily, the declaration of ''Calories from fat'' on the Nutrition Facts label.

Section 403(q)(2)(B) of the FD&C Act (21 U.S.C. 343(q)(2)(B)) grants the Secretary of HHS (and by delegation, FDA) discretion to remove information relating to a nutrient required to be declared on food labels by regulation if the Secretary determines that it is not necessary to assist consumers in maintaining healthy dietary practices. FDA considered a number of factors related to the declaration of ''Calories from Fat,'' including dietary recommendations and consensus reports that emphasize intake of total calories and the type of fat consumed, as well as comments from their 2005 and 2007 Advanced Notices of Proposed Rulemaking (ANPRMS) (April 4, 2005, 70 FR 17008; November 2, 2007; 72 FR 62149) that supported eliminating the declaration of ''Calories from fat'' in order to place greater emphasis on total calories. FDA determined that the declaration of ''Calories from fat'' is not necessary to assist consumers in maintaining healthy dietary practices (81 FR 33780). Under FDA's Nutrition Labeling Final Rule, FDA no longer requires, and does not allow voluntarily, the declaration of ''Calories from fat'' on the Nutrition Facts label (81 FR 33780). FSIS has reviewed FDA's analysis and has tentatively concluded that the declaration of ''Calories from fat'' is not necessary to assist consumers in maintaining healthy dietary practices. FSIS agrees with FDA that ''the amount of fat being consumed can still be obtained from the total fat declaration elsewhere on the Nutrition Facts label, and consumers can still use the percent DV for total fat to put fat content in the context of a total daily diet, compare products, and plan diets'' (79 FR 11891; 81 FR 33780).

2. Calories From Saturated Fat

Under current FSIS regulations, the declaration of ''Calories from saturated fat'' on the Nutrition Facts label is voluntary (9 CFR 317.309(c)(1)(iii); 9 CFR 381.409(c)(1)(iii); will be consolidated in proposed 9 CFR 413.309(c)(1)(ii)). FSIS continues to believe that ''Calories from saturated fat'' can be declared voluntarily. The amount of saturated fat can be obtained from the total saturated fat declaration on the Nutrition Facts label, and consumers can use the percent DV for saturated fat to put saturated fat content in the context of a total daily diet, compare products, and plan diets (79 FR 11892; 81 FR 33781). Therefore, FSIS does not believe it is necessary to require the mandatory declaration of ''Calories from saturated fat'' on the Nutrition Facts label. But with the revisions to the Nutrition Facts label, FSIS is proposing to require that ''Calories from saturated fat'' be indented when declared under the statement of calories (proposed 9 CFR 413.309(c)(1)(ii)).

3. Two Thousand Calories as the Reference Caloric Intake Level

FSIS regulations (9 CFR 317.309(c)(9) and 381.409(c)(9)) set a percent DRV for fat, saturated fatty acids, cholesterol, total carbohydrate, fiber, sodium, potassium, and protein, based on a reference caloric intake of 2,000 calories. Just as FDA did not make any changes to the reference calorie intake, FSIS is not proposing any changes to the reference caloric intake currently used to set the DRVs under 9 CFR 317.309(c)(9) and 381.409(c)(9) (which will both be consolidated in proposed 9 CFR 413.309(c)(9)).

FDA considered a number of factors related to the reference calorie intake of 2,000 calories, including the relevant recommendations from the IOM macronutrient report [2] that provided estimated energy requirements, the IOM Labeling Report,[3] and the comments regarding the 2,000 calorie reference intake level received in response to FDA's 2007 ANPRM (79 FR 11892). FDA decided not to propose changes to the reference calorie intake level (81 FR 33782). ''The IOM Labeling Committee concluded that retaining the current 2,000 reference calorie intake level would be the best approach as it would provide continuity and would not encourage higher calorie intake and overconsumption of energy'' (79 FR 11892). FSIS agrees with FDA and the recommendation of the IOM Labeling Committee.

4. Percent Daily Value (DV) Declaration for Calories

FSIS's current regulations do not establish a DRV for calories and do not require a percent DV declaration for calories. FDA reviewed recommendations in current consensus reports, including the IOM macronutrient report,[4] and comments received in response to their 2005 and 2007 ANPRMs (79 FR 11892, 11893). FDA decided not to require a percent DV for total calories because of a lack of an appropriate quantitative intake recommendation or other data or information on which FDA could rely to establish a DRV for calories (81 FR 33782). FSIS agrees with FDA's conclusion.

C. Fat

1. Total Fat

a. Definition and Mandatory Declaration

FSIS is not proposing any changes to its definition of ''total fat'' under 9 CFR 317.309(c)(2) and 381.409(c)(2) (which will both be consolidated in proposed 9 CFR 413.309(c)(2)). FSIS is proposing to define ''fatty acids'' in 9 CFR 413.309(c)(2) as aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group to harmonize with FDA's Nutrition Labeling Final Rule and clarify what FSIS considers to be a fatty acid. FSIS is not proposing to change the requirement for mandatory declaration for total fat on the Nutrition Facts label.

b. DRV

FSIS's regulations 9 CFR 317.309(c)(9) and 381.409(c)(9), which would be consolidated in proposed 9 CFR 413.309(c)(9), set 65 grams as the DRV for total fat based on a reference calorie intake of 2,000 calories (*i.e.,* 30 percent of a 2,000 calorie diet). In FDA's Nutrition Labeling Final Rule, FDA increased the DRV for total fat to 78 grams, or 35 percent of a 2,000 calorie diet. The upper level of the IOM Acceptable Macronutrient Distribution Range (AMDR) [5] for total fat for adults is 35 percent and serves as an appropriate basis on which to set the DRV for total fat (81 FR 33784). FDA reviewed new information and evidence that corroborated the position that the types of fats consumed are more important in influencing the risk of heart disease than is the total amount of fat (81 FR 33784). FDA stated that keeping the DRV for total fat at 30 percent of calories could be misinterpreted as advising consumers to limit their intake of total fat to 30 percent or less, and that it is conceivable that consumers could view foods that are good sources of mono and polyunsaturated fats negatively because their percent DV declaration for total fat is high (81 FR 33784). FSIS agrees with FDA's analysis, and is proposing to increase the DRV for total fat from 30 percent of calories to 35 percent of calories for a DRV of 78 grams.

2. Saturated Fat

a. Definition

FSIS regulations currently define ''Saturated fat'' as the sum of all fatty acids, including stearic acid, containing no double bonds (*see* 9 CFR 317.309(c)(2)(i); 381.409(c)(2)(i); and 21 CFR 101.9(c)(2)(i)). However, in FSIS's 1993 Nutrition Labeling of Meat and Poultry Products final rule, based on requests from the red meat industry and the scientific knowledge in 1993 that stearic acid did not have the same serum cholesterol-raising effects of the other three saturated fatty acids, myristic, palmitic, and lauric acids, FSIS provided for the voluntary declaration of stearic acid as a subcomponent of saturated fat (58 FR 641). FDA had no similar request for the voluntary listing of stearic acid and did not provide for such listing.

In FDA's Nutrition Labeling Proposed Rule, FDA considered voluntary declaration of stearic acid on the Nutrition Facts label, as recommended by a few comments to their 2007 ANPRM (79 FR 11894). The effects of stearic acid on Low-density lipoprotein (LDL) cholesterol levels appear to vary depending on the macronutrient component that is replaced by stearic acid (79 FR 11894). FDA found that moderate evidence indicates that when stearic acid substitutes for other saturated fatty acids or *trans* fat, plasma LDL cholesterol levels decrease, whereas when it replaces monounsaturated or polyunsaturated fatty acids, LDL cholesterol levels increase (79 FR 11894). Considering such scientific data, the *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans,* 2010 (2010 DGAC),[6] concluded that the potential effects of changes in dietary intake of stearic acid on the risk of CVD remain unclear (79 FR 11894). In FDA's Nutrition Labeling Proposed Rule, FDA tentatively concluded that the individual declaration of stearic acid is not necessary to assist consumers in maintaining healthy dietary practices, and proposed to not permit the declaration on the Nutrition Facts label (79 FR 11894). FDA addressed the evidence for a role of stearic acid in human health (*e.g.,* changes in plasma LDL cholesterol levels), which is not well-established, and the fact that there is no quantitative intake recommendation available for stearic acid (*Id.*) In FDA's final rule, FDA did not exclude stearic acid from the calculation of the percent DV for

[2] Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 5: Energy'', Washington, DC: National Academies Press; 2002.

[3] The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.

[4] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*-α-tocopherol.

[5] ''The AMDR for a macronutrient is based on the amount of the macronutrient that is associated with a reduced risk of chronic disease while providing adequate intakes of essential nutrients'' (79 FR 11886).

[6] U.S. Department of Agriculture and U.S. Department of Health and Human Services. (2010) ''Report of the Dietary Guidelines Advisory Committee on the *Dietary Guidelines for Americans, 2010*'', Washington, DC: U.S. Government Printing Office. Retrieved from *http://www.cnpp.usda.gov/dietary-guidelines-2010.*

saturated fat because the scientific evidence supporting the current dietary recommendations for saturated fat does not differentiate among the individual saturated fatty acids (81 FR 33786).

Based on this updated scientific information and the fact that few if any companies have included stearic acid as a voluntary nutrient in the current Nutrition Facts label, FSIS is proposing to remove the voluntary declaration of stearic acid below saturated fat.

Also, consistent with FDA's final rule, FSIS is not proposing to exclude acetic, propionic, and butyric acids from the definition of saturated fat.

b. Mandatory Declaration

FSIS requires the mandatory declaration of the number of grams of saturated fat per serving (9 CFR 317.309(c)(2)(i) and 381.409(c)(2)(i) will be consolidated in proposed 9 CFR 413.309(c)(2)(i)). FSIS is not proposing to change this requirement because FSIS is unaware of any evidence that supports that this information is no longer needed to assist consumers in maintaining healthy dietary practices.

c. Dietary Reference Value (DRV)

FSIS's regulations 9 CFR 317.309(c)(9) and 381.409(c)(9), which will be consolidated in proposed 9 CFR 413.309(c)(9), set 20 grams as the DRV for saturated fat based on a reference calorie intake of 2,000 calories. FSIS is not proposing to change the DRV for saturated fat.

FDA reviewed the IOM Labeling Committee recommendation,[7] the comments in response to their 2007 ANPRM, and current consensus reports relating to the DRV for saturated fat, and stated that ''the existing scientific evidence does not support a change to the current 20 g DRV'' for saturated fat (79 FR 11895–11896). FDA determined ''the existing DRV of 20 grams is consistent with the scientific evidence supporting a maximum intake level that covers the general U.S. population.'' (81 FR 33786). FSIS has reviewed FDA's analysis and has tentatively concluded not to change the DRV for saturated fat.

3. Trans Fat

On July 11, 2003, FDA published a final rule requiring manufacturers to declare *trans* fatty acids, or *trans* fat, on the Nutrition Facts label of conventional foods and some dietary supplements (68 FR 41461). At that time, FSIS published information on its Web site stating that FSIS was planning rulemaking on *trans* fat label declarations to consider provisions in the meat and poultry regulations that are consistent with FDA's rules.[8] In the interim, FSIS has not objected to the voluntary declaration of *trans* fat in Nutrition Facts labels on food products under its jurisdiction if the declaration is made in accordance with FDA regulations published in the **Federal Register** on July 11, 2003, that amended 21 CFR part 101. There are no FDA or FSIS provisions for claims regarding *trans* fatty acids. Thus, any labeling that includes a statement regarding *trans* fatty acids that is outside of and in addition to the Nutrition Facts label declaration would need to be submitted to FSIS (the Labeling and Program Delivery Staff (LPDS)) for evaluation. To date, FSIS has not permitted any claims regarding *trans* fatty acids.

Based on FSIS's label review, FSIS believes that the majority of meat and poultry product Nutrition Facts labels voluntarily declare *trans* fat. However, because FSIS is now proposing major modifications to the Nutrition Facts label, FSIS believes it is time to address the need for *trans* fat labeling on meat and poultry products. According to FDA's Nutrition Labeling Proposed Rule, *trans* fat continues to be a nutrient with public health significance because of its role in chronic disease (79 FR 11896). FDA is unaware of evidence to support a determination that information relating to *trans* fat on the Nutrition Facts label is not necessary to assist consumers in maintaining healthy dietary practices (79 FR 11896). FDA tentatively concluded that information on the amount of *trans* fat in food products allows consumers to reduce their intake of trans fat and thus reduce the risk of coronary heart disease (CHD) (79 FR 11896). However, in 2013, FDA published a tentative determination that partially hydrogenated oils (PHOs), the source of industrially produced *trans* fat, may not be generally recognized as safe (GRAS)(78 FR 67169; November 8, 2013). FDA requested comment on whether mandatory labeling of *trans* fat would still be necessary if this determination is finalized (79 FR 11896). Per 21 CFR 101.9(c)(2)(ii), if a food contains less than 0.5 g of *trans* fat per serving, the content, when declared, is to be expressed as zero. On June 17, 2015, FDA published a final determination that there is no longer a consensus among qualified experts that PHOs, which are the primary dietary source of industrially-produced *trans* fatty acid are GRAS for any use in human food and therefore are food additives subject to section 409 of the FD&C Act (80 FR 34650). FDA has set a compliance period of three years for companies to either reformulate products without PHOs or petition FDA to permit specific uses of PHOs. Following the compliance period, no PHOs can be added to human food unless they are otherwise approved by FDA. In FDA's Nutrition Labeling Final Rule, FDA did not make any changes to the requirement for mandatory declaration of *trans* fat on the Nutrition Facts label in 21 CFR 101.9(c)(2)(ii), stating ''it is premature to consider removing trans fat from the Nutrition Facts label at this time.'' (81 FR 33786–88).

Although FDA's final determination that PHOs are not GRAS for use in any human food may eliminate the source of industrially produced *trans* fat, FSIS recognizes that there are *trans* fats caused by the way that some animals, such as cattle, sheep and goats, digest their food (the ruminating process). Consistent with FDA's Nutrition Labeling Final Rule (81 FR 33786–33787), FSIS is proposing to require the declaration of *trans* fat in the Nutrition Facts label (proposed 9 CFR 413.309(c)(2)(ii)). The mandatory declaration of *trans* fat will assist consumers in making informed choices and maintaining healthy dietary practices.

4. Polyunsaturated Fat

a. Voluntary Declaration

FSIS permits the voluntary declaration of the number of grams of polyunsaturated fat per serving (defined as *cis, cis*-methylene interrupted polyunsaturated fatty acids) on the Nutrition Facts label (9 CFR 317.309(c)(2)(ii) and 381.409(c)(2)(ii), which will be consolidated in proposed 9 CFR 413.309(c)(2)(iii)). FDA considered current consensus reports and comments received in response to their 2007 ANPRM when deciding to propose to continue to permit the voluntary declaration of polyunsaturated fat on the Nutrition Facts label (79 FR 11897; 81 FR 33788). FDA recognized that, although polyunsaturated fat is related to public health as a replacement for saturated fat, there is no dose-response relationship between polyunsaturated fat and risk of CHD, independent of saturated fat, and therefore continued to permit the voluntary declaration of polyunsaturated fat (81 FR 33788–89). FSIS has reviewed FDA's analysis and agrees with its conclusion and therefore,

[7] Institute of Medicine (IOM) of the National Academies, ''Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification'', Washington, DC: National Academies Press; 2003.

[8] *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/trans-fat-declarations.*

is not proposing to make any changes to the voluntary declaration of polyunsaturated fat. Polyunsaturated fat has public health significance because replacing saturated fatty acids with polyunsaturated and monounsaturated fatty acids reduces blood LDL cholesterol levels and in turn the risk of cardiovascular disease (CVD).[9] Polyunsaturated fat is a macronutrient, not an essential vitamin or mineral, does not have a quantitative intake recommendation, but does have public health significance. Therefore, FSIS believes it is appropriate to continue to permit the voluntary declaration of polyunsaturated fat consistent with FDA's final rule.

b. DRV

FSIS's regulations do not provide a DRV for polyunsaturated fat. FDA did not propose a DRV for polyunsaturated fat, tentatively concluding ''that there is no appropriate quantitative intake recommendation to form a basis for setting a DRV for polyunsaturated fat'' (79 FR 11898). FDA did not change its position in the final rule (81 FR 33789). Consistent with FDA's final rule, FSIS is not proposing to provide a DRV for polyunsaturated fat.

c. Declaration of Individual Polyunsaturated Fatty Acids

FSIS's regulations do not permit the declaration of individual polyunsaturated fatty acids on the Nutrition Facts label. Consistent with FDA's final rule, FSIS is not proposing to provide for the individual declaration of either *n*-3 or *n*-6 polyunsaturated fatty acids or the declaration of eicosapentaeneoic acid (EPA) or docosahexaenoic acid (DHA) on the Nutrition Facts label (81 FR 33789).

5. Monounsaturated Fat

a. Voluntary Declaration

FSIS's regulations currently allow the voluntary declaration of monounsaturated fat (defined as *cis*-monounsaturated fatty acids (*e.g.,* oleic acid)) on the Nutrition Facts label (9 CFR 317.309(c)(2)(iii) and 381.409(c)(2)(iii), which would be consolidated in proposed 9 CFR 413.309(c)(2)(iv)). Consistent with FDA's final rule, FSIS is not proposing to change the voluntary declaration of monounsaturated fat (81 FR 33788).

b. DRV

FSIS's regulations do not provide a DRV for monounsaturated fat. FDA did not provide a DRV for monounsaturated fat for the same reasons it did not set a DRV for polyunsaturated fat (81 FR 33789). Consistent with FDA's final rule, FSIS is not proposing to set a DRV for monounsaturated fat.

D. Cholesterol

1. Mandatory Declaration

FSIS's regulations require the amount of cholesterol be declared on the Nutrition Facts label (9 CFR 317.309(c)(3) and 381.409(c)(3), which would be consolidated in proposed 9 CFR 413.309(c)(3)). Consistent with FDA's final rule, FSIS is not proposing changes to the requirement for mandatory declaration of cholesterol.

2. DRV

FSIS sets 300 mg as the DRV for cholesterol based on the reference calorie intake of 2,000 calories (9 CFR 317.309(c)(9) and 381.409(c)(9), which would be consolidated in proposed 9 CFR 413.309(c)(9)). FSIS is not proposing to change the DRV for cholesterol.

E. Carbohydrate

1. Total Carbohydrate

a. Calculation of Total Carbohydrate

FSIS requires the number of grams of total carbohydrate per serving be listed on the Nutrition Facts label (9 CFR 317.309(c)(6) and 381.409(c)(6), which would be consolidated in proposed 9 CFR 413.309(c)(6)). Total carbohydrate content must be calculated by subtracting the sum of the crude protein, total fat, moisture, and ash from the total weight of the product (9 CFR 317.309(c)(6) and 381.409(c)(6), which would be consolidated in proposed 9 CFR 413.309(c)(6)).

FDA considered a citizen petition requesting that dietary fiber be excluded from the calculation of total carbohydrate, comments received on its 2007 ANPRM, and scientific evidence and declined to change the current method for calculating total carbohydrate (79 FR 11899–11900; 81 FR 33794–33795). Just as FDA is not making any change, FSIS has reviewed FDA's analysis and has decided not to propose to change the current method for calculating total carbohydrate.

b. Classification of Carbohydrates Based on a Chemical Definition or Physiological Effect

FSIS is not proposing to change its requirements for the classification or declaration of carbohydrates (9 CFR 317.309(c)(6) and 381.409(c)(6), which would be consolidated in proposed 9 CFR 413.309(c)(6)). FSIS agrees with FDA that a chemical definition for total carbohydrate is still consistent with the classification and declaration of fat on the Nutrition Facts label (79 FR 11901; 81 33795). It would be difficult to apply a definition for total carbohydrates based on physiological effects because the different components of carbohydrates have different physiological effects.

c. Separate Declaration of Additional Individual Types of Carbohydrates

FSIS is not proposing to require the separate declaration of additional types of individual carbohydrates (*e.g.,* starch) because, as FDA also concluded, the comments to the 2007 ANPRM did not support the declaration of additional types of carbohydrates, such as starch (81 FR 33795).

d. Mandatory Declaration

FSIS requires the number of grams of total carbohydrate per serving be listed on the Nutrition Facts label (9 CFR 317.309(c)(6) and 381.409(c)(6), which would be consolidated in proposed 9 CFR 413.309(c)(6)), and has tentatively concluded, that the mandatory declaration of total carbohydrates continues to be necessary to assist consumers in making informed choices. Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to change the requirement for mandatory declaration of total carbohydrate.

e. DRV

FSIS sets 300 grams as the DRV for total carbohydrate based on 60 percent of a 2,000 calorie diet ((0.60 × 2,000 calories)/4 calories per gram of carbohydrate = 300 grams) (9 CFR 317.309(c)(9) and 381.409(c)(9), which would be consolidated in proposed 9 CFR 413.309(c)(9)). The percentage of calories from total carbohydrate, total fat, and protein must add up to 100 percent on the Nutrition Facts label. Because, as discussed in part (II)(C)(1), FSIS is proposing to increase the DRV for total fat from 30 to 35 percent of calories consistent with FDA's final rule, either the DRV for total carbohydrate or protein must be decreased. As discussed in FDA's Nutrition Labeling Final Rule, decreasing the DRV for protein from 10 percent of calories to 5 percent of calories to account for the increase in the DRV for total fat would result in a DRV of 5 grams of protein, which falls below the RDA for protein for children

[9] U.S. Department of Agriculture and U.S. Department of Health and Human Services. (2010) ''Report of the Dietary Guidelines Advisory Committee on the *Dietary Guidelines for Americans, 2010*'', 4 . Washington, DC: U.S. Government Printing Office. Retrieved from *http://www.cnpp.usda.gov/dietary-guidelines-2010.*

and adults 9 years and older (81 FR 33784). Therefore, consistent with FDA's final rule, FSIS is proposing to decrease the DRV for total carbohydrate from 60 percent of calories to 55 percent of calories for a DRV of 275 grams to account for the increase in the DRV for total fat.

f. Calculation of Calories From Carbohydrate

FSIS requires that calories from total carbohydrate be calculated using the general factor of 4 calories per gram total carbohydrate less the amount of insoluble dietary fiber (9 CFR 317.309(c)(1)(i)(C) and 381.409(c)(1)(i)(C)). Consistent with FDA's final rule, FSIS is proposing a new definition for dietary fiber (see section II.E.5) that only allows for the declaration of dietary fibers that FDA has determined to have a physiological effect that is beneficial to human health. The new definition of dietary fiber includes: (1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; and (2) isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. For the purpose of calculating calories from carbohydrate, all soluble and insoluble non-digestible carbohydrates should be excluded from the calculation, not just those known to meet the definition of dietary fiber. Therefore, FSIS is proposing that all soluble and insoluble non-digestible carbohydrates be excluded from the calculation for calories from total carbohydrate (proposed 9 CFR 413.309(c)(1)(i)(C)).

2. Sugars

a. Mandatory Declaration

FSIS requires a statement of the number of grams of sugars per serving on the Nutrition Facts label, except for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content (9 CFR 317.309(c)(6)(ii) and 381.409(c)(6)(ii); would be consolidated in proposed 9 CFR 413.309(c)(6)(ii)). FSIS defines sugars as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose) (9 CFR 317.309(c)(6)(ii) and 381.409(c)(6)(ii)). Consistent with FDA's final rule, FSIS has tentatively concluded that the mandatory declaration of sugars continues to be necessary to assist consumers in making informed choices and maintaining healthy dietary practices. But, FSIS is proposing to replace the declaration of ''Sugars'' with the term ''Total Sugars,'' which is also consistent with FDA's final rule. The rationale for this proposed change is discussed in part K(5).

b. DRV

FSIS's regulations do not provide a DRV for sugars. FDA did not propose a DRV for sugars because there are no upper limits or set dietary reference values on which a DRV for sugars could be based (79 FR 11902). Consistent with FDA's final rule, FSIS is not proposing to set a DRV for sugars.

3. Added Sugars

a. Declaration

FSIS's regulations do not define ''added sugars'' nor permit its declaration on the Nutrition Facts label. FDA is requiring the declaration of added sugars on the Nutrition Facts label and considered, in its review, new data and information from U.S. consensus reports and scientific evidence supporting recommendations related to the consumption of added sugars, a citizen petition, and public comments (79 FR 11902–11906; 81 FR 33799–33851) and FDA's consumer study on added sugars [10] (80 FR 44306). FSIS has reviewed FDA's analysis and is also proposing to require the declaration of added sugars on the Nutrition Facts label to provide consumers with the information they need to make more informed choices and meet the dietary recommendation to reduce caloric intake from added sugars. FSIS is proposing changes consistent with FDA's final rule. FSIS is proposing to require the mandatory declaration of added sugars as an indented line item underneath the declaration of ''Total Sugars'' on the Nutrition Facts label. FSIS is also proposing that the phrase ''Not a significant source of added sugars'' be placed at the bottom of the table of nutrient values if a statement of the added sugars content is not required and, as a result, is not provided. FSIS is also proposing that a statement of added sugars content would not be required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content (proposed 9 CFR 413.309(c)(6)(iii)). FSIS is also proposing to permit alternative statements for added sugars similar to the current alternative statements for total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugars, and sugar alcohol, when a serving contains less than 1 gram of the nutrient. Proposed 9 CFR 413.309(c)(6)(iii) would provide for the alternative statements ''Contains less than 1 gram'' or ''less than 1 gram,'' or, if the serving contains less than 0.5 g of added sugars, the content can be expressed as zero.

b. Proposed Definition

FSIS regulations do not currently define the term ''added sugars.'' Because FSIS is proposing to require the mandatory declaration of added sugars on the Nutrition Facts label, FSIS is also proposing to define the term ''added sugars.'' Proposed 9 CFR 413.309(c)(6)(iii) defines ''added sugars'' as sugars that are either added during the processing of foods or are packaged as such and include sugars (free, mono- and disaccharides), sugars from syrups, honey, and fruit juice concentrates (see proposed 9 CFR 413.309(c)(6)(iii) for specific requirements for fruit juice concentrates) (see proposed 9 CFR 413.309(c)(6)(iii) for the complete ''added sugars'' definition). Examples of ''added sugars'' added to meat and poultry products include: Table sugar, brown sugar, corn sweetener, corn syrup, dextrose, fructose, apple juice concentrate glucose, Glucono-Delta-Lactone (GDL), high-fructose corn syrup, invert sugar, lactose, maltose, malt sugar, maple syrup, molasses, raw sugar, turbinado, sugar, trehalose, and sucrose. Sugar alcohols would not be considered added sugars.

c. Daily Value

FDA established a DRV for added sugars of 10 percent of total energy intake based on new information in the ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee'' (the ''2015 DGAC report'' [11]) regarding added sugars (80 FR 44308; 81 FR 33842). Consistent with FDA's final rule, FSIS is proposing a DRV for added sugars of 50 g for children and adults 4 years of age and older, including pregnant women and lactating women, and that the percent DV for added sugars be declared on the Nutrition Facts label. As discussed in FDA's supplemental proposed rule, the 2015 DGAC report recommended reducing the intake of added sugars, including an added sugars declaration and a percent DV for added sugars declaration in the Nutrition Facts label, and recommended that Americans keep added sugars intake below 10 percent of total energy intake (80 FR

[10] U.S. Food and Drug Administration. Memorandum to the File—''Experimental study on consumer responses to Nutrition Facts labels with declaration of amount of added sugars (OMB No. 0910–0764),'' 2015.

[11] *http://www.health.gov/dietaryguidelines/2015-scientific-report/.*

44308). FSIS's proposed DRV of 50 g for added sugars was determined by taking 10 percent of the 2,000 reference calorie intake for adults and children 4 years of age and older (.10 × 2,000 = 200 calories) and then dividing by 4 calories/gram, which provides a 50 g reference amount for added sugars as the DRV.

d. Compliance

FSIS is not aware of an analytical method that is capable of distinguishing between added and intrinsically occurring sugars in a food product, nor did FDA identify such a method (79 FR 11906). Therefore, to verify compliance with the proposed mandatory declaration of added sugars, FSIS is proposing in 9 CFR 413.309(h)(8)(iv) that establishments make and keep certain records to verify the amount of added sugars in the product (see compliance section II.N. below for more details about this requirement). For example, FSIS is proposing that a manufacturer must make and keep written records of the amount of sugars added to the product during the processing of the product and, if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient).

FSIS is aware that sugars in some foods may undergo chemical changes as a result of non-enzymatic browning (*i.e.,* Maillard reactions and caramelization) or fermentation during food processing. Some sugars are metabolized or otherwise transformed and converted into compounds that are no longer recognizable or detectable as sugars through conventional analytical methods.[12] As FDA concluded, FSIS expects that the amount of added sugars transformed during non-enzymatic browning reactions in most products is insignificant relative to the initial levels of sugars (81 FR 33830–33831). Unlike browning reactions, fermentation is a process that typically involves the action of desirable microorganisms (*e.g.,* yeasts and lactic acid bacteria) and enzymes that convert organic compounds, especially sugars and other carbohydrates, into simpler compounds such as carbon dioxide, lactic acid, and ethyl alcohol.[13 14] Fermented sausages are one example of a fermented meat product and include certain types of pepperoni, salami, Lebanon bologna, mettwurst, and certain types of chorizo. Fermentation can affect the flavor, color, and microbiological safety of meat products. Both natural and controlled meat fermentation involve lactic acid bacteria. This type of bacteria converts naturally occurring glycogen and added sugars into lactic acid. This conversion reduces the amount of sugar in a meat product.[15] However, FSIS expects that the majority of manufacturers would be able to use the amount of sugars added as an ingredient as a reasonable approximation of the amount of added sugars in a serving of their product. When the amount of added sugars is reduced through non-enzymatic browning or fermentation, FSIS is proposing in 9 CFR 413.309(h)(8)(v) to require: (1) Records of scientific data and information that demonstrate the amount of added sugars in the food after non-enzymatic browning or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food manufactured; or (2) records of the amount of sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label.

In some food products, non-enzymatic browning or fermentation could result in a significant reduction in the amount of added sugars, leaving manufacturers with no way to reasonably approximate the amount of added sugars in a serving of the finished food. Similar to FDA, FSIS is proposing that manufacturers may submit a request to FSIS's LPDS to use an alternative means of compliance. The request must provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning or fermentation.

4. Sugar Alcohols

For nutrition labeling purposes, consistent with FDA, FSIS defines sugar alcohols ''as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (*e.g.,* mannitol or xylitol) or is generally recognized as safe (*e.g.,* sorbitol)'' (9 CFR 317.309(c)(6)(iii) and 381.409(c)(6)(iii), which would be consolidated in proposed 9 CFR 413.309(c)(6)(iv)). Consistent with FDA, FSIS permits the voluntary declaration of sugar alcohols on the Nutrition Facts label (9 CFR 317.309(c)(6)(iii) and 381.409(c)(6)(iii)). FSIS is not proposing to change the voluntary declaration of sugar alcohols on the Nutrition Facts label, just as FDA did not.

a. DRV

Consistent with FDA, FSIS does not provide a DRV for sugar alcohols and is not proposing a DRV for sugar alcohols because there is no quantitative reference intake recommendation for sugar alcohols from current consensus reports on which to base a DRV.

b. Caloric Value

Caloric content for total carbohydrate less the amount of insoluble dietary fiber is calculated using a factor of 4 calories per gram (9 CFR 317.309(c)(1)(i)(C) and 381.409(c)(1)(i)(C)). FSIS has reviewed the Life Sciences Research Office reports[16 17] that recommended the following caloric values for sugar alcohols: isomalt (2.0 kcal/g); lactitol (2.0 kcal/g), xylitol (2.4 kcal/g); maltitol (2.1 kcal/g); sorbitol (2.6 kcal/g); hydrogenated starch hydrolysates (3.0 kcal/g); and mannitol (1.6 kcal/g). FSIS has tentatively concluded that the values recommended by the Life Sciences Research Office are closer to the energy contribution of sugar alcohols than the current factors. FSIS also reviewed FDA's analysis for determining a caloric value for erythritol and agrees with the analysis (81 FR 33852). Therefore, consistent with FDA's final rule (81 FR 33852), FSIS is proposing to amend its regulations to establish the following general factors for caloric values for sugar alcohols: isomalt (2.0 kcal/g); lactitol (2.0 kcal/g), xylitol (2.4 kcal/g); maltitol (2.1 kcal/g); sorbitol (2.6 kcal/g); hydrogenated starch hydrolysates (3.0 kcal/g); mannitol (1.6 kcal/g); and erythritol (0 kcal/g). Proposed 9 CFR 413.309(c)(1)(i)(F) will establish these values, and proposed 9 CFR 413.309(c)(1)(i)(C) will clarify that the

[12] Skibsted, L.H., Risbo, J., Andersen, M.L. ''Chemical Deterioration and Physical Instability of Food and Beverages''. Woodhead Publishing; 2010; pp. 70–94.

[13] Lewis, R.J., Sr., editor. Hawley's Condensed Chemical Dictionary. 15th Ed. John Wiley & Sons, 2007; pp. 549–550.

[14] Murano, P.S. ''Understanding Food Science and Technology''. Belmont, California: Wadsworth/Thomas Learning; 2003; pp. 123–125.

[15] Toldrá, et al., ''Handbook of Fermented Meat and Poultry,'' Wiley Blackwell; 2015; Chapters 1–2.

[16] Life Sciences Research Office. ''The Evaluation of the Energy of Certain Sugar Alcohols Used as Food Ingredients'', Bethesda, MD: Life Sciences Research Office; 1994.

[17] Life Sciences Research Office. ''Evaluation of the Net Energy Value of Maltitol'', Bethesda, MD: Life Sciences Research Office; 1999.

factor of 4 kcal/g does not apply to sugar alcohols.

5. Fiber

a. Dietary Fiber

i. Definition

FSIS's regulations do not define ''dietary fiber.'' After considering IOM recommendations, comments received on FDA's 2007 ANPRM, and international guidelines (*e.g.,* The Codex Alimentarius Commission's definition of dietary fiber), FDA adopted a definition of dietary fiber that is equivalent to the IOM's definition of ''total fiber'' and emphasizes the beneficial physiological effects in humans (81 FR 33853). FSIS has reviewed FDA's analysis and is proposing to include a definition for dietary fiber in 9 CFR 413.309(c)(6)(i) that is consistent with FDA's definition. FSIS is proposing the following definition for dietary fiber: (1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; and (2) isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

FSIS is proposing to include isolated or synthetic non-digestible carbohydrates that have been determined by FDA to have a physiological effect that is beneficial to human health in the proposed definition of dietary fiber in 9 CFR 413.309(c)(6)(i). For example, β-glucan soluble fiber and psyllium husk that are added to foods meet the proposed definition of dietary fiber and would be listed in 9 CFR 413.309(c)(6)(i). FSIS would consider amending 9 CFR 413.309(c)(6)(i) to list any additional isolated or synthetic non-digestible carbohydrates that FDA determines have a physiological effect that is beneficial to human health.

ii. Mandatory Declaration

FSIS requires that a statement of the number of grams of total dietary fiber per serving be declared on the Nutrition Facts label, except when a serving contains less than 1 gram of total dietary fiber (9 CFR 317.309(c)(6)(i) and 381.409(c)(6)(i), which would be consolidated in proposed 9 CFR 413.309(c)(6)(i)). FSIS is not proposing to change the requirement for mandatory declaration of dietary fiber, just as FDA did not.

iii. Analytical Methods

The amount of dietary fiber may be calculated by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the proposed definition of dietary fiber from the value obtained using AOAC 2009.01, AOAC 2011.25, or an equivalent AOAC method of analysis as given in the ''Official Methods of Analysis of the AOAC International'' 19th Edition. Because an AOAC method would not accurately quantify the dietary fiber that meets the proposed definition if the product contains both non-digestible carbohydrates that meet the definition and those that do not, consistent with FDA's final rule, FSIS is proposing to require that manufacturers maintain written records to verify the amount of added non-digestible carbohydrates that do not meet the proposed definition of dietary fiber. (See Compliance section II.N. below.)

iv. DRV

Currently, 25 g is the DRV for total dietary fiber based on the reference calorie intake of 2,000 calories (9 CFR 317.309(c)(9) and 381.409(c)(9)). FSIS is proposing to amend its regulations to establish 28 g as the DRV for total dietary fiber (proposed 9 CFR 413.309(c)(9)). FSIS is proposing to use 28 g as the DRV for total dietary fiber because: (1) the IOM set an adequate intake level (AI) of 14 g/1,000 kcal for total fiber primarily based on the intake level that was associated with the greatest reduction in the risk of CHD; [18] and (2) FDA now uses 14 g/1,000 kcal as the basis for a DRV for dietary fiber and setting a DRV of 28 g for dietary fiber using a reference calorie intake of 2,000 calories (81 FR 33865–33866).

b. Soluble and Insoluble Fiber

Soluble fibers (*e.g.,* pectin) dissolve in water and are digested by the bacteria in the large intestine. Insoluble fibers (*e.g.,* cellulose) do not dissolve in water and are not digested by the bacteria in the large intestine. FSIS regulations do not define the terms soluble and insoluble fiber, but provide for the voluntary declaration of soluble and insoluble fiber (9 CFR 317.309(c)(6)(i) and 381.409(c)(6)(i)), which would be consolidated in proposed 9 CFR 413.309(c)(6)(i)). Consistent with FDA, FSIS is proposing that when soluble fiber or insoluble fiber is declared, the soluble fiber and insoluble fiber must meet the definition of ''dietary fiber'' in proposed 9 CFR 413.309(c)(6)(i) because they are components of dietary fiber.

i. Analytical Methods

AOAC 2011.25 or an equivalent AOAC method may be used to calculate soluble and insoluble fiber that meet the proposed definition of dietary fiber and can be declared on the Nutrition Facts label. AOAC 2011.25 can measure low molecular weight non-digestible carbohydrates, as well as separately measure soluble and insoluble non-digestible carbohydrates.[19] Consistent with FDA, if a product contains a mixture of non-digestible carbohydrates that do not meet the proposed dietary fiber definition, and the label of the product declares soluble or insoluble fiber content, FSIS is proposing to require establishments to make and keep records to verify the amount of non-digestible carbohydrate(s) that does not meet the proposed definition of dietary fiber present in the food. (See discussion in compliance section II.N. below.)

ii. DRV

FDA did not find a basis on which to derive DRVs for soluble or insoluble fiber. Consistent with FDA's final rule, FSIS is not proposing DRVs for soluble fiber or insoluble fiber.

iii. Caloric value

FSIS regulations provide that the caloric content of a product may be calculated by, among other methods, using general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively (9 CFR 317.309(c)(1)(i)(C) and 381.409(c)(1)(i)(C)). Soluble fiber, which is included in total carbohydrate, is assigned a general factor of 4 kcal/g. FDA established a general factor of 2 kcal/g as the caloric value of soluble non-digestible carbohydrates (81 FR 33867). Insoluble non-digestible carbohydrates are not included in the caloric calculation (81 FR 33867). FDA required that calories from carbohydrate be calculated using a general factor of 4 kcal/g of total carbohydrate less the amount of non-digestible carbohydrates, which includes soluble (2 kcal/g) and insoluble non-digestible carbohydrates (0 kcal/g) that do and do not meet the definition of dietary fiber (81 FR 33867). The calorie contribution of soluble non-digestible carbohydrate would be added

[18] Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 7: Dietary, Functional, and Total Fiber'', Washington, DC: National Academies Press; 2002.

[19] McCleary, B.V., DeVries, J.W., Rader, J.I., et al. ''Determination of Total Dietary Fiber (CODEX definition) by Enzymatic-Gravimetric Method and Liquid Chromatography: Collaborative Study''. *Journal of AOAC International.* 2010;93:221–233.

to that sum to determine the total carbohydrate calorie contribution (Id.). Therefore, in order to harmonize with FDA's regulations, FSIS is proposing the same changes to the caloric value for soluble non-digestible carbohydrates and the calculation of calories from carbohydrate.

6. Other Carbohydrate

FSIS's regulations define ''Other carbohydrate'' as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), ''Other carbohydrate'' is defined as the difference between total carbohydrate and the sum of dietary fiber and sugars (9 CFR 317.309(c)(6)(iv) and 381.409(c)(6)(iv)). A statement of the number of grams of ''Other carbohydrate'' per serving may be voluntarily declared on the Nutrition Facts label (9 CFR 317.309(c)(6)(iv) and 381.409(c)(6)(iv)).

FDA concluded that ''Other carbohydrate'' should no longer be permitted on the Nutrition Facts label because of its lack of public health significance and a quantitative intake recommendation for ''Other carbohydrate'' is not available from relevant consensus reports (81 FR 33867–33868). FDA removed the provision that allows for its voluntary declaration in the regulations (81 FR 33867–33868). FSIS has reviewed FDA's analysis and is proposing to no longer permit the voluntary declaration of ''Other carbohydrate'' on the Nutrition Facts label for the reasons above.

F. Protein

FSIS's regulations require that a statement of the number of grams of protein per serving be declared on the Nutrition Facts label (9 CFR 317.309(c)(7) and 381.409(c)(7), which would be consolidated in proposed 9 CFR 413.309(c)(7)). The DRV for protein is 50 g and represents 10 percent of the 2,000 reference calories intake level. Consistent with FDA, FSIS is not proposing to change the mandatory declaration of protein or the DRV for protein.

1. Analytical Methods

Under FSIS's regulations (9 CFR 317.309(c)(7) and 381.409(c)(7)), protein may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with 9 CFR 317.309(h) or 9 CFR 381.409(h), except when the procedure for a specific food requires another factor. According to 9 CFR 317.309(h)(2) and 381.409(h)(2), FSIS determines compliance by appropriate methods and procedures used by the Department for each nutrient in accordance with the *Chemistry Laboratory Guidebook,* or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the *Official Methods of Analysis of the AOAC International,* formerly Association of Official Analytical Chemists, 15th ed., to determine compliance with the nutrition labeling regulations. FSIS is proposing to update the version of the *Official Methods of Analysis of the AOAC International* referenced in the regulations because more analytical methods for nutrients have been published in later versions. The 20th edition is the most recent edition of the published AOAC methods, so FSIS is proposing in 9 CFR 413.309(h) that the 20th edition be used if no USDA method is available. If a newer version of the *Official Methods of Analysis of the AOAC International* is published before a final rule is published for this rulemaking, FSIS will consider using the most recent version of the official AOAC methods in the final rule.

G. Sodium

FSIS's regulations require the declaration of the number of milligrams of sodium per serving on the Nutrition Facts label (9 CFR 317.309(c)(4) and 381.409(c)(4), which would be consolidated in proposed 9 CFR 413.309(c)(4)). Consistent with FDA, FSIS is not proposing to change the requirement that sodium be declared.

FSIS's regulations set a DRV of 2,400 mg of sodium based on a reference caloric intake of 2,000 calories (9 CFR 317.309(c)(9) and 381.409(c)(9)). FDA considered the following options for updating the DRV for sodium: ''(1) A DRV of 2,300 mg which reflects the Upper Intake Level (UL) [20] for individuals aged 14 years and older; (2) An RDI of 1,500 mg which reflects the AI for individuals 9 to 50 years of age; and (3) Alternative approaches such as retaining a DRV of 2,400 mg, using a tiered approach or setting a DRV of 1,900 mg based on the UL for children 4 to 9 years of age'' (79 FR 11915). In FDA's Nutrition Labeling Proposed Rule, FDA tentatively concluded that 2,300 mg is the most appropriate DV for sodium to ''assist consumers in maintaining healthy dietary practices and in understanding the relative significance of the sodium content within the context of a total daily diet'' (79 FR 11917). FDA did not change its view in the final rule that 2,300 mg/day is an appropriate DRV for sodium (81 FR 33874–33880). FSIS has reviewed FDA's analysis, and consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to set a DRV of 2,300 mg for sodium (proposed 9 CFR 413.309(c)(9)).

H. Fluoride

FSIS's regulations do not permit the declaration of fluoride on the Nutrition Facts label. FDA amended its regulations to provide for the voluntary declaration of fluoride because fluoride's positive health effects are well established (*e.g.,* reduces the risk of dental caries), but an appropriate quantitative intake recommendation is not available for setting a DRV (81 FR 33880–33884) (proposed 9 CFR 413.309(c)(5)). FSIS has reviewed FDA's analysis and consistent with FDA, FSIS is proposing to (i) permit the voluntary declaration of fluoride on the Nutrition Facts label; (ii) require the mandatory declaration of fluoride when a claim about fluoride is made on the label or in labeling of the product; and (iii) require that when fluoride content is declared, it must be expressed as zero when a serving contains less than 0.1 mg of fluoride, to the nearest 0.1 mg increment when a serving contains less than or equal to 0.8 mg of fluoride, and the nearest 0.2 mg when a serving contains more than 0.8 mg of fluoride, consistent with how FSIS and FDA have approached incremental values for other nutrients that are present in products in small amounts. FSIS is not proposing a DRV for fluoride because an appropriate quantitative intake recommendation is not available for setting a DRV.

I. Essential Vitamins and Minerals

1. Updates to Declaration of Vitamins and Minerals and Reference Daily Intakes

FSIS currently requires the declaration of vitamin A, vitamin C, calcium, and iron on the Nutrition Facts label (9 CFR 317.309(c)(8)(ii) and 381.409(c)(8)(ii)). Vitamin D, vitamin E, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, copper, and potassium may all be declared voluntarily on the Nutrition Facts label (9 CFR 317.309(c)(8)(iv),

[20] ''The UL is the highest average daily intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. The UL is not intended to be a recommended level of intake. The UL is used to assess the risk of adverse health effects from excessive nutrient intake. As intake above the UL increases, so does the potential for risk of adverse health effects'' (79 FR 11885).

381.409(c)(8)(iv), 317.309(c)(9), and 381.409(c)(9)). FSIS has also permitted the voluntary declaration of nutrients for which FSIS has not codified RDIs, but that are codified in Title 21 of FDA's regulations.[21] These nutrients are vitamin K, selenium, manganese, chromium, molybdenum, and chloride.

FDA amended its regulations to: (i) Require the declaration of vitamin D, calcium, iron, and potassium on the Nutrition Facts label; (ii) allow the voluntary declaration of vitamin A and C; (iii) retain the voluntary declaration of vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride; and (iv) allow the voluntary declaration of choline (81 FR 33884–33897). FDA made these changes based on its analysis of data and consideration of such factors as public health significance, quantitative intake recommendations, and the role of a nutrient in chronic disease risk (81 FR 33884–33897). Consistent with FDA and proposed 9 CFR 413.309(c)(8)(ii), the vitamins and minerals would be updated in proposed 9 CFR 413.363(b)(4) to replace ''vitamin A, vitamin C, calcium, and iron'' with ''vitamin D, calcium, iron, and potassium.''

FDA also revised the existing RDIs for vitamins and minerals after considering the Dietary Reference Intakes (DRIs)[22] set by the IOM that reflect current nutrient requirements (81 FR 33897–33901). Percent DVs for vitamins and minerals that are required or permitted on the Nutrition Facts label are based on RDIs (9 CFR 317.309(c)(8)(iv) and 381.409(c)(8)(iv)).

FSIS is proposing to adopt FDA's list of nutrients as mandatory or voluntary components of nutrition labeling, the definition of those nutrients, and the increments for declaring nutrients, in the interest of harmonizing with FDA (proposed 9 CFR 413.309(c)(8)(iv)). Consistent with FDA's final rule, FSIS is also proposing to update the RDIs for calcium, copper, folate, iodine, iron, magnesium, niacin, phosphorus, riboflavin, thiamin, zinc, and vitamins A, B_6, B_{12}, C, D, and E and to establish RDIs for vitamin K, selenium, manganese, chromium, molybdenum, chloride, and choline (proposed 9 CFR 413.309(c)(8)(iv)) (see Table 2). A more extensive discussion of FDA's list of nutrients and RDIs can be found in the preamble of FDA's Nutrition Labeling Proposed and Final Rules (79 FR 11918–11931; 81 FR 33897–33901).

TABLE 2—CURRENT AND PROPOSED RDIS FOR NUTRITION LABELING

[Based on a 2,000 calorie intake for adults and children 4 or more years of age]

Nutrient	Current RDIs	Proposed RDIs
Vitamins:		
Biotin	.3 milligram	30 micrograms.
Choline	N/A	550 milligrams.
Folate [6]	.4 milligram	400 micrograms DFE.[1]
Niacin	20 milligrams	16 milligrams NE.[2]
Pantothenic acid	10 milligrams	5 milligrams.
Riboflavin	1.7 milligrams	1.3 milligrams.
Thiamin	1.5 milligrams	1.2 milligrams.
Vitamin A	5,000 International Units	900 micrograms RAE.[3]
Vitamin B_6	2.0 milligrams	1.7 milligrams.
Vitamin B_{12}	6 micrograms	2.4 micrograms.
Vitamin C	60 milligrams	90 milligrams.
Vitamin D	400 International Units	20 micrograms.[4]
Vitamin E	30 International Units	15 milligrams.[5]
Vitamin K	N/A	120 micrograms.
Minerals:		
Calcium	1.0 gram	1,300 milligrams.
Chloride	N/A	2,300 milligrams.
Chromium	N/A	35 micrograms.
Copper	2.0 milligrams	0.9 milligrams.
Iodine	150 micrograms	150 micrograms.
Iron	18 milligrams	18 milligrams.
Magnesium	400 milligrams	420 milligrams.
Manganese	N/A	2.3 milligrams.
Molybdenum	N/A	45 micrograms.
Phosphorus	1.0 gram	1,250 milligrams.
Potassium [7]	3,500 milligrams	4,700 milligrams.
Selenium	N/A	55 micrograms.
Zinc	15 milligrams	11 milligrams.

[1] DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally-occurring folate = 0.6 mcg of folic acid.
[2] NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 mg of tryptophan.
[3] RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 micrograms supplemental β-carotene, 12 micrograms β-carotene, or 24 micrograms α- carotene, or 24 micrograms β-cryptoxanthin.
[4] The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.
[5] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*-α-tocopherol.
[6] ''Folate'' and ''Folic Acid'' must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.
[7] These minerals currently have a DRV and we are proposing to establish an RDI.

[21] *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/trans-fat-declarations/trans-fat-declaration.*

[22] A set of reference values that include the Estimated Average Requirement, RDA, Adequate Intake, and Tolerable Upper Intake Level. *See* 79 FR 11885–6 for more background on DRIs.

2. Terms for Vitamins and Minerals

FSIS currently allows the term ''Folacin'' to be added in parenthesis immediately following the term ''Folate'' on the Nutrition Facts label (9 CFR 317.309(c)(8)(v) and 381.409(c)(8)(v)). FSIS is proposing to remove the synonym ''folacin'' from 9 CFR 317.309(c)(8)(v) and 381.409(c)(8)(v) and require that the term ''folate'' be used on meat and poultry products that contain folate, folic acid, or a mixture of folate and folic acid (proposed 9 CFR 413.309(c)(8)(vii)). The declaration must be folate in mcg DFE (when expressed as a quantitative amount by weight) and the percent Daily Value based on folate in mcg DFE, or may be expressed as folate and the percent DV based on folate in mcg DFE. Because of the proposed changes to the units of measure for folate that take into account the differences between folate and folic acid, FSIS is proposing that when folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses as mcg of folic acid after the folate declaration. FSIS's proposed changes are consistent with FDA's Nutrition Labeling Final Rule (81 FR 33909–33912).

J. Labeling of Foods for Infants, Young Children, and Pregnant or Lactating Women

The general labeling requirements for foods in 9 CFR 317.309(c) and 381.409(c) apply to foods for infants, young children, and pregnant women and lactating women with certain exceptions. For example, meat and poultry products represented or purported to be specifically for infants and children less than 4 years of age are not permitted to include declarations of percent DV for the following nutrients: Total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber (9 CFR 317.400(c)(2)(i) and 381.500(c)(2)(i)). There are additional exceptions to labeling for meat and poultry products represented or purported to be specifically for infants and children less than 2 years of age. For example, these foods are also not permitted to declare calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat and cholesterol on the Nutrition Facts label (9 CFR 317.400(c)(1) and 381.500(c)(1)).

FSIS regulations do not include DRVs or RDIs for nutrients, generally, for infants, children under 4 years of age, or pregnant women and lactating women. However, there are requirements for a DRV for protein for children 4 or more years of age, and an RDI for protein for each of the following subpopulations: (1) Children less than 4 years of age; (2) infants; (3) pregnant women; and (4) lactating women (9 CFR 317.309(c)(7)(iii) and 381.409(c)(7)(iii)).

FDA changed its requirements for the labeling of foods, other than infant formula, represented or purported to be specifically for infants, children under 4 years of age, and pregnant women and lactating women after considering current consensus reports, changes to the Nutrition Facts label, and comments to its 2007 ANPRM (81 FR 33916–33932). FSIS has reviewed FDA's analysis and is proposing to make consistent changes to its requirements for the labeling of meat and poultry products represented or purported to be specifically for infants, children under 4 years of age, and pregnant women and lactating women (proposed 9 CFR 413.309(c)).

1. Age Range for Infants and Young Children

FSIS regulations currently use the age ranges ''less than 2 years of age'' and ''less than 4 years of age'' to establish labeling requirements for meat and poultry products represented or purported to be specifically for infants and young children (9 CFR 317.400(c) and 381.500(c)). FDA amended its regulations so that the age categories were changed to infants through 12 months and young children 1 through 3 years (13 through 48 months) which would be consistent with the age ranges used in the IOM's DRIs for infants and children (81 FR 33916–33917). FDA's new DVs are also based on these age-specific DRIs (81 FR 33916–33917)

Consistent with FDA's final rule, FSIS is proposing to replace the current category of infants and children less than 4 years in 9 CFR 317.400(c)(1); 381.500(c)(1); 317.309(c)(7)–(8); 381.409(c)(7)–(8); 317.309(d)(1); 381.409(d)(1); 317.313(b)(3); 381.413(b)(3); 317.313(q)(3); and 381.413(q)(3) with infants through 12 months and children 1 through 3 years of age (proposed 9 CFR 413.400(c)(1); 413.309(c)(7)–(9); 413.309(d)(1); 413.313(b)(3); and 413.313(q)(3)).

2. Mandatory Declaration of Calories and Other Nutrients

Currently, meat and poultry products represented or purported to be specifically for infants and children less than 4 years must declare certain nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein (9 CFR 317.400(c)(2) and 381.500(c)(2)). For meat and poultry products represented or purported to be for infants and children less than 2 years, the declaration of certain nutrients, which include calories from fat, saturated fat, and cholesterol, is not required or permitted (9 CFR 317.400(c)(1) and 381.500(c)(1)).

a. Declaration of Saturated Fat and Cholesterol

Because FSIS is proposing new categories of infants through 12 months and children 1 through 3 years of age, FSIS is considering whether there is a need to require or permit the declaration of calories from fat, saturated fat, and cholesterol in the labeling for foods represented or purported to be specifically for these subpopulations. As discussed in section II.B.1. above, FSIS is proposing to no longer require and not permit the declaration of calories from fat on the Nutrition Facts label (proposed 9 CFR 413.309(c)(1)(ii)). Therefore, if these proposed changes are finalized, the exception in 9 CFR 317.400(c)(1) and 381.500(c)(1) for calories from fat will no longer be needed, and the reference to calories from fat will be removed. FSIS's regulations currently do not require or permit the labeling of any fat, with the exception of total fat, or fatty acids on meat and poultry products represented or purported to be specifically for children less than 2 years of age.

FDA considered a recent consensus report suggesting that: Fat intake in infants less than 12 months of age should not be restricted. Fat is still an important source of calories for infants and young children. Evidence suggests a diet with saturated fat of less than 10 percent of calories and cholesterol intake less than 300 mg/d can safely and effectively reduce the levels of total and LDL cholesterol in healthy children, and that the 2010 DGA recommended that Americans 2 years of age and older consume less saturated fatty acids and less than 300 mg/d of cholesterol (79 FR 11934). FDA requires, except for the declaration of calories from fat, the mandatory declaration of statutorily required nutrients under section 403(q) of the FD&C Act that include saturated fat and cholesterol on the label of foods represented or purported to be specifically for infants through 12 months and children 1 through 3 years of age (81 FR 33917–33918). Therefore, consistent with FDA's final rule, FSIS is proposing to require the declaration of saturated fat and cholesterol on the label of meat and poultry products purported to be for infants through 12 months and children 1 through 3 years of age (proposed 9 CFR 413.400(c)(1)).

Currently, meat and poultry products consumed by pregnant women and lactating women must declare certain nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein. As discussed in FDA's Nutrition Labeling Proposed Rule, women of reproductive age consume the same foods as the general population and, in general, continue consuming similar foods during pregnancy and lactation (79 FR 11934). FDA requires, except for the declaration of calories from fat, the mandatory declaration of statutorily required nutrients under section 403(q) of the FD&C Act (81 FR 33917–33918).

Accordingly, FSIS is proposing to require the mandatory declaration of calories and the amount of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein on foods represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, and pregnant women and lactating women and to permit the declaration of calories from saturated fat such that these nutrients would be subject to the same requirements applicable to meat and poultry products for the general population (proposed 9 CFR 413.309(c)).

b. Percent DV Declaration

Currently, the percent DV declaration is not permitted on the Nutrition Facts label for meat and poultry products represented or purported to be specifically for infants and children less than 4 years of age (which includes infants and children less than 2 years of age) for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber (9 CFR 317.400(c)(2)(i) and 381.500(c)(2)(i)). Percent DV is required for protein and vitamins and other minerals and, as discussed in sections II.F and II.I, provides information in a manner that enables consumers to understand the relative significance of nutrition information in the context of a total daily diet. FDA concluded that it is appropriate to require declarations of percent DV for those nutrients for which FDA is establishing a DRV or RDI for infants through 12 months, for children 1 through 3 years of age, and for pregnant women and lactating women (81 FR 33918–33919). Accordingly, FSIS is proposing in 9 CFR 413.400(c)(2)(i) to require declarations of percent DV for those nutrients for which FSIS is establishing a DRV or RDI for infants through 12 months, for children 1 through 3 years of age, and for pregnant women and lactating women consistent with FDA's Nutrition Labeling Final Rule.

c. Mandatory Declaration of Added Sugars

As discussed in section II.E.3, FSIS is proposing to require the mandatory declaration of added sugars on the Nutrition Facts label. The 2010 DGA provides recommendations for consumption of added sugars for the U.S. population 2 years of age and older but not for infants and children under age 2. It is expected, however, that the role of added sugars are not markedly different between children 1 and 2 years of age (79 FR 11936). Similarly, the IOM has established DRI ranges for 1-through-3-year-olds because growth velocity is most similar during this age range (79 FR 11936; 81 FR 33916). FDA has concluded that mandatory declaration of added sugars is needed for foods for infants through 12 months, just as it is for the general population, to provide consumers with information to construct a healthy dietary pattern that meets the dietary recommendations for added sugars (81 FR 33921).

Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing the mandatory declaration of added sugars on the Nutrition Facts label of meat and poultry products represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women.

d. Mandatory Declaration of Trans Fat

As discussed in section II.C.3, FSIS is proposing to require the mandatory declaration of *trans* fat on the Nutrition Facts label. The mandatory declaration of *trans* fat is needed for foods for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women, just as it is needed for the general population to assist in maintaining healthy dietary practices. For example, the relationship between the consumption of *trans* fat and risk of CHD is well established [23] [24] and cardiovascular disease is also known to begin in childhood.[25] [26]

Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to require the declaration of trans fat on the Nutrition Facts label of meat and poultry products represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women.

3. Voluntary Declaration of Nutrients Other Than Essential Vitamins and Minerals

Currently, meat and poultry products represented or purported to be specifically for infants and children less than 2 years of age are not permitted to declare calories from fat, calories from saturated fat, and the amount of polyunsaturated fat and monounsaturated fat (9 CFR 317.400(c)(1) and 381.500(c)(1)), whereas soluble fiber, insoluble fiber, and sugar alcohols can be voluntarily declared. Polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, and sugar alcohols can be voluntarily declared on the label of meat and poultry products represented or purported to be specifically for children 2 through 4 years of age and pregnant women and lactating women (9 CFR 317.400(c)(2) and 381.500(c)(2)). FSIS is proposing the following changes to voluntary declaration of certain nutrients.

a. Voluntary Declaration of Calories From Saturated Fat, and the Amount of Polyunsaturated and Monounsaturated Fat

For infants through 12 months, there are no specific recommendations provided about calories from saturated, polyunsaturated, or monounsaturated fat. However, as discussed in FDA's Nutrition Labeling Proposed Rule, there is some evidence to suggest that reduction of total and LDL cholesterol levels can occur with reducing saturated fat intake to less than 10 percent of calories, beginning in infancy and sustained throughout childhood into adolescence (79 FR 11935). Because consensus reports provide no discussion or recommendation about providing nutrient guidelines for fatty acids to children under the age of 2 years, and there is no evidence to suggest that infants through 12 months of age would

[23] U.S. Department of Agriculture and U.S. Department of Health and Human Services. (2010) ''*Dietary Guidelines for Americans, 2010*'', 7th Ed., Washington DC: U.S. Government Printing Office. Retrieved from *http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.*

[24] Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 8: Dietary Fats: Total Fat and Fatty Acids'', Washington, DC: National Academies Press; 2002.

[25] U.S. Department of Health and Human Services, National Institutes of Health, and National, Heart Lung and Blood Institute. (October, 2012) ''Integrated Guidelines for Cardiovascular Health and Risk Reduction In Children and Adolescents: The Report of the Expert Panel''; NIH Publication No. 12–7486A. Retrieved from *http://www.nhlbi.nih.gov/guidelines/cvd_ped/index.htm.*

[26] American Academy of Pediatrics. ''Chapter 32: Hyperlipidemia and Prevention of Cardiovascular Disease''. In: *Pediatric Nutrition Handbook* 6th Ed. Kleinman, R.E., ed. American Academy of Pediatrics; 2009; p.723.

be different than children 1 through 3 years of age, FDA explained that there is no basis to continue to prohibit the declaration of calories from saturated fat or polyunsaturated and monounsaturated fats on foods represented or purported to be specifically for infants and children less than 2 years of age (81 FR 33919–33920).

Also, as discussed in FDA's Nutrition Labeling Proposed Rule, quantitative intake recommendations are not available from relevant U.S. consensus reports for monounsaturated and polyunsaturated fats for children 1 through 3 years of age or pregnant women and lactating women. There is well-established evidence to indicate that replacing saturated fatty acids with polyunsaturated and monounsaturated fatty acids reduces blood LDL cholesterol levels and, therefore, the risk of CVD; and that monounsaturated and polyunsaturated fats have public health significance when they replace saturated fat (79 FR 11936). FDA finalized its proposed requirements and permits the declaration of calories from saturated fat, polyunsaturated and monounsaturated fat on foods represented or purported to be specifically for infants through 12 months and children 1 through 3 years of age (81 FR 33919–33920).

Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to revise 9 CFR 317.400(c)(1) and 381.500(c)(1) (which would be consolidated in proposed 9 CFR 413.400(c)(1)) to remove the exceptions for the declaration of calories from saturated fat and the amount of polyunsaturated fat and monounsaturated fat on meat and poultry products represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant or lactating women. If finalized, these declarations for the new age categories, infants through 12 months and children 1 through 3 years of age, would be the same as the proposed voluntary declarations for foods for the general population.

b. Voluntary Declaration of Soluble Fiber, Insoluble Fiber, and Sugar Alcohols

As discussed in section II.E, FSIS is proposing to allow the declaration of soluble fiber and insoluble fiber that meet the definition of ''dietary fiber'' on the Nutrition Facts label for the general population. FDA has concluded that there is no evidence to suggest that the role of these nutrients would be different among infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women compared to the general population (81 FR 33920).

FSIS has reviewed FDA's analysis and is not proposing any changes to the provisions for the voluntary declaration of soluble fiber, insoluble fiber, and sugar alcohols on the label of meat and poultry products represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women, consistent with FDA's Nutrition Labeling Final Rule (81 FR 33920).

c. Voluntary Declaration of Fluoride

FSIS regulations currently do not provide for the declaration of fluoride on the Nutrition Facts label of any meat or poultry product. For the reasons discussed in section II.H, FSIS is proposing to permit voluntary declaration of fluoride on the labeling of meat and poultry products for the general population. As discussed in FDA's Nutrition Labeling Proposed Rule and Final Rule (in which FDA did not change its tentative conclusions from the proposed rule), because fluoride provides protection against dental caries by strengthening the tooth enamel before and after teeth appear, and because excessive fluoride intake can cause dental fluorosis in young children, the declaration of fluoride on foods represented or purported to be specifically for children 1 through 3 years of age and for pregnant women and lactating women can assist in maintaining healthy dietary practices (79 FR 11936; 81 FR 33921). Further, while evidence on dental caries is lacking for infants through 12 months of age, there is no reason to expect the role of fluoride in the protection against dental caries to be different from other age groups (*Id.*). Therefore, consistent with FDA's Nutrition Labeling Final Rule on the voluntary declaration of fluoride for these subpopulations, FSIS is proposing to permit the voluntary declaration of fluoride on meat and poultry products represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, and pregnant women and lactating women (proposed 9 CFR 413.309(c)(5)).

4. Declaration of Essential Vitamins and Minerals

FSIS requires the declarations of vitamin A, vitamin C, calcium, and iron on the Nutrition Facts label, and there are no specific exceptions to this requirement for meat and poultry products represented or purported to be specifically for infants and children less than 2 years and children less than 4 years of age, and pregnant women and lactating women (9 CFR 317.309(c)(8) and 381.409(c)(8)). FSIS is proposing to replace the current categories ''infants and children less than 2 years of age and children less than 4 years of age'' with ''infants through 12 months and children 1 through 3 years of age.''

Since the needs of essential vitamin and minerals are increased for both pregnant women and lactating women, FDA applied its conclusions about nutrient inadequacy during pregnancy to lactating women and made the requirements related to essential vitamins and minerals in labeling of foods for pregnant women and lactating women the same (81 FR 33921–33922). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to remove the current provision in 9 CFR 317.309(c)(8)(i) and 381.409(c)(8)(i) that requires separate declaration of percent DVs based on both RDI values for pregnant women and for lactating women in the labeling of foods represented or purported to be for use by both pregnant women and lactating women (proposed 9 CFR 413.309(c)(8)(i)).

a. Mandatory Declaration of Calcium and Iron

FSIS is not proposing any changes to the mandatory declaration of calcium on foods for the general population (see section II.I.1.). As discussed in FDA's Nutrition Labeling Proposed Rule, the AI for calcium for infants through 12 months of age is based on average calcium consumption of this nutrient rather than on chronic disease risk, health related-condition, or physiological endpoints (79 FR 11937). For children 1 through 3 years of age and pregnant women and lactating women, the Recommended Dietary Allowances (RDAs) [27] for calcium are based, in part, on bone health (79 FR 11937).

FDA's analysis of the Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Survey (NHANES) 2003–2006 data estimated that infants ages 7 to 12 months have usual calcium intakes above the AI and estimated that about 12 percent of children 1 through 3 years of age had usual intakes of calcium below the Estimated Average

[27] ''The RDA is an estimate of the average intake level that meets the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group'' (79 FR 11885).

Requirement (EAR),[28] based on intakes from conventional foods only (79 FR 11937). FDA has found that promoting the development of eating patterns that are associated with adequate calcium intake later in life is important given that calcium intakes are inadequate for the majority of the population. Intakes of calcium, which is necessary for growth and bone development, are inadequate among children. Also, similar to the general population, approximately 20 percent of pregnant women consumed less than the EAR for calcium from conventional foods as well as from conventional foods and supplements (79 FR 11937).

FDA concluded that calcium is a nutrient of public health significance for children 1 through 3 years of age and pregnant women and lactating women and infants through 12 months and requires the mandatory declaration of calcium on foods purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant and lactating women (81 FR 33922). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to change the mandatory declaration of calcium for meat and poultry products purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant or lactating women.

FSIS is not proposing any changes to the mandatory declaration of iron on foods for the general population (see section II.I.1.). As discussed in FDA's Nutrition Labeling Proposed Rule, although the EAR and RDA are based on daily iron requirements and not directly on chronic disease risk, iron deficiency is associated with delayed normal infant motor function (*i.e.,* normal activity and movement) and mental function (*i.e.,* normal thinking and processing skills) (79 FR 11937). FDA's analysis of NHANES 2003–2006 data estimated that about 18 percent of infants ages 7 to 12 months have usual iron intakes below the EAR, based on intakes from conventional foods only and 4 percent of infants ages 7 to 12 months have usual iron intakes below the EAR based on intakes from conventional foods and supplements (79 FR 11937; 81 FR 33922).

As discussed in FDA's Nutrition Labeling Proposed Rule, about 1 percent of children 1 through 3 years of age have usual iron intakes below the EAR, based on intakes from conventional foods only, and 0.4 percent of children have usual iron intakes below the EAR based on intakes from conventional foods and supplements (79 FR 11937). The IOM set the EAR by modeling components of iron requirements. The prevalence of iron deficiency in children ages 1 to 2 years has been reported to be 14.4 percent, and the prevalence of iron deficiency anemia in children younger than 5 years has been reported to be 14.9 percent. FDA requires the mandatory declaration of iron in the labeling of foods for infants through 12 months and children 1 through 3 years of age (81 FR 33922).

As discussed in FDA's Nutrition Labeling Proposed Rule, inadequate iron intakes during pregnancy are of public health significance because of the adverse effects for both the mother and the fetus (such as maternal anemia, premature delivery, low birth weight, and increased perinatal infant mortality) (79 FR 11938). FDA analyzed NHANES 2003–2006 data and estimated that 5 percent of pregnant women 14 to 50 years of age had usual iron intakes below the EAR based on intakes from conventional foods, and 4 percent of pregnant women 14 to 50 years of age had usual iron intakes below the EAR based on intakes from conventional foods and supplements. The EAR for iron for pregnant women was based on estimates of iron stores needed during the first trimester (79 FR 11938). FDA's analysis of NHANES 2003–2006 data also indicated that, among pregnant women aged 12 to 49 years, 25 percent were iron deficient, and 13 percent had iron deficiency anemia (79 FR 11938). FDA considered iron deficiency based on two out of three cutoffs of iron deficiency variables (transferrin saturation, serum ferritin, and erythrocyte protoporphyrin) (79 FR 11938).

FDA found that calcium and iron have quantitative intake recommendations and have public health significance for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women. FDA did not receive comments to its proposed rule to change its tentative conclusion that the declaration of calcium and iron is necessary to assist consumers in maintaining healthy dietary practices (81 FR 33922). FSIS has reviewed FDA's analysis and is proposing to require the mandatory declaration of calcium and iron on foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women without providing any exceptions for these subpopulations from the requirement for declaration of calcium and iron applicable to foods for the general population (proposed 9 CFR 413.309(c)(8)(ii)).

b. Mandatory Declaration of Vitamin D and Potassium

FSIS is proposing to require the declaration of vitamin D on meat and poultry products for the general population (see section II.I.1.). FDA identified vitamin D as a nutrient of public health significance in children 1 through 3 years of age and pregnant women based on the high prevalence of inadequate intakes of vitamin D and its important role in bone development and health (81 FR 33922–33923). FDA also identified vitamin D as a nutrient of public health significance for infants through 12 months of age based on its importance for growth and development during infancy (81 FR 33922–33923).

FSIS is proposing to require the declaration of potassium on foods for the general population (see proposed 9 CFR 413.309(c)(8)(ii) and section II.I.1.). As discussed in FDA's Nutrition Labeling Proposed Rule, the AI for infants is based on average potassium intake from breast milk and complementary foods (79 FR 11938). The AI for the other life-stage and gender groups is set at a level to maintain blood pressure, reduce the adverse effects of sodium chloride intake on blood pressure, and reduce the risk of recurrent kidney stones (79 FR 11938).

FSIS has reviewed FDA's analysis of potassium intake from NHANES 2003–2006 for infants 7 to 12 months of age; potassium intake for children 1 through 3 years of age; and the importance of potassium in the risk reduction of chronic diseases for children 2 years of age and older (79 FR 11938). Because of the benefits of adequate potassium intake in lowering blood pressure and data indicating low likelihood of potassium adequacy, FSIS agrees with FDA that it is important to establish healthy dietary practices for later life (79 FR 11938). FDA tentatively concluded in the Nutrition Labeling Proposed Rule that there is no basis to conclude that the public health significance of potassium among infants through 12 months of age would be different than the science-based evidence for children 1 through 3 years of age, and that potassium is of public health significance to infants through 12 months, children 1 through 3 years of age and pregnant women and lactating women (79 FR 11938). FDA did not change its tentative conclusion in the final rule (81 FR 33922–33923).

[28] "The EAR is the average daily nutrient intake level that is estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender group. EARs are used for assessing the statistical probability of adequacy of nutrient intakes of groups of people" (79 FR 11885).

Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to require the labeling of vitamin D and potassium on foods represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, and pregnant women and lactating women based on the quantitative intake recommendations for vitamin D and potassium and the public health significance of these nutrients. Consequently, FSIS is not providing for any exceptions for these subpopulations from the general requirement in proposed 9 CFR 413.309(c)(8)(ii) to declare vitamin D and potassium.

c. Voluntary Declaration of Vitamin A and Vitamin C

FSIS is proposing to no longer require the declaration of vitamin A and vitamin C on foods for the general population (see section II.I.1.). As discussed in FDA's Nutrition Labeling Proposed Rule, none of the DRIs (AIs or RDAs) for vitamin A were based on chronic disease risk, a health related-condition, or health-related physiological endpoints (79 FR 11939).

FDA looked at vitamin A intake from NHANES 2003–2006 for children and pregnant women and found a very low prevalence of inadequate intakes of vitamins A and C or inadequate status among children 1 through 3 years of age or pregnant women and also the lack of evidence to indicate that this would be different for infants or lactating women (79 FR 11939). FDA concluded that vitamin A and vitamin C are not of public health significance among infants through 12 months of age, children 1 through 3 years of age, and pregnant women and lactating women and that this supports the voluntary declaration of vitamins A and C in the labeling of foods for young children (81 FR 33923–33924). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to permit, but not to require, that the declaration of vitamin A and vitamin C on foods represented and purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women. Similar to other voluntary nutrients, the declaration of vitamins A and C would be required when claims are made about them on the label or labeling (proposed 9 CFR 413.309(c)(8)(ii)).

d. Voluntary Declaration of Other Vitamins and Minerals

As discussed in section II.I.3., for the general population, FSIS is proposing to permit the voluntary declaration of vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline (proposed 9 CFR 413.309(c)(8)(ii)). As discussed in FDA's Nutrition Labeling Proposed Rule, vitamins and minerals other than iron, calcium, vitamin D, and potassium for infants either have DRIs that are not based on chronic disease risk, heath-related conditions, or health-related physiological endpoints or are not shown to have public health significance because of the prevalence of a clinically relevant nutrient deficiency (79 FR 11939). FDA determined, in the final rule that, for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women, the essential vitamins and minerals, other than iron, calcium, vitamin D and potassium, do not have public health significance, and there is no basis for the declaration of these nutrients to be different from that proposed for the general population (81 FR 33924). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to allow the voluntary declaration of vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline on foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women, unless the labeling makes a claim about them, in which case the nutrients would have to be declared (proposed 9 CFR 413.309(c)(8)(ii)).

5. DRVs and Reference Daily Intakes (RDIs) for Infants Through 12 Months of Age

FSIS regulations do not include DRVs or RDIs for nutrients for infants through 12 months of age, except an RDI for protein of 14 g for infants. Consistent with FDA, FSIS is considering establishing DRVs and RDIs for nutrients for infants through 12 months of age and revisions to the current RDI for protein.

a. Calories

FSIS's regulations do not provide, and FDA has not established, a reference calorie intake level for infants and children less than 2 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, there is no quantitative intake recommendation for calories for infants, and FDA is not aware of other scientific data and information on which it could rely to establish that level (79 FR 11939). FDA did not establish a reference calorie intake for infants through 12 months of age in the final rule (81 FR 33925). Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to establish a reference calorie intake level for infants through 12 months (81 FR 33925).

b. Total Fat

As discussed in FDA's Nutrition Labeling Proposed Rule, the IOM set an AI of 30 g/d for fat for infants through 12 months of age based on the average intake of human milk and complementary foods. There was no AI available in 1993, and the current AI provides a basis to determine an appropriate DRV for total fat for this subpopulation that can assist consumers in maintaining healthy dietary practices among this subpopulation (79 FR 11939). FDA established a DRV of 30 g for fat for infants through 12 months in its final rule (81 FR 33925). Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to include a DRV of 30 g for fat for infants through 12 months of age (proposed 9 CFR 413.309(c)(9)).

c. Saturated Fat, Trans Fat, Cholesterol, Dietary Fiber, and Sugars

As discussed in FDA's Nutrition Labeling Proposed Rule, there are no quantitative intake recommendations from U.S. consensus reports available for saturated fat, *trans* fat, cholesterol, dietary fiber, and sugars for infants (79 FR 11939). FDA was not aware of other reliable scientific data and information on which to establish DRVs for these nutrients for infants through 12 months of age (79 FR 11939). FDA did not establish DRVs for infants through 12 months of age for these nutrients in its final rule (81 FR 33925). Accordingly, FSIS is not proposing to establish DRVs for these nutrients for infants through 12 months of age, consistent with FDA's Nutrition Labeling Final Rule because appropriate scientific data is not available.

d. Polyunsaturated Fat, Monounsaturated Fat, Insoluble Fiber, Soluble Fiber, Insoluble Fiber, Added Sugars, and Sugar Alcohols

As discussed in FDA's Nutrition Labeling Proposed Rule, quantitative intake recommendations from U.S. consensus reports are not available for polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, or sugar alcohols for infants (79

FR 11940). FDA was not aware of other reliable scientific data and information on which to establish DRVs for these nutrients for this subpopulation (79 FR 11940). FDA did not establish DRVs for infants through 12 months of age for these nutrients in its final rule (81 FR 33925). Accordingly, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to establish DRVs for these nutrients for infants through 12 months of age because appropriate scientific data are not available.

e. Total Carbohydrate

As discussed in FDA's Nutrition Labeling Proposed Rule, the IOM set an AI of 95 g/d for carbohydrate for infants through 12 months of age based on the average intake of human milk and complementary foods. There was no AI available in 1993, and the current AI provides a basis on which FDA could determine an appropriate DRV for total carbohydrate for this subpopulation that can assist consumers in maintaining healthy dietary practices among this subpopulation (79 FR 11940). FDA established a DRV of 95 g for total carbohydrate for infants through 12 months of age in its final rule (81 FR 33925). Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish a DRV of 95 g for total carbohydrate for infants through 12 months of age (proposed 9 CFR 413.309(c)(9)).

f. Protein

As discussed in FDA's Nutrition Labeling Proposed Rule, the DV for protein for infants is an RDI, rather than a DRV. Before 1993, FDA established the RDIs for protein for all age groups based on the 1989 RDA. In 1993, FDA changed the RDI for protein for the general population to a DRV (58 FR 2206 at 2216). FDA retained the RDI for infants based on the highest 1968 RDA value (14 g/d for infants) to be consistent with a population-coverage approach, but it found no reason to change the approach of using the RDI for infants through 12 months. FDA determined that it would be appropriate to revise the RDI to rely on current quantitative intake recommendations. In 2002, the IOM established an RDA for infants through 12 months of 1.2 g/kg/d based on nitrogen balance studies and using a reference body weight of 9 kg consistent with current growth charts for infants. Protein intakes are well above the current and proposed RDI, and mean protein intake for infants 6 to 11 months of age was well above the RDA of 11 g/d (79 FR 11940). FDA established an RDI of 11 grams for protein for infants through 12 months of age in its final rule (81 FR 33925). Accordingly, consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish an RDI of 11 g for protein for infants through 12 months of age (proposed 9 CFR 413.309(c)(8)(iv)).

g. Sodium

FSIS is proposing to establish a DRV for sodium based on the IOM's UL for the general population (section II.G.). However, as discussed in FDA's Nutrition Labeling Proposed Rule, the IOM did not set a UL for sodium for infants through 12 months of age because there was insufficient data on adverse effects of chronic overconsumption in this age group (79 FR 11940). In addition, FDA was not aware of other reliable scientific data and information on which to establish a DRV for sodium for this subpopulation (79 FR 11940). FDA did not establish a DRV for sodium for infants through 12 months of age in its final rule (81 FR 33926). Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing a DRV for sodium for infants through 12 months of age because of the lack of appropriate scientific data.

h. Fluoride

As discussed in section II.H, although the IOM set an AI for fluoride, the AIs for infants through 12 months and children 1 through 3 years are close to the Environmental Protection Agency benchmarks for total fluoride intake. FDA did not propose a DRV for fluoride for use in the labeling of foods for the general population because of a concern about excess intakes associated with dental fluorosis (79 FR 11918). FDA did not establish a DRV for fluoride for infants through 12 months in its final rule (81 FR 33926). The use of such a DRV to calculate percent DV may have the unintended effect of consumers selecting foods with higher fluoride amounts, which are not necessary or advised (79 FR 11940). Accordingly, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to establish a DRV for fluoride for infants through 12 months of age.

i. Vitamins and Minerals

FSIS regulations do not include DRVs or RDIs for nutrients, generally, for infants, children under 4 years of age, or pregnant women and lactating women. However, there are requirements for a DRV for protein for children 4 or more years of age and an RDI for protein for (1) children less than 4 years of age; (2) infants; (3) pregnant women; and (4) lactating women (9 CFR 317.309(c)(7)(iii) and 381.409(c)(7)(iii)).

FDA reviewed current quantitative intake recommendations for vitamins and minerals for infants and considered comments received in response to its 2007 ANPRM to determine appropriate RDIs for vitamins and minerals for infants through 12 months of age (79 FR 11940). FSIS agrees with FDA that it is important to establish RDIs for infants through 12 months of age because infants in this age range transition from a diet of mostly breast milk and infant formula to infant cereal and baby foods; that labeling foods for this subpopulation with percent DV declarations can assist parents in making nutritious food choices; that the DRIs (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for this subpopulation; that it is appropriate to use RDAs and, in the absence of RDAs, AIs to determine appropriate micronutrient RDIs for infants; that both RDAs and AIs are sufficient for setting RDIs because they both represent intake levels that are expected to meet or exceed the nutrient needs of the majority of infants; that the IOM established DRIs based on scientific knowledge that update and supersede previous RDA recommendations; and that DRIs are available for infants through 12 months of age (79 FR 11940).

FDA established RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for infants through 12 months of age in its final rule (81 FR 33926–33927). Accordingly, consistent with FDA's Nutrition Labeling Final Rule (81 FR 33926–33927), FSIS is proposing to include a listing of RDIs for these same nutrients for infants through 12 months of age (proposed 9 CFR 413.309(c)(8)(iv)).

6. DRVs and RDIs for Children 1 Through 3 Years of Age

FSIS regulations do not include DRVs or RDIs for nutrients for children 1 through 3 years of age, except an RDI for protein of 16 g for children less than 4 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA reviewed scientific evidence and current recommendations, as well as comments in response to FDA's 2007 ANPRM, to consider establishing DRVs and RDIs for nutrients for this subpopulation and to consider revisions to the current RDI for protein (79 FR 11940).

a. Calories

FSIS regulations currently do not provide a reference calorie intake level for nutrition labeling for children ages 1 through 3 years. FDA established a reference calorie intake level for children 1 through 3 years of age and set DRVs using quantitative intake recommendations that are based on calories (*e.g.,* total fat, saturated fat, and dietary fiber). Current recommendations from the IOM, American Heart Association (AHA), American Academy of Pediatrics (AAP), and the 2015–2020 DGA for caloric intake range from 800 to 900 calories/d for children 1 year old, approximately 1,000 calories/d for children 2 years of age, and from 1,000 to 1,200 calories/d for children 3 years of age. FDA considered that an average of the range of these caloric intake recommendations (800 to 1,200 calories/d), *i.e.,* 1,000 calories/d, provides a reasonable reference calorie intake level (79 FR 11941). FDA established a reference calorie intake of 1,000 calories/day for children aged 1 through 3 years in its final rule (81 FR 33927). FSIS has reviewed FDA's analysis and is proposing to provide a reference calorie intake level of 1,000 calories/day for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)) consistent with FDA's Nutrition Labeling Final Rule.

b. Total Fat

Currently, FSIS regulations do not provide a DRV for total fat for children ages 1 through 3 years. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA agreed with a comment to its 2007 ANPRM that 35 percent of calories from fat for children 1 through 3 years of age, the midpoint of the IOM AMDR of 30 to 40 percent, serves as an appropriate basis on which to set the DRV for total fat. The approach to calculating the DRV for total fat is consistent with FDA's approach to setting the DRV for total fat for the general population. Thirty-five percent is consistent with AHA and AAP recommendations that 30 to 40 percent of calories consumed by children 12 through 24 months of age, and 30 to 35 percent of calories consumed by children 24 through 48 months of age, should come from fat (79 FR 11941). In FDA's Nutrition Labeling Proposed Rule, FDA tentatively concluded that 35 percent of total calories from fat (*i.e.,* 39 g using the finalized reference calorie intake level of 1,000 calories/d) is an appropriate DRV for total fat for children 1 through 3 years of age (*Id.*). FDA established a DRV of 39 grams for total fat in its final rule (81 FR 33927–33928). FSIS has reviewed FDA's analysis and is proposing to establish a DRV of 39 g for fat for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)) consistent with FDA's Nutrition Labeling Final Rule.

c. Saturated Fat, Trans Fat, and Cholesterol

FSIS has not established DRVs for saturated fat, *trans* fat, or cholesterol for children 1 through 3 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA considered a comment to its 2007 ANPRM that suggested using the midpoint of 10 to 15 percent of calories for saturated fat, 2 percent of calories for *trans* fat based on estimates of mean *trans* fat intake for the U.S. population 3 years of age and older, and less than or equal to 300 mg/d for cholesterol based on the 2005 DGA recommendation. CVD is known to begin in childhood, and the 2010 DGA recommended that Americans 2 years of age and older consume less than 10 percent of calories from saturated fat and less than 300 mg/d of cholesterol (79 FR 11941). FDA tentatively concluded that it is appropriate to set a DRV of 10 g for saturated fat, based on 10 percent of total calories from saturated fat and using the proposed reference calorie intake level of 1,000 calories/d which equals 11 g, rounded down to 10 g, and a DRV of 300 mg for cholesterol for children 1 through 3 years of age (79 FR 11941). FDA established a DRV of 10 g for saturated fat and a DRV of 300 mg for cholesterol for children 1 through 3 years of age in its final rule (81 FR 33928). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish a DRV of 10 g for saturated fat and a DRV of 300 mg for cholesterol for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)).

FSIS is not proposing to establish a DRV for *trans* fat because the IOM and 2015–2020 DGA do not provide any specific appropriate levels of intake and FDA did not establish a DRV for *trans* fat (81 FR 33928).

d. Polyunsaturated Fat, Monounsaturated Fat, Sugars, Added Sugars, Insoluble Fiber, Soluble Fiber, and Sugar Alcohols

FSIS has not established DRVs for polyunsaturated fat, monounsaturated fat, sugars, added sugars, insoluble fiber, soluble fiber, or sugar alcohol for children 1 through 3 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA stated that there was no reliable data or information available to establish DRVs for polyunsaturated fat, monounsaturated fat, sugars, insoluble fiber, soluble fiber, and sugar alcohols, and tentatively concluded that there was no basis for setting DRVs for these nutrients (79 FR 11941). FDA established a DRV reference point for the added sugars declaration at 10 percent of calories in its final rule, after considering the scientific evidence in the 2015 DGAC report (81 FR 33842). FDA set a DRV for children 1 through 3 years of age of 25 g of added sugars (1,000 calorie reference amount × .10 = 100 calories and 100 calories ÷ 4 calories/gram = 25 grams) (81 FR 33928–33929). FSIS has reviewed FDA's analysis and is proposing a DRV for added sugars of 25 g for children 1 through 3 years of age and that the percent DV for added sugars be declared on the Nutrition Facts label consistent with FDA's final rule. FSIS is not proposing DRVs for polyunsaturated fat, including *n*-3 or *n*-6 polyunsaturated fatty acids, monounsaturated fat, sugars, soluble fiber, insoluble fiber, or sugar alcohols for children 1 through 3 years of age consistent with the FDA Nutrition Labeling Final Rule.

e. Total Carbohydrate

FSIS has not established a DRV for total carbohydrate for children 1 through 3 years of age. As discussed in section II.E.1, consistent with FDA, FSIS is proposing a DRV for total carbohydrate for the general population based on the percentage of calories in a 2,000 calorie diet remaining after the sum of the DRV for fat (30 percent) plus the DRV for protein (10 percent) have been subtracted consistent with FDA's Nutrition Labeling Final Rule. As discussed in FDA's proposed rule, FDA considered this method to be appropriate for setting a DRV for total carbohydrate for children 1 through 3 years of age because it falls within the IOM AMDR recommendation of 45 to 65 percent of calories from carbohydrates for children 1 through 3 years of age (79 FR 11941). FDA tentatively concluded that an appropriate DRV for total carbohydrate is 60 percent of calories (*i.e.,* 150 g using the proposed reference calorie intake level of 1,000 calories/d) (*Id.*) FDA did not receive comments on its tentative conclusion and finalized this requirement as proposed (81 FR 33929). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to set a DRV of 150 g for total carbohydrate for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)).

f. Dietary Fiber

FSIS has not established a DRV for dietary fiber for children 1 through 3 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA tentatively concluded that the AI of 14 g/1,000 calories for dietary fiber for children 1 through 3 years of age should be used to set a DRV for dietary fiber to be consistent with how other proposed DRVs are being set; for example, proposing a reference calorie intake level of 1,000 calories/d for this subpopulation (79 FR 11941–11942). FDA established a DRV of 14 g for dietary fiber in its final rule (81 FR 33929). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish a DRV of 14 g for dietary fiber for children 1 through 3 years of age (9 CFR 413.309(c)(9)).

g. Protein

The current RDI for protein for children less than 4 years of age was based on the 1989 RDA for protein of 16 g/d (9 CFR 317.309(c)(7)(iii) and 381.409(c)(7)(iii)).

As discussed in FDA's Nutrition Labeling Proposed Rule, FDA considered current recommendations and acknowledged that protein intakes are well above the current RDI; the mean protein intake for children 12 to 23 months of age was 44 g/d; the protein AMDR for children 1 through 3 years of age is 5 to 20 percent of calories; and the proposed reference calorie intake level and the approaches used for the proposed DRVs for fat and carbohydrate are based on percent of calories (79 FR 11942). FDA tentatively concluded that the DV for protein for children 1 through 3 years of age should be a DRV, rather than an RDI (using the RDA), and that a DRV for protein should be based on 5 percent of 1,000 calories or 50 calories, which equals 12.5 g or, when rounded up, is 13 g (*Id.*) FDA established a DRV for protein of 13 g for children 1 through 3 years of age in its final rule (81 FR 33929). FSIS agrees with FDA's conclusion and is proposing to establish a DRV for protein of 13 g for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)) consistent with FDA's Nutrition Labeling Final Rule.

h. Sodium

For the general population, FSIS is proposing to establish a DRV based on the UL for sodium (section II.G.). There is no current DRV for sodium for children 1 through 3 years of age.

As discussed in FDA's Nutrition Labeling Proposed Rule, FDA agreed with comments to its 2007 ANPRM that 1,500 mg is an appropriate DRV for sodium for children 1 through 3 years of age (79 FR 11942). FDA did not receive comments on this proposed requirement and finalized this requirement (81 FR 33929). Consistent with FSIS's proposed approach for the general population and FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish a DRV of 1,500 mg for sodium for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)).

i. Fluoride

FSIS has not established a DV for fluoride for children 1 through 3 years of age. As discussed in section II.H, FSIS is not establishing a DRV for fluoride for the general population. FSIS agrees with FDA that a DRV for fluoride is not warranted for children 1 through 3 years of age and is not proposing to establish a DRV for fluoride for children 1 through 3 years of age (79 FR 11942; 81 FR 33929).

j. Vitamins and Minerals

FSIS regulations do not currently include a table listing the RDIs for children less than 4 years of age. The preamble to FDA's 1993 DRV/RDI final rule provides a table listing RDIs for children less than 4 years of age (58 FR 2206 at 2213), which is also provided in FDA's Food Labeling Guide. FDA reviewed current quantitative intake recommendations for vitamins and minerals for infants and considered comments received in response to their 2007 ANPRM to determine appropriate RDIs for vitamins and minerals for children 1 through 3 years of age.

As discussed in FDA's Nutrition Labeling Proposed Rule, the IOM's quantitative intake recommendations (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for this subpopulation. The IOM determined that available evidence was sufficient to establish appropriate RDAs and AIs for vitamins and minerals for this subpopulation; that it is appropriate to use RDAs and, in the absence of RDAs, AIs to determine appropriate micronutrient RDIs for children 1 through 3 years of age; that the RDA, when available, is the best estimate of an intake level that will meet the nutrient goals of practically all consumers who would use the Nutrition Facts label; that AIs have less certainty than RDAs, but they represent goals for nutrient intake for individuals and provide the best estimate based on current science for use in setting RDIs for such nutrients; that promoting the development of eating patterns associated with adequate potassium intake later in life is important because chronic conditions such as elevated blood pressure, bone demineralization, and kidney stones likely result from inadequate potassium intakes over an extended period of time, including childhood; and that the AI for potassium is 3,000 mg/d and is considered an appropriate basis for establishing a RDI for potassium for children 1 through 3 years of age (79 FR 11942). FDA established RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for children 1 through 3 years of age in its final rule (81 FR 33929–33930).

Therefore, consistent with FDA's Nutrition Labeling Final Rule (81 FR 33927), using the RDAs and AIs, FSIS is proposing to establish RDIs as set forth in proposed 9 CFR 413.309(c)(8)(iv) for these same nutrients for children 1 through 3 years of age.

7. DRVs and RDIs for Pregnant Women and Lactating Women

a. Calories

The reference calorie intake of 2,000 used for the general population applies to pregnant women and lactating women (9 CFR 317.309(c)(9) and 381.409(c)(9)). As discussed in FDA's Nutrition Labeling Proposed Rule, the calorie needs for pregnant women and lactating women are similar to the general population, and few products are purported for pregnant women and lactating women (79 FR 11943). FDA explained that the calorie needs for pregnant and lactating women are similar to the general population (*Id.*) FDA established a 2,000 reference calorie intake level for the DRV for pregnant women and lactating women in its final rule (81 FR 33931). Consistent with FDA's final rule, FSIS is proposing to use the 2,000 reference calorie intake level for setting DRVs for pregnant women and lactating women (proposed 9 CFR 413.309(c)(9)).

b. Total Fat, Saturated Fat, Cholesterol, Total Carbohydrate, Sodium, Added Sugars, and Dietary Fiber

FSIS regulations do not provide DRVs for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant women and lactating women. As discussed in FDA's Nutrition Labeling Proposed Rule, quantitative intake recommendations for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant women and lactating women are generally similar to the general population (79 FR 11943). FDA tentatively concluded that the DRVs for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant women and lactating women should remain the same as for the general population (*Id.*). FDA established DRVs for pregnant women and lactating women using the same DRVs for these nutrients as used for the general population (81 FR 33931). FDA also requires a DRV of 50 g of added sugars for adults and children 4 years of age and older, including pregnant women and lactating women (81 FR 33931). Consistent with FDA's final rule, FSIS is proposing to establish DRVs for pregnant women and lactating women using the proposed DRVs for the general population for total fat, saturated fat, cholesterol, total carbohydrate, sodium, added sugars and dietary fiber (proposed 9 CFR 413.309(c)(9)).

c. Trans Fat, Polyunsaturated Fat, Monounsaturated Fat, Soluble Fiber, Insoluble Fiber, Sugars, and Sugar Alcohols

There are no DRVs for *trans* fat, polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugars, or sugar alcohol for pregnant women and lactating women. As discussed in sections II.C. and II.E., FSIS is not proposing DRVs for these nutrients for the general population because of a lack of quantitative intake recommendations. Similarly, quantitative intake recommendations are lacking for these nutrients for pregnant women and lactating women. Therefore, FSIS is not proposing to establish DRVs for *trans* fat, polyunsaturated and monounsaturated fat, soluble fiber, insoluble fiber, sugars, or sugar alcohols for pregnant women and lactating women consistent with FDA's Nutrition Labeling Final Rule (81 FR 33931).

d. Protein

FSIS has established RDIs of 60 g protein for pregnant women and 65 g protein for lactating women (9 CFR 317.309(c)(7)(iii) and 381.409(c)(7)(iii)). As discussed in FDA's Nutrition Labeling Proposed Rule, the IOM established 71 g/d protein as the RDA for pregnant women and lactating women based on the needs for maternal and fetal development and human milk production (79 FR 11943). FDA tentatively concluded that the DV for protein for pregnant women and lactating women should remain an RDI (using the RDA) instead of a DRV because the DRV approach used to calculate protein for the general population based on 10 percent of 2,000 calories, which equals 50 g of protein/d, falls short of the recommended protein needs of pregnant women and lactating women of 71 g/d (*Id.*). FDA did not receive comments on its tentative conclusion and established an RDI of 71 g for protein for pregnant women and lactating women in its final rule (81 FR 33931). Consistent with FDA's final rule, FSIS is proposing to establish an RDI of 71 g for protein for pregnant women and lactating women (proposed 413.309(c)(7)(iii)).

e. Fluoride

There is no DRV for fluoride for the general population or for pregnant women and lactating women. While an AI has been established for fluoride, FSIS is not proposing to establish a DRV for fluoride for the general population for the reasons discussed in section II.H. Similarly, because the AI for fluoride for pregnant women and lactating women is not different from the general population, as discussed in FDA's Nutrition Labeling Proposed Rule (79 FR 11943), FSIS is not proposing a DRV for fluoride for pregnant women and lactating women.

f. Vitamins and Minerals

While not included in FSIS regulations, the preamble to the FDA 1993 DRV/RDI final rule provides a table listing RDIs for pregnant women and lactating women (58 FR 2206 at 2213), which is also provided in FDA's Food Labeling Guide (79 FR 11943). As discussed in FDA's Nutrition Labeling Proposed Rule, FDA reviewed current quantitative intake recommendations for vitamins and minerals for pregnant women and lactating women and concluded that it is appropriate to establish RDIs for pregnant women and lactating women for vitamins and minerals that have DRIs, using population-coverage RDAs and AIs, instead of population-weighted EARs (79 FR 11943). In addition, FDA established a single set of RDIs intended for both pregnant women and lactating women because nutrient needs during pregnancy and lactation are similar and because using one set of RDIs would address practical concerns related to limited space on food labels (81 FR 33932).

Therefore, FSIS is proposing to establish RDIs as set forth in proposed 9 CFR 413.309(c)(8)(iv) for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for pregnant women and lactating women consistent with FDA's Nutrition Labeling Final Rule.

K. Format

FSIS requires that nutrition information for meat and poultry products be presented in a specific format on the labels of those products (see 9 CFR 317.309(d)(1)–(f) and 381.409(d)(1)–(f)). Since 1995 when FSIS last published a final rule effecting the nutrition labeling format regulations (60 FR 174; January 3, 1995), more research has been done on trends in health conditions and how best to present information to consumers. FDA, in its changes to the Nutrition Facts label format, took into consideration ''graphic design principles such as alignment, consistency, repetition, and contrast,'' emphasizing ''key nutrients and key information'' through highlighting and ''removing or modifying parts of the label to assist consumers in maintaining healthy dietary practices'' (79 FR 11948; 81 FR 33936). FSIS has reviewed FDA's rationale for the changes to the Nutrition Facts label format (*see* 79 FR 11948–11955; 81 FR 33936–33959) and agrees with its approach. FSIS believes it is necessary to propose changes to the Nutrition Facts label format for meat and poultry products that will parallel, to the extent possible, FDA's new regulations. This approach will help prevent consumer confusion and non-uniformity in the marketplace. Therefore, FSIS is proposing the following changes to the Nutrition Facts label format.

1. Increasing the Prominence of Calories and Serving Size

Consistent with FDA's final rule (81 FR 33937–33940), FSIS is proposing (i) to increase the type size for ''Calories'' and the numeric value for ''Calories,'' and (ii) to require that the numeric value for calories be highlighted in bold or extra bold type (proposed 9 CFR 413.309(d)). These changes will emphasize the importance of calories on the label and draw more consumer attention to the calories declaration.

2. Changing the Order of the ''Serving Size'' and ''Servings per Container'' Declarations and Increasing the Prominence of ''Servings per Container''

FSIS currently requires that information on serving size, which includes a statement of the serving size and the number of servings per container, follow the heading ''Nutrition Facts'' (9 CFR 317.309(d)(3) and

381.409(d)(3)). Consistent with FDA's Nutrition Labeling Final Rule (*see* 81 FR 33940–33943), FSIS is proposing to (i) reverse the order of the declarations of ''Servings Per Container'' and ''Serving Size;'' (ii) require that no capital letters are used for serving size information, except for the first letter in ''Serving size;'' (iii) require that ''__servings per container'' (with the blank filled in with the actual number of servings) be in type size no smaller than 10 point (except for the tabular and linear displays for small packages) (proposed 9 CFR 413.309(d)(3)(i)); and (iv) require that the serving size information be highlighted in bold or extra bold type and be in a type size no smaller that 10 point (except for the linear display for small packages)(proposed 9 CFR 413.309(d)(3)(i)). FSIS has tentatively concluded that these proposed changes will help consumers better locate, identify, and understand the information in the Nutrition Facts label and assist consumers in making informed purchase decisions and maintaining health dietary practices.

3. Right-Justifying the Quantitative Amounts Declared in the ''Serving size'' Statement

Currently, the label statement for ''Serving size'' expressed in common household measures (*e.g.,* cup, tablespoon, piece or slice) and gram amounts is stated immediately adjacent to the ''Serving Size'' declaration as seen in 9 CFR 317.309(d)(12) and 381.409(d)(12). FSIS is proposing to require that the ''Serving size'' declaration be left-justified and the corresponding numerical value as determined in proposed 9 CFR 413.309(b)(9) be right-justified (proposed 9 CFR 413.309(d)(3)(i)). FSIS agrees with FDA that the proposed change will create more white space on the Nutrition Facts label that ''would result in a less cluttered appearance, heightened focus and emphasis, and improved readability'' and will improve ease of use for consumers (79 FR 11950).

4. Presentation of Percent DVs

FSIS currently requires that the column heading ''% Daily Value'' and a list of nutrient names and amounts as described in 9 CFR 317.309(d)(7) and 381.409(d)(7) be to the left of and below this column heading in the Nutrition Facts label (9 CFR 317.309(d)(6) and (7) and 381.409(d)(6) and (7)). On all dual column labels, including those (1) for two or more forms of the same food (proposed 9 CFR 413.309(e)(5)); (2) displaying nutrition information per container and per unit, in addition to nutrition information per serving (proposed 9 CFR 413.309(e)(6)(i); (3) using the tabular display (proposed 9 CFR 413.309(e)(6)(ii)); and (4) that provide the aggregate display (proposed 9 CFR 413.309(d)(13)(ii)), FSIS is proposing to use thin vertical lines to separate the information in the ''% Daily Value'' column from the information in the column containing the quantitative weights. Further, FSIS is proposing to use the same style of thin vertical lines to separate each of the dual columns and aggregate display columns from each other. FSIS has tentatively concluded that the use of these vertical lines will help differentiate the columns and make the information easier to read for consumers. In addition, FSIS is proposing that protein would no longer be listed with the vitamins and minerals at the bottom of these labels as currently required.

5. Placement of ''Added Sugars''

As discussed in section II.E.3 of this proposed rule, FSIS is proposing to require the declaration of added sugars as an indented line item underneath the declaration of ''Total Sugars'' on the Nutrition Facts label. ''Added Sugars'' would be the only mandatory nutrient required to be listed in a double indentation format on the Nutrition Facts label.

FDA conducted a consumer study that, among other things, looked at how consumers would use the new information regarding added sugars, but did not evaluate the impact of listing a percent DV for added sugars on the Nutrition Facts label (80 FR 44306). The study was a controlled, randomized, web-based experiment where participants viewed three different Nutrition Facts label formats and responded to questions regarding their ability to accurately recognize and compare nutrients on the Nutrition Facts label and their judgments about the foods' overall healthfulness and relative nutrient levels (80 FR 44306). The study found that when both total and added sugars declarations appeared on the label, the majority of study participants correctly reported the added sugars amount and accurately identified which products had less added sugars (80 FR 44306). The study also found that where an added sugars declaration was indented below a ''Total Sugars'' declaration the study participants' understanding that added sugars are part of the total amount of sugars in the product improved (80 FR 44306). Therefore, consistent with FDA's final rule, FSIS is proposing to use the term ''Total Sugars'' instead of ''Sugars'' on the label. A summary of FDA's Added Sugars Experiment is available at 80 FR 44306 and a full description is available in the FDA Nutrition Labeling Supplemental Proposed Rule docket.[29]

FDA's Nutrition Labeling Final Rule also addressed commenters' concerns regarding potential consumer confusion when including an ''Added Sugars'' declaration under ''Total Sugars'' on the Nutrition Facts label. Based on the recommendations of two independent FDA experts, as well as literature suggesting linking terms are useful for increasing comprehension, FDA added the word ''Includes'' in front of ''Added Sugars'' (81 FR 33827.) FDA also minimized the line between ''Total Sugars'' and ''Added Sugars'' to help denote that ''Added Sugars'' are a subcomponent of ''Total Sugars.'' Consistent with FDA, FSIS is proposing to add the word ''Includes'' in front of ''Added Sugars'' such that the added sugars declaration reads ''Includes X g Added Sugars.'' FSIS is also proposing to minimize the hairline between ''Total Sugars'' and ''Added Sugars.''

6. Declaration of Absolute Amounts of Vitamins and Minerals

FSIS currently requires that the quantitative amount by weight of mandatory and voluntary nutrients be declared on the Nutrition Facts label, except for vitamins and minerals (other than sodium and potassium) which must be declared only as percent DVs(9 CFR 317.309(c)(8) and 381.309(c)(8)). Consistent with FDA's Nutrition Labeling Final Rule (81 FR 33946–33949), FSIS is not proposing to require the declaration of the absolute amounts of all mandatory and voluntary vitamins and minerals as well as the percent DV declaration on the Nutrition Facts label. FSIS is, however, proposing to clarify in proposed 9 CFR 413.309(c)(8) that the declaration of voluntarily declared vitamins and minerals listed in proposed 9 CFR 413.309(c)(8)(iv) may include the quantitative amount by weight and percent of the RDI. FSIS is also proposing that if vitamins or minerals are added or there is a claim made about them, the manufacturer must include a declaration of the nutrient as a percent DV, or alternatively, as a quantitative amount by weight and percent DV (proposed 9 CFR 413.309(c)(8)(ii)).

[29] U.S. Food and Drug Administration. Memorandum to the File—''Experimental study on consumer responses to Nutrition Facts labels with declaration of amount of added sugars (OMB No. 0910–0764),'' 2015.

7. The Footnote

FSIS currently requires that a footnote, preceded by an asterisk, be placed beneath the list of vitamins and minerals and be separated from that list by a hairline on the Nutrition Facts label (9 CFR 317.309(d)(9) and 381.409(d)(9)). The footnote must state ''Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs'' followed by a table that lists the DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets. (9 CFR 317.309(d)(9)(i) and 381.409(d)(9)(i)). Caloric conversion information on a per-gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph 9 CFR 317.309(d)(9) and 381.409(d)(9) separated by a hairline (9 CFR 317.309(d)(10) and 381.409(d)(10)).

Comments to FDA's 2007 ANPRM cited to research that the comments said showed that consumers do not understand what information is being conveyed in the footnote (79 FR 11953). In 2014, FDA conducted a controlled, randomized, web-based experiment that compared consumer reactions to seven footnote formats, which included five modified footnotes, in addition to the current footnote and no footnote at all, for explaining percent DVs and how to use them (the ''Footnote Experiment'').[30] In FDA's Nutrition Labeling Final Rule, FDA finalized a revised footnote requirement (81 FR 33952). FDA removed the requirement for the footnote table listing the DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for 2,000 and 2,500 calorie diets that is specified in 21 CFR 101.9(d)(9)(i) and added the following footnote text: ''*The %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.'' *Id.* The footnote text is similar to one of the options tested in the Footnote Experiment, except that the sentences in the footnote are reversed (80 FR 44309). The study participants perceived the language in this footnote to be more useful than the current footnote; and FDA switched the order of the sentences in the footnote so the explanation of the %DV clearly follows the asterisk that leads to the footnote in the %DV column (80 FR 44309).

FDA stated that the new footnote ''which explains the term ''% Daily Value'' and provides a reference calorie level will assist consumers in better understanding the information of the Nutrition Facts label and in maintaining healthy dietary practices'' (81 FR 33952). FDA did not change the caloric conversion information in the footnote specified in 21 CFR 101.9(d)(10. FDA stated, in its Nutrition Labeling Proposed Rule, that ''increasing the type size, bolding key elements of the footnote (space permitting), and adding a bar clearly separating it from the micronutrient information directly above will assist consumers in using the information'' (79 FR 11953). FDA did not finalize this proposed requirement.

Under the Nutrition Labeling Final Rule, FDA now allows the footnote to be omitted from products that qualify for a simplified format (21 CFR 101.9(f)), provided that the following abbreviated statement is used ''%DV = %Daily Value'' in a type size no smaller than 6 point on these package labels when Daily Value is not spelled out in the column heading (81 FR 33952). FDA is also not requiring the footnote on small or intermediate-sized packages (21 CFR 101.9(j)(13)(ii)(A)(*1*) and (*2*)), but manufacturers may voluntarily include the abbreviated footnote on these packages. The abbreviated statement would allow for more space on the label and informs consumers what %DV means. In addition, FDA is providing an exemption from the footnote requirement for foods that can use the terms ''calorie free,'' ''free of calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietary insignificant source of calories'' on the label or in the labeling of foods, as defined in 21 CFR 101.60(b) (81 FR 33952). FDA is also allowing the voluntary use of the first part of the footnote statement, ''*The %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet'' on these products (81 FR 33952). FDA stated that such products would have little to no impact on the average daily 2,000 calorie intake, which the footnote addresses (80 FR 44309).

Consistent with FDA's Nutrition Labeling Final Rule (81 FR 33949–33954), FSIS is proposing to remove the requirement for the footnote table listing the DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for 2,000 and 2,500 calorie diets (proposed 9 CFR 413.309(d)(9)(i)). FSIS is also proposing the following footnote text: ''The %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.'' Consistent with FDA, FSIS is not proposing changes to the caloric conversion information in the footnote currently specified in 9 CFR 317.309(d)(10) and 381.409(d)(10) (which would be consolidated in proposed 9 CFR 413.309(d)(10)). FSIS is proposing that the footnote may be omitted from products that qualify for a simplified format (proposed 9 CFR 413.309(f)), provided that the following abbreviated statement is used ''%DV = %Daily Value,'' when the package labels do not spell out Daily Value in the column heading. FSIS is also proposing that the footnote may be omitted from small or intermediate-sized packages (proposed 9 CFR 413.309(g)). FSIS is also proposing an exemption from the footnote requirement for foods that can use the terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietarily insignificant source of calories'' on the label or in the labeling of foods as defined in proposed 9 CFR 413.360(b). FSIS is also proposing to allow the voluntary use of the first part of the footnote statements, ''*The %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet,'' on these products.

8. Addition of a Horizontal Line Beneath the Nutrition Facts Heading

FSIS requires that the ''Nutrition Facts'' heading on the Nutrition Facts label be set in a type size larger than all other print size in the nutrition label (9 CFR 317.309(d)(2) and 381.409(d)(2)). FDA amended its regulations to require a hairline rule be inserted directly beneath the ''Nutrition Facts'' heading on all label formats, except for the linear display for small packages, to direct the reader's eye to the serving size information, place emphasis on the information about servings, and break the information into smaller chunks to make it easier to process (79 FR 11954; 81 FR 33954). Consistent with FDA's final rule, FSIS is proposing to require that a hairline rule be inserted immediately below the ''Nutrition Facts'' heading on all nutrition label formats except for the linear display for small packages (proposed 9 CFR 413.309(d)(1)(iii)).

[30] U.S. Food and Drug Administration. Memorandum to the File—''Experimental study on consumer responses to Nutrition Facts labels with various footnote formats (OMB No. 0910–0764),'' 2015.

L. Single-Serving Containers/Units and Dual-Column Labeling

1. Single-Serving Containers/Units

FSIS's current regulations require that a product that is packaged and sold individually and that contains less than 200 percent of the applicable RACC be considered a single-serving container, and that the entire content of the product be labeled as one serving, except that for products that have RACCs of 100g or 100mL or larger, manufacturers may decide whether a package containing more than 150 percent but less than 200 percent of the RACC be labeled as 1 or 2 servings (9 CFR 317.309(b)(8) and 381.409(b)(8)). FSIS's current regulations also require that for products that have RACCs of 100g or 100mL or larger and are individual units within a multi-serving package, manufacturers may decide whether an individual unit that contains more than 150 percent but less than 200 percent of the RACC be labeled as 1 or 2 servings (9 CFR 317.309(b)(4)(v) and 381.409(b)(4)(v)).

Based on a review of recent research, FDA has determined that many consumers do not correctly calculate nutrient amounts in food products by multiplying the nutrient amount by the number of servings per container (79 FR 11998–11999). FDA also found that the exemption from the requirement to label a product with a large RACC as a single-serving container is no longer warranted because ''there is a low correlation between the RACCs (whether the reference amount is more than or less than 100 g or mL) and the consumption variation for all products containing less than 200 percent of the RACC, regardless of whether the RACC is 'large' (*i.e.,* greater than 100 g or 100 mL) or not'' (79 FR 12001). Under pre-existing FDA regulations, if a package or discrete unit of food with a ''large'' RACC contained more than 150 percent but less than 200 percent of the RACC, the manufacturer was permitted to decide whether to declare the package or individual unit as 1 or 2 servings (81 FR 34004–34008). The FDA Serving Size Final Rule, however, removed this exemption and, for products subject to FDA requirements, requires that all packages of food containing less than 200 percent of the RACC be labeled as a single serving (see 21 CFR 101.9(b)(6)), and that discrete units containing at least 67 percent of the RACC but less than 200 percent of the RACC be labeled as a single serving (see 21 CFR 101.9(b)(2)(i)(C)). FDA also removed the provision that products packaged and sold individually and containing 200 percent or more of the applicable RACC may be labeled as a single serving if the entire contents of the container can reasonably be consumed at a single eating occasion (81 FR 34004–34008).

FSIS has reviewed FDA's research and analysis and tentatively agrees with FDA's conclusions. Therefore, FSIS is proposing to revise the requirements for single-serving labeling so that a product packaged and sold individually that contains less than 200 percent of the applicable RACC must be considered a single serving, and that a discrete unit containing at least 150 percent but less than 200 percent of the RACC must be labeled as one serving regardless of whether the RACC exceeds 100 g or mL (proposed 9 CFR 413.309(b)(8)).

2. Dual-Column Labeling

FSIS currently permits manufacturers to voluntarily provide an additional column of nutrition information (*i.e.,* dual column labeling) in the following situations:

- Per 100 g, 100 mL, or 1 oz of the product as packaged or purchased (9 CFR 317.309(b)(13)(i) and 381.409(b)(13)(i));
- Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit (9 CFR 317.309(b)(13)(ii) and 381.409(b)(13)(ii));
- For the product alone if the product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided (*e.g.,* a cream soup mix may be labeled with one set of DVs for the dry mix (per serving), and another set for the serving of the final soup when prepared (*e.g.,* per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)(9 CFR 317.309 (b)(15) and 381.409(b)(15));
- For two or more forms of the same product (*e.g.,* both ''raw'' and ''cooked'') as provided in 9 CFR 317.309(b)(3) and (e) and 381.409(b)(3) and (e); and
- For two or more groups for which RDIs are established (*e.g.,* both infants and children less than 4 years of age) as provided in 9 CFR 317.309(c)(8)(i) and (e) and 381.409(c)(8)(i) and (e).

Research has shown that package and portion sizes have a considerable impact on the amount of food consumed, and that the size of the package or unit of food can set a consumption norm for consumers; that consumers do not correctly calculate nutrient amounts in food products by multiplying the nutrient amount by the number of servings per container; and that dual-column labeling with the nutrition information given per serving and per package may help certain consumers recognize nutrient amounts per package in certain types of packaged food (79 FR 11998–11999). Therefore, consistent with FDA's Serving Size Final Rule, FSIS is proposing mandatory dual-column labeling on certain packages of meat and poultry products.

FSIS is proposing that meat and poultry products in packages or units that contain at least 200 percent and up to and including 300 percent of the applicable RACC be required to have two columns in the Nutrition Facts label. One column would list the quantitative amounts and percent DVs for the entire package or unit, and the other column would list the quantitative amounts and percent DVs for a serving, based on the amount most closely approximating the RACC, that is less than the entire package or unit (proposed 9 CFR 413.309(b)(4)(iv) and 9 CFR 413.309(b)(16)). FSIS is proposing an upper limit of 300 percent for dual-column labeling based on FDA's analysis that showed that '' providing an upper limit at 300 percent of the RACC would ensure that dual-column labeling captures 90 percent of the consumption habits for about 91 percent of food products and limit the possibility that dual-column labeling will be required for package sizes that are not likely to be consumed in a single eating occasion'' (81 FR 34015–34016). Providing nutrition information for these products in dual columns will make it easier for consumers, regardless of whether they consume the entire container or unit in a single eating occasion, consume part of the entire container or unit in a single eating occasion, or share the container or unit, to identify the amount of nutrients consumed without having to perform mathematical calculations.

FSIS is proposing that meat and poultry products in packages that meet the requirements to use a tabular display for small packages or to use a linear format be exempt from the dual-column labeling requirements (proposed 9 CFR 413.309(b)(16)(i)(A)). FSIS is also proposing that products that require further preparation and provide two columns of nutrition information (*e.g.,* one column ''as purchased'' and one column ''as prepared'') would be exempt from the dual-column labeling requirements in proposed 9 CFR 413.309(b)(16). If products that already provide two columns of nutrition information for ''as purchased'' and ''as prepared'' forms of the product were required to have dual-column labeling with nutrition information per serving size and per the entire container, the products would have at least three columns of nutrition information, or manufacturers would decide to no longer provide the voluntary information for the prepared form of the product. FSIS is also proposing that products that are commonly consumed in combination with another food and provide an additional column of nutrition information under proposed 9 CFR 413.309(e) be exempt from the dual-column labeling requirements in proposed 9 CFR 413.309(b)(16). Similar to the products that require further preparation, nutrition information based on the entire container of an uncombined food (*e.g.,* the dry mix alone for a cream soup mix) (for a food that is commonly combined with another food) may be less meaningful to consumers than information on a serving of the combined food (*e.g.,* per serving of cream soup mix and 1 cup of vitamin D fortified whole milk) because these types of products are commonly consumed in combination with another food. FSIS is also proposing that products that provide an additional column of nutrition information for two or more groups for which RDIs are established (*e.g.,* both infants through 12 months and children 1 through 3 years of age) and random weight products be exempt from the dual-column labeling requirements (proposed 9 CFR 413.309(b)(16)(i)(C)). Information provided for subpopulations will be more useful to distinct populations for certain products than information per-container or unit.

FSIS is proposing that the Nutrition Facts label for a meat or poultry product that is packaged and sold individually that contains more than 150 percent and less than 200 percent of the applicable reference amount, may voluntarily provide, to the left of the column that provides nutrition information per container (*i.e.,* per serving), an additional column that lists the quantitative amounts and percent Daily Values per common household measure that most closely approximates the reference amount (proposed 9 CFR 317.309(b)(8)).

3. Use of Nutrient Content Claims and Health Claims on Products With Dual-Column Labeling per Serving and per Container

RACCs set forth in 9 CFR 317.312(b)–(e) and 381.412(b)–(e) are currently used to determine whether a product meets the criteria for a nutrient content claim (9 CFR 317.313(p) and 381.413(p)). Consistent with the FDA Serving Size Final Rule, if nutrition information is presented on a per serving basis and on a per container or unit basis (*i.e.,* the proposed dual-column labeling requirements or if a dual-column is provided voluntarily) on the Nutrition Facts Label, FSIS is proposing to require that the nutrient content claim be followed by a statement that sets forth the basis on which the claim is made (proposed 9 CFR 413.309(b)(16)(ii)). The statement must express the amount of the nutrient in a serving (*e.g.,* ''good source of calcium'' ''a serving of __oz of this product contains __mg of calcium'' or for a health claim ''A serving of _ ounces of this product conforms to such a diet''). However, if the serving size declared on the product label differs from the RACC, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, FSIS is proposing that the claim must be followed by the criteria for the claim as required by proposed 9 CFR 413.313(p). This criteria statement would help clarify that the nutrient content claim or health claim is based on the RACC and not the amount in the entire container. FSIS is also proposing that this criteria statement would not be required for products when the nutrient that is the subject of the claim meets the criteria based on the entire container amount or the unit amount, as applicable (proposed 9 CFR 413.309(b)(16)(ii)).

4. Additional Changes to Serving Size Regulations

FSIS currently allows by policy the use of an ounce unit in the serving size, *e.g.,* 4oz (112g), instead of a household unit, *e.g.,* 1 piece (112g), when the size of the product naturally varies in weight and is not uniform in size (*e.g.,* poultry parts, such as chicken breasts and chicken wings, and non-formed meat cuts, such as pork chops). Consistent with 21 CFR 101.9(b)(2)(i)(G), proposed 9 CFR 413.309(b)(4)(vii) would permit the use of an ounce unit in the serving size for products that naturally vary in size (*e.g.,* poultry parts or non-formed cuts of meat).

Current FSIS regulations require the serving size to declare the as-packaged amount in accordance with 9 CFR 317.309(b)(3) and 381.409(b)(3). Consistent with 21 CFR 101.9(b)(7)(v), proposed 9 CFR 413.309(b)(9)(5) would permit the serving size to include the finished product amount as part of the serving size when water or other ingredients with insignificant amounts of nutrients are instructed to be added during preparation. For example, when the consumer is directed to add a specific amount of water to prepare a condensed soup, the serving size may state ''½ cup (120g) concentrated soup (makes 1 cup prepared)'' instead of ''½ cup (120g).''

Currently, FSIS requires the serving size for a product marketed for two different purposes, *e.g.,* gravy or a soup, to be based on the larger serving size, *e.g.,* soup (1 cup RACC) instead of gravy (¼ cup RACC) (9 CFR 317.312 and 381.412). Consistent with 21 CFR 101.9(b)(11), proposed 9 CFR 413.309(b)(13)(iii) would require the Nutrition Facts label to include the nutrient information for both marketed serving sizes when the amount served for each differs in quantity by twofold or greater based on the RACC in accordance with proposed 9 CFR 413.313(b) (*e.g.,* the Nutrition Facts label would provide nutrient data for both soup (1 cup) and gravy (¼ cup) because the soup serving size is greater than twofold over the serving size for gravy).

M. Reference Amounts Customarily Consumed

1. Factors Considered To Determine the Existing RACCs To Update

The current RACCs for meat and poultry products are listed in 9 CFR 317.312 and 381.412, respectively. The RACCs represent the amount of food customarily consumed per eating occasion and are listed by product categories. The RACCs and product categories are used as the basis for determining serving sizes for specific products. The current RACCs were primarily derived from the 1977–1978 (*http://www.ars.usda.gov/Services/docs.htm?docid=16184*) and the 1987–1988 (*http://www.ars.usda.gov/Services/docs.htm?docid=16185*) Nationwide Food Consumption Surveys conducted by USDA. Since the current RACCs were established, there is new consumption data that shows that the amount of foods Americans customarily consume has changed, and there are new food products in the marketplace. Therefore, FSIS analyzed more up-to-date consumption data to determine whether the RACCs and product categories for meat and poultry products needed to be updated or revised.

FSIS analyzed the recent consumption data from the NHANES 2003–2008 surveys using Statistical Analysis Systems (SAS) [31] and Survey Data Analysis (SUDAAN) [32] procedures to determine the amount of food being consumed by individuals. FSIS

[31] SAS version 9.2 Cary, NC, 2011 *http://www.sas.com/technologies/analytics/statistics/stat/index.html.*

[32] SUDAAN version 10.1 Research Triangle Park, NC, 2011 *http://www.rti.org/page.cfm/Survey_Statistics.*

considered the following factors in determining whether to revise the 1993 RACCs and product categories: (1) Whether there was an adequate sample size from the NHANES 2003–2008 consumption data for the product category; (2) whether the median intake estimate from the NHANES 2003–2008 consumption data for the product significantly differs (*i.e.,* at least a 25 percent difference) from the 1993 RACC; (3) whether the intake distribution was skewed (based on comparing the median intake estimate with the mean intake estimate from the NHANES 2003–2008 consumption data); (4) the ''reasonable consumption amount'' from the Food and Nutrient Database for Dietary Studies (FNDDS)[33]; (5) the difference between the median intake estimates, converted to common household measures as applicable, and the 1993 RACC for the product; (6) the median intake estimates for comparable products; and (7) the RACCs for comparable FDA-regulated products. More detailed information about how the factors were applied to change or not change the RACCs for a specific food product are contained in a rationale chart available on the FSIS Web site.[34] FDA used similar methodology for updating the RACCs for foods regulated by FDA. The following sections describe the proposed changes to the RACC tables in FSIS's regulations.

2. Changes to Table 1: Reference Amounts Customarily Consumed per Eating Occasion: Food Labeling for Infants and Children 1 Through 3 Years of Age

FSIS is proposing to combine the tables containing the RACCs for infant and toddler foods that exist in 9 CFR 317.312 for meat products and 9 CFR 381.412 for poultry products into a new table for meat and poultry products in proposed 9 CFR 413.312 for infants and children 1 through 3 years of age. FSIS is also proposing to add a third column titled ''label statement'' to the RACC table to provide examples of how the ''label statement'' may appear in the Nutrition Facts label as a formatted serving size and to parallel the FDA proposed RACC table 1 (21 CFR 101.12(b)). The titles of the combined product categories would stay the same, except the combined product category for meat sticks and poultry sticks would be titled ''Plain meats, plain poultry, meat sticks, poultry sticks, ready to serve.''

FSIS is also proposing to change the RACC from 60 g to 110 g for the product category ''Dinners, ready-to-serve, strained type.'' The 2003–2008 median intake estimates for dinner, ready-to-serve, strained type poultry was 101.8 g, and dinner, ready-to-serve, strained type, meat was 88.9 g. FDA, which regulates products containing less than 2% cooked meat or poultry, and less than 3% raw meat, increased the RACC for the comparable product category, ''Dinner, desserts, fruits, vegetables, or soups, ready-to-serve, strained type'' from 60 g to 110 g. The 2003–2008 median intake estimates for these two product categories was 104 g and 103 g, respectively. The products in these FDA regulated product categories are comparable to the FSIS regulated product category, ''Dinner, ready-to-serve, strained type, poultry'' and ''Dinner, ready-to-serve, strained type meat'', because all of the products have similar type usage and product characteristics as strained baby foods. In addition, the current RACC for ''Dinner, soups, ready-to-serve junior type'' is 110 g, and the same RACC for both strained type and junior baby foods would help consumers compare nutrition information.

FSIS is also proposing to update the footnotes to proposed RACC Table 1 as follows: Footnote 1 would be updated to include new data sources, footnote 2 would be updated to include ''brown and serve'' as a type of ''almost ready-to-serve'' product and to include ''(*e.g.,* ready to serve)'' after ''prepared for consumption,'' and footnote 4 would be added to explain the purpose and use of the third column titled ''label statement'' in RACC Table 1.

3. Changes to Table 2: Reference Amounts Customarily Consumed per Eating Occasion: General Food Supply

FSIS is proposing to combine the tables containing the RACCs for the general food supply that currently exist in 9 CFR 317.312 for meat products and 9 CFR 381.412 for poultry products into a new table for meat and poultry products in proposed 9 CFR 413.312. FSIS is proposing to include a third column titled ''label statement'' in the new RACC table for meat and poultry products. The ''label statement'' column, which provides similar examples to what FDA provides in FDA RACC table 2 (21 CFR 101.12(b), provides examples of how serving size statements may appear in the Nutrition Facts label as a formatted serving size. For example, the RACC for a raw poultry cut is 114 grams but the formatted serving size in the Nutrition Facts label would be based on instructions in proposed 9 CFR 413.309(b), for example, 4oz (112g).

FSIS is also proposing to change some of the RACCs and product categories, establish new product categories for the general food supply, and update the footnotes to RACC table 2 as follows.

In the product category ''Egg mixtures (western style omelet, soufflé, egg foo young),'' FSIS is proposing to combine the meat and poultry categories for egg mixtures into one product category. The new name for the product category would be ''Egg mixtures with meat or poultry; *e.g.,* western style omelet, souffleé, egg foo young.'' Egg mixtures with meat and egg mixtures with poultry are comparable products with similar dietary usage and product characteristics. The same RACC will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for luncheon meat into one product category as follows, ''Luncheon products, luncheon meat, bologna, poultry bologna, Canadian style bacon, poultry Canadian style bacon, meat or poultry pattie crumbles, blood pudding, meat or poultry luncheon loaf, old fashioned loaf, berlinger, bangers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelat, Lebanon bologna, potted meat or poultry food product, taco fillings, pie fillings.'' Luncheon meat and luncheon products made with poultry are comparable products with similar dietary usage and product characteristics. The same RACC will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for entrees without sauce into one product category as follows, ''Entrees without sauce; *e.g.,* cuts of meat or poultry including marinated, tenderized, injected cuts of meat or poultry, patties, corn dogs, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, cured poultry ham products, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.'' Entrees without sauce made with meat or poultry are comparable products with similar dietary usage and product characteristics. The same RACC will

[33] The reasonable consumption amount is a default consumption amount of food that researchers have defined and is used in NHANES when survey participants cannot recall the amount of food that was consumed at one eating occasion. Agricultural Research Service, Food Surveys Research Group, ''U.S. Department of Agriculture, Food and Nutrient Database for Dietary Studies, 4.1'' Beltsville, MD, 2010.

[34] *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules*>.

help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for mixed dishes not measurable with a cup into one product category as follows, ''Mixed dishes NOT measurable with a cup; *e.g.,* burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches with meat or poultry, cracker and meat/poultry lunch type packages, gyro, Stromboli, burger on a bun, poultry burger on a bun, frank on a bun, poultry frank on a bun, calzone, taco, stuffed pockets, foldovers, stuffed vegetables with meat or poultry, shish kabobs, empanada, chicken cordon bleu.'' Mixed dishes not measurable with a cup made with meat or poultry are comparable products with similar dietary usage and product characteristics. The same RACC will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for mixed dishes measurable with a cup into one product category as follows, ''Mixed dishes measurable with a cup; *e.g.,* casserole, macaroni and cheese with meat or poultry, pot pie, spaghetti with sauce, poultry spaghetti with sauce, meat or poultry chili, meat or poultry chili with beans, hash, creamed chipped beef, creamed dried poultry, ravioli in sauce, stroganoff, Brunswick stew, goulash, poultry a la king, meat or poultry stew, ragout, meat or poultry lasagna, meat or poultry filled pasta.'' Mixed dishes measurable with a cup made with meat or poultry are comparable products with similar dietary usage and product characteristics. The same RACC (1 cup) will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for ''Salads-all other'' into one product category as follows, ''Salads—all other meat salads, all other poultry salads; *e.g.,* chicken salad, ham salad, turkey salad.'' Salads made with meat and salads made with poultry are comparable products with similar dietary usage and product characteristics. The same RACC (100g) will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for ''Soups-all varieties'' into one category as follows, ''Soups with meat or poultry-all varieties.'' Soups made with meat and soups made with poultry are comparable products with similar dietary usage and product characteristics. The same RACC (245g) will help consumers compare nutrition information between these products.

FSIS is proposing to create a new product category ''Appetizers, hors d'oeuvres, Mini mixed dishes with meat or poultry; *e.g.,* mini bagel pizzas, mini egg rolls, dumplings, mini pizza rolls, mini quesadilla, mini quiche'' with a RACC of 85 g ready-to-serve (plus 35 g for products with sauce toppings). Recently, several mini or snack-size versions of several products in the ''Mixed dishes, not measurable with a cup'' product category have become available, such as mini pizza rolls, mini egg rolls, mini quiche, and mini sandwiches. Also, since 1993, other miniature products (smaller individual piece products) that are often used as appetizers and hors d'oeuvres have become available in the market place. To accommodate appetizer type products, the USDA's Guide to Federal Food Labeling Requirements for Meat and Poultry Products (2007) [35] includes a RACC of 85 g for ''Appetizers (*e.g.,* meat (or poultry), hors d'oeuvers, mini eggrolls, mini pizza rolls, bagel pizza).'' Miniature products with or without meat have similar dietary usage and product characteristics and are often used interchangeably by consumers. If the product is marketed for use with a sauce, FSIS is proposing to use 35 g for the amount of the sauce. This amount is calculated proportionally based on adding 55 g of sauce or gravy for a RACC of 140 g for the product category, ''Mixed dishes not measurable with cup,'' under the general category ''Mixed Dishes.''

FSIS is proposing to create a new category ''Appetizers, hors d'oeuvres—Dips with meat or poultry; *e.g.,* chicken dip, chicken and cheese dip, meat dip'' with a RACC of 2 tbsp. ready-to-serve. Recently, dip products with amenable amounts of meat or poultry, for example, cheesy chicken dip and chicken dip, meant to be served with chips such as corn chips, have been introduced into the market place. The ''All dips (*e.g.,* bean dips, dairy-based dips, salsa)'' product category in FDA's regulations is comparable to the proposed FSIS ''Dip with Meat or Poultry'' product category, because dips with meat or poultry have similar dietary usage and product characteristics as dips regulated by FDA. Therefore, FSIS is proposing to establish a RACC of 2 tablespoons for the proposed ''Dip with Meat or Poultry'' product category. Establishing the same RACC for products with similar dietary usage, similar amounts customarily consumed, and product characteristics whether they are regulated by FDA or FSIS will help consumers compare nutrition information between these products.

FSIS is proposing to create a new product category ''Candies with meat or poultry; *e.g.,* chocolate with bacon, chocolate dipped bacon, chocolate with salami'' with a RACC of 30 g ready-to-serve. Recently, candies with amenable amounts of meat or poultry, for example, chocolate bars with bacon, chocolate dipped bacon, and chocolate bars with salami, have been introduced into the market place. Such products have been marketed as ''Candies'' based on information available from the Mintel Global New Products Database [36] for products that are currently available in the market, and they are comparable to products in the ''All Other Candies'' product category, which is regulated by FDA. FDA's Serving Size Final Rule updated the RACC from 40 g to 30 g for the ''All Other Candies'' product category. Because the products in both FDA's and FSIS's candy product categories have similar usage and product characteristics, the same RACC (30g) for FDA's ''All Other Candies'' product category and FSIS's ''Candies with meat or poultry; *e.g.,* chocolate with bacon, chocolate dipped bacon, chocolate with salami'' product category will help consumers compare nutrition information between these products.

FSIS is proposing to combine the separate canned meat and poultry categories into one product category as follows, ''Canned Meats (*e.g.,* canned beef, canned pork) and Canned Poultry (*e.g.,* canned chicken, canned turkey).'' FSIS is also proposing to increase the RACC from 55 g to 85 g. There was an inadequate sample size for a reliable 2003–2008 intake estimate (82.1 g) for ''Canned Meats,'' and the 2003–2008 median intake estimate (89.5 g) for ''Canned Poultry'' did not show a significant change from the 1993 RACC. But, FDA updated the 1993 RACC for the ''Fish, shellfish, and game meat, canned'' product category from 55 g to 85 g. FDA's ''Fish, shellfish, and game meat, canned'' product category is comparable to FSIS's ''Canned Meats (*e.g.,* canned beef, canned pork) and Canned Poultry'' category. The same RACC for products with similar dietary usage and product characteristics whether regulated by FDA or FSIS will

[35] *http://www.fsis.usda.gov/shared/PDF/Labeling_Requirements_Guide.pdf. 85* g for Appetizers is a suggested RACC provided in Guidance by USDA (see question 68 at *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/faq-generic-labeling*).

[36] Mintel Global New Products Database (GNPD). Mintel Group Ltd. 333 West Wacker Drive, Suite 1100, Chicago, IL 60606. Internet: *http://www.gnpd.com/sinatra/gnpd/frontpage/* (accessed September 23, 2014).

help consumers compare nutrition information between these products. Therefore, FSIS is proposing that the RACC for ''Canned Meats (*e.g.,* canned beef, canned pork) and Canned Poultry (*e.g.,* canned chicken, canned turkey)'' be 85 g.

FSIS is proposing to include pork back fat into the category for ''Bacon'' with the category name of ''Bacon; *e.g.,* bacon, beef breakfast strips, pork breakfast strips, pork rinds, pork back fat'' because its use is most similar to that of bacon and pork rinds. FSIS is proposing the RACC for pork back fat to be 15 g ready-to-eat and 54 g ready-to-cook to reflect the previously established RACCs for bacon and pork rinds. The categories for bacon and poultry bacon products were not combined into one category because of their differing ready-to-cook RACCs. In addition, FSIS is proposing to modify the category name for poultry bacon to ''poultry bacon, poultry breakfast strips'' to clarify that these are different products as indicated by the differing ready-to-cook amounts from the 1993 regulation.

FSIS is proposing the following category names for the combined meat and poultry product categories that have the same RACC values and did not meet any of the factors for updating the RACCs: ''Salad and potato toppers; *e.g.,* bacon bits, poultry bacon bits,'' ''Dried meat or poultry products; *e.g.,* jerky, dried beef or poultry, Parma ham, meat or poultry sausage products with a moisture/protein ratio of less than 2:1; *e.g.,* pepperoni,'' ''Snacks, *e.g.,* meat or poultry snack food sticks,'' ''Linked meat or poultry products, Vienna sausage, frankfurters, poultry franks, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, poultry Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, poultry smoked sausage, smoked pickled meat or poultry meat, pickled pigs feet,'' ''Salads—pasta or potato, potato salad with bacon, potato salad with poultry, macaroni and meat or poultry salad,'' ''Major main entrée type sauce; *e.g.,* spaghetti sauce with meat or poultry, spaghetti sauce with meatballs, spaghetti sauce with poultry meatballs,'' ''Minor main entrée type sauce; *e.g.,* pizza sauce with meat or poultry, gravy,'' and ''Seasoning mixes dry, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with meat or poultry: As reconstituted: Amount to make one Reference Amount of the final dish; *e.g.,* Gravy, Major main entrée type sauce, Soup, Entrée measurable with a cup.''

FSIS is proposing to update the footnotes to proposed 9 CFR 413.312 Table 2 as follows: Footnote 1 will be updated to include new data sources and to clarify that the RACC values presented in the table are for the ''edible portion'' of the food, and Footnote 6 will be added to explain the purpose and use of the ''label statement'' column.

N. Compliance

Currently, 9 CFR 317.309(h) and 381.409(h) provide information about how FSIS determines compliance with its nutrition labeling requirements, including the methods of analysis used, reasonable excesses and deficiencies of nutrients, acceptable levels of variance from declared values, and records requirements. FSIS is proposing to consolidate 9 CFR 317.309(h) and 381.409(h) into a single section (proposed 9 CFR 413.309(h)). The following discusses the additional revisions that FSIS will be proposing in 9 CFR 413.309(h), as compared to current 9 CFR 317.309(h) and 381.409(h).

1. Level of Variance Allowed for the Label Declaration of Specific Nutrients

Proposed 9 CFR 413.309(h)(5) establishes that a meat or poultry product with a label declaration of calories, sugars, added sugars (when the only source of sugars in the food is added sugars), total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under sections 1(n) of the FMIA (21 U.S.C. 601(n)(1)) or 4(h) of the PPIA (21 U.S.C. 453(h)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. However, no regulatory action will be based on such a determination if the excess is less than the inherent nutrient variation in a product or the variability generally recognized for the analytical method used in that product at the level involved. FSIS is not proposing to change the level of variance allowed for the label declaration of nutrients.

2. Methods Used To Determine Compliance

Under proposed 9 CFR 413.309(h)(2), a sample for nutrient analysis must consist of at least six consumer units, each from a production lot, or alternatively, chosen randomly to be representative of a production lot. In each case, the units may be individually analyzed, and the results averaged, or the units may be combined, and the composite analyzed. FSIS will consider the results—whether the average or the single result from the composite—to be the nutrient content of the composite. All analyses must be performed, if possible, by the appropriate methods and procedures used by the U.S. Department of Agriculture (USDA) for each nutrient in accordance with the ''Chemistry Laboratory Guidebook.'' If no USDA method is available, the appropriate methods for the nutrient in accordance with the 2016 edition of the ''Official Methods of Analysis'' of the AOAC International, 20th ed., must be used, unless a particular method of analysis is specified in 9 CFR 413.309(c). If no USDA, AOAC, or specified method is available or appropriate, any other reliable and appropriate analytical procedures may be used, as determined by FSIS. The current edition (20th ed.) of the ''Official Methods of Analysis'' includes many updates to the 15th edition.

When FSIS issued 9 CFR 317.309(h) and 381.409(h) on compliance with nutrition labeling requirements, the most current version of the AOAC methods was its 15th edition, and, therefore, FSIS identified the 15th edition in its regulation. Newer and better methods of analysis have since been validated and recognized as ''official'' methods in the current 20th edition. Accordingly, FSIS is proposing, in 9 CFR 413.309(h)(2), to use the 20th edition and incorporate it by reference in 9 CFR (h)(9)(i). The ''Official Methods of Analysis of AOAC International'' is a comprehensive collection of chemical and microbiological methods of analysis. The Official Methods of Analysis have undergone rigorous scientific review and validation to determine the performance characteristics for the intended analytical application and fitness for purpose. Each method includes specific instructions for performing the chemical analysis of a substance in a particular matrix. If a newer edition of the Official Methods of Analysis is published before issuance of a final rule, FSIS intends to finalize this rule with the newer edition, as appropriate, provided there are no substantive changes in the newer edition requiring additional comment.

FSIS does not currently sample or conduct routine nutrient analyses of products for regulatory purposes because FSIS has not, in the past, found gross non-compliance with the nutrition labeling requirements (*i.e.,* large variations in the nutrient content of the samples compared to the declared nutrition information provided on product labels). FSIS, for a limited period of time, is conducting surveillance sampling for nutrient content of raw ground beef samples collected for pathogen analysis, such as Shiga toxin-producing *Escherichia coli* (STEC) and *Salmonella,* to ascertain compliance with the recent nutrition labeling requirements for raw ground product packages. FSIS randomly analyzes samples of raw ground beef products in consumer-ready packaging bearing a Nutrition Facts label that have already been collected for pathogen analysis at Federally-inspected establishments. In addition, when Office of Investigation, Enforcement and Audit (OIEA) Investigators collect samples of raw ground beef in consumer-ready packaging bearing a Nutrition Facts label at retail for pathogen analysis, the FSIS laboratory also randomly selects some of these samples for nutrient content analysis. The nutrient content results are non-regulatory and are for surveillance purposes only at this time. If there is a discrepancy between the laboratory results and the Nutrition Facts label, LPDS directly contacts the establishment or the OIEA-Compliance and Investigation Division Regional Director with the results of the nutrient content testing.

FSIS will explore its regulatory options, including seeking criminal penalties or rescinding label approvals, if it discovers a violation of the nutrition labeling requirements. In addition, FSIS will consider when additional surveillance sampling for nutrient content should be conducted for various products, as well as when regulatory verification testing should occur.

3. Records Requirements

Currently, FSIS regulations require that establishment management maintain records to support the validity of nutrient declarations contained on meat and poultry product labels (9 CFR 317.309(h)(8) and 381.409(h)(8)). Such records are required to be made available to the inspector or any duly authorized representative of FSIS upon request (9 CFR 317.309(h)(8) and 381.409(h)(8)). These records are generally required to be retained for 2 years (9 CFR 320.3 and 381.177). FSIS is proposing to consolidate the requirements in 9 CFR 317.309(h)(8) and 381.409(h)(8) into proposed 9 CFR 413.309(h)(8).

As discussed in sections II.E.5.a. (dietary fiber), II.E.5.b. (soluble and insoluble fiber), II.E.3. (added sugars), II.J.2. (vitamin E), and II.J.3. (folate), there are no suitable analytical procedures for measuring the following nutrients under the circumstances described: (1) Dietary fiber (when non-digestible carbohydrates that do and do not meet the proposed definition of dietary fiber are both contained in a food product); (2) soluble fiber (when a mixture of soluble fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber is present in a food); (3) insoluble fiber (when a mixture of insoluble fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber is present in a food); (4) added sugars (when a food product contains both naturally occurring sugars and added sugars); (5) vitamin E (when a food product contains both RRR-α-tocopherol and all rac-α-tocopherol); and (6) folate (when a food product contains both folate and folic acid).

Because there are no reliable or appropriate analytical procedures available for FSIS to ensure that the declared nutrient amount for certain nutrients is truthful, accurate, and in compliance with all applicable labeling requirements, FSIS is proposing to require specific recordkeeping for certain nutrients. FSIS is proposing to require that manufacturers make and keep written records to verify the declaration of: (1) The amount of added non-digestible carbohydrates that do not meet the proposed definition of dietary fiber when the dietary fiber present in a food is a mixture of dietary fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber (proposed 9 CFR 413.309(h)(8)(i)); (2) the amount of added non-digestible carbohydrates that do not meet the proposed definition of dietary fiber when the food contains a mixture of soluble fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber (proposed 9 CFR 413.309(h)(8)(ii)); (3) the amount of added insoluble non-digestible carbohydrates that do not meet the proposed definition of dietary fiber when the food contains a mixture of insoluble fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber (proposed 9 CFR 413.309(h)(8)(iii)); (4) the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single-ingredient), when both naturally occurring and added sugars are present in a food (proposed 9 CFR 413.309(h)(8)(iv)); (5)(a) scientific data and information that demonstrate the amount of added sugars in the food after non-enzymatic browning or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food manufactured; or (b) records of the amount of sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label (proposed 9 CFR 413.309(h)(8)(v); (6) the amount of all rac-α-tocopherol added to the food and RRR-α-tocopherol in the finished food when a mixture of both forms of vitamin E is present in a food (proposed 9 CFR 413.309(h)(8)(vi)); and (7) the amount of synthetic folate or folic acid added to the food and the amount of naturally-occurring folate in the finished food, when a mixture of folate and folic acid is present in a food (proposed 9 CFR 413.309(h)(8)(vii)).

Most manufacturers should already have the types of records needed to validate the declared amount of each nutrient. They are in the best position to know which records will contain the information necessary for FSIS to determine compliance. These records may include analyses of databases, recipes or formulations, or batch records. FSIS recognizes that the nutrient profile of processed foods that have dietary fiber, soluble fiber, insoluble fiber, added sugars, vitamin E, or folate/folic acid can vary depending on the recipe or formulation, the suppliers of ingredients, and other factors. Although the nutrient levels in foods may change if a manufacturer changes ingredient suppliers or recipes, manufacturers still need to ensure that the records they maintain substantiate the nutrient composition of the specific food. Therefore, manufacturers must be able to distinguish among the same or similar products they have in the marketplace that may contain differing amounts of a declared nutrient. The records required under proposed 9 CFR 413.309(h)(8) must be available for review and copying while the product is available for purchase in the marketplace. There is a wide range of shelf lives among food products. The current retention period for nutrition labeling records under 9 CFR 320.3 and 381.177—a period not to exceed two years after December 31 of the year in which the transaction to which the record relates has occurred—will be sufficient to enforce the nutrient declarations on the nutrition labels.

4. Inclusion of Potassium as a Mineral

Potassium is currently the only vitamin or mineral specified as a Class I and Class II nutrient in 9 CFR

317.309(h)(4)(i–ii) and 381.409(h)(4)(i–ii). Potassium is a mineral for which an RDI is being proposed (proposed 9 CFR 413.309(c)(8)(iv)), and the absolute amount would be required to be declared along with a percent DV on the Nutrition Facts label. FSIS has tentatively concluded that there is no need to separately list potassium under the description of Class I and Class II nutrients because it is encompassed within the minerals category. Therefore, FSIS is proposing to omit a specific reference to potassium in proposed 9 CFR 413.309(h)(4) and (h)(6). Any listing of potassium on the Nutrition Facts label will have to meet the specific compliance requirements for minerals under 9 CFR 413.309(h)(4) and (h)(6).

5. Requirements for Other Carbohydrate, Soluble and Insoluble Fiber, Added Sugars, and Sugar Alcohols

The labeling requirements for Class I and Class II nutrients are provided in proposed 9 CFR 413.309(h)(4). For the reasons discussed in section II.E.6., FSIS is proposing to omit the provision for voluntary declaration of ''Other carbohydrate'' in proposed 9 CFR 413.309(c)(6) that is in 9 CFR 317.309(c)(6)(iv) and 381.409(c)(6)(iv). Therefore, FSIS is proposing to omit the compliance requirements related to ''Other carbohydrate'' in proposed 9 CFR 413.309(h)(4) and (h)(6) that are in 9 CFR 317.309(h)(4) and (h)(6) and 381.409(h)(4) and (h)(6)).

Dietary fiber is included as both a Class I and Class II nutrient because food products may contain only non-digestible carbohydrates that meet the definition of dietary fiber and that may be naturally occurring or that may be added to fortified or fabricated foods. The same is true for soluble and insoluble fiber, yet these nutrients are not currently listed as Class I or Class II nutrients (see 9 CFR 317.309(h)(4) and 381.409(h)(4)). Therefore, FSIS is proposing to include dietary fiber in 9 CFR 413.309(h)(4) as both a Class I and Class II nutrient.

Currently, 9 CFR 317.309(h)(5) and 381.409(h)(5) (consolidated in proposed 9 CFR 413.309(h)(5)) specify that a food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium is deemed to be misbranded under section 1(n) of the FMIA (21 U.S.C. 601(n)(1)) or 4(h) of the PPIA (21 U.S.C. 453(h)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. The nutrients listed in this section can have a negative impact on health in the general U.S. population if consumed in excess, and there are current dietary recommendations to reduce the consumption of these nutrients. Therefore, FSIS is ensuring in proposed 9 CFR 413.309(h)(5) that foods do not contain excessive amounts of these nutrients of which the consumer is unaware.

Current dietary recommendations acknowledge that Americans consume excess amounts of added sugars and encourage reducing intake of calories from added sugars. A FSIS has an interest in ensuring that foods do not contain excessive amounts of added sugars that are not declared on the label (see section II.E.3) and is proposing to include added sugars in 9 CFR 413.309(h)(5). In some food products, all of the sugars are added. In such cases, an analytical method could be used to determine the amount of added sugars, and the permitted analytical variability would be applicable. Accordingly, FSIS is proposing to include ''added sugars (when the only source of sugars in the food is added sugars)'' among the list of nutrients in proposed 9 CFR 413.309(h)(5).

Reasonable excesses or deficiencies in relation to certain declared nutrients are acceptable within current good manufacturing practice. FSIS is proposing to allow reasonable excesses over the labeled amount of soluble and insoluble fiber and sugar alcohols when they are acceptable within current good manufacturing practice, and reasonable deficiencies under labeled amounts of added sugars when they are acceptable within current good manufacturing practice (proposed 9 CFR 413.309(h)(6)). FSIS expects that when a food product only contains added sugars, when all of the dietary fiber (both soluble and insoluble) is added non-digestible carbohydrates that meet the definition of dietary fiber, when all of the vitamin E is all rac-α-tocopherol, and when only folic acid is present in a food, the declared amount must be at least equal to the amount of the nutrient added to the food.

In summary, FSIS is proposing the following changes related to compliance in 9 CFR 413.309(h) as compared to current 9 CFR 317.309(h) and 381.409(h): (1) Cite the 20th edition of the Official Methods of Analysis of the AOAC International and incorporate it as the reference for the appropriate methods used to determine compliance with amounts of nutrients declared on the Nutrition Facts label (proposed 9 CFR 413.309(h)(2) and (h)(9)(i)); (2) establish general recordkeeping requirements when records are necessary to verify information related to dietary fiber, soluble and insoluble fiber, added sugars, folate, and vitamin E provided on the label (proposed 9 CFR 413.309(h)(8)); (3) omit a specific reference to potassium in proposed 9 CFR 413.309(h)(4)(i–ii) and (h)(6) such that any listing of potassium on the Nutrition Facts label would meet the specific compliance requirements for minerals under proposed 9 CFR 413.309(h)(4) and (h)(6); (4) include dietary fiber, under proposed 9 CFR 413.309(h)(4); (5) include added sugars within proposed 9 CFR 413.309(h)(5) such that the label declaration of added sugars will be deemed misbranded under sections 1(n) of the FMIA (21 U.S.C. 601(n)(1)) or 4(h) of the PPIA (21 U.S.C. 453(h)) if the nutrient content of the composite is greater than 20 percent in excess of the added sugars declared on the label, and within proposed 9 CFR 413.309(h)(6) such that reasonable deficiencies of added sugars would be permitted; (6) include soluble and insoluble fiber and sugar alcohols within proposed 9 CFR 413.309(h)(6) such that reasonable excesses of these nutrients would be permitted; and (7) consistent with the tentative conclusion in section II.E.6., omit references to ''Other carbohydrate'' in proposed 9 CFR 413.309(h).

O. Technical Amendments

FSIS is proposing to update the name of Food Labeling Division in proposed 9 CFR 413.312 and 413.369 to the Labeling and Program Delivery Staff, Office of Policy and Program Development. FSIS is also proposing to update the docket room address in proposed 9 CFR 413.309.

Proposed 9 CFR 413.400(a)(1)(ii) is updated to remove compliance criteria that expired in July 1997.

FSIS is proposing to update the cross-references to parts 317 and 381 in sections 301.2, 304.2, 316.8, 316.11, 316.13, 317.16, 318.10, 319.1, 319.10, 320.1, 327.15, 362.2, 381.172, 381.2, and 412.2.

III. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated an ''economically significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Need for the Rule

The USDA began requiring nutrition and serving size information on food labels in the early 1990's (58 FR 632). The requirements were intended to provide producers with a credible way of communicating nutrient related information to consumers and ensure consumers had access to the necessary information for maintaining a healthy diet. Today, nearly 80 percent of U.S. adults report using nutrition labels at least some of the time,[37] Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home. However, over the past 20 years American caloric and nutritional consumption and recommendations [38] for daily nutrition requirements have changed and no longer match the current nutrition labeling requirements. This gradual reversion to underlying information asymmetries raises concerns over the usefulness of the information provided on nutritional facts and serving size labels. In addition, consumer groups have raised concerns over the required formats. According to national consumer surveys,[39] a sizeable number of consumers effectively lack access to the provided information because of their inability to simply read or quickly comprehend nutritional labels, leading to inadequate information distribution. The proposed rule seeks to correct the market failures caused by asymmetric and inadequate information by ensuring that nutritional and serving size requirements for FSIS products is consistent with FDA's requirements and are based on current diets and nutritional needs as well as addressing those issues that inhibit consumers from using this information.

TABLE 1—USE OF NUTRITIONAL FACTS LABEL BY AVERAGE DAILY CALORIC, SODIUM AND SUGAR INTAKE FROM FOOD AT HOME

Nutritional facts label use	Portion of the population [1]	Caloric intake [2] (kcal)	Sodium intake [2] (mg)	Sugar intake [2] (mg)
Always or Most of the Time	102,281,465 (43%)	1,439	2,327	85
Sometimes	83,877,978 (36%)	1,462	2,325	89
Rarely	33,653,297 (14%)	1,554	2,429	103
Never	15,807,324 (7%)	1,741	2,517	122

[1] Population includes all individuals 16 years of age and older.
[2] Intake values are limited to food consumed at home.
Source: NHANES. 2013. ''Questionnaires, Datasets, and Related Documentation'' Centers for Disease Control and Prevention. Accessed on 5/6/2014. Table derived from data in the Consumer Behavior Phone Follow-up Module—Adult, Dietary Interview—Individual Foods, First Day, and Demographic Variables & Sample Weights. *http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.*

Government labeling requirements provide producers with a credible way to communicate product attributes that are not obvious to consumers, *e.g.,* calorie count or amount of fiber per serving. In this manner, labeling requirements allow producers to compete based on nutritional quality. In turn, consumers use nutritional fact and serving size labels to select products with desired qualities and tie individual decisions to overall health impacts.[40] More than 185 million adults reported referencing the Nutrition Facts label at least some of the time.[41] Further still, recent research conducted by the Economic Research Service indicated that use of nutritional and health information is on the rise.[42] The 2008 Health and Diet Survey conducted by the FDA provides further insight into food label use.[43] When consumers were asked ''when you buy a product for the first time, how often do you read (ingredient and nutrition) information,'' 54 percent reported often, and 23 percent reported sometimes. Ninety percent of label users reported using food labels to see how high or low the food is in calories and macro- and micro-nutrients like sodium, fat, or vitamins either often or sometimes (66 percent often, 24 percent sometimes). Lastly, 49 percent of survey respondents affirmed that during the previous two weeks, they had based a decision to buy or use a food product based on the nutrition label. Clearly, many consumers demand and use nutritional information on food labels. However, the changes in consumers' diets and basing the nutrition facts and serving size labels on outdated recommendations does not clearly and conspicuously reveal the essential information to consumers.

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[37] NHANES. 2013. ''Questionnaires, Datasets, and Related Documentation'' Centers for Disease Control and Prevention. Accessed on 5/6/2014. Data derived from the Consumer Behavior Phone Follow-up Module—Adult *http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.*

[38] U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015–2020 Dietary Guidelines for Americans.* 8th Edition. December 2015. Available at *http://health.gov/dietaryguidelines/2015/guidelines/.*

[39] Health and Diet Survey. 2008. U.S. Food and Drug Administration. *http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm193895.htm* National Health and Nutrition Examination Survey Questionnaire, NHANES. 2009–2010. *http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.*

[40] Caswell, J. and E.M. Mojduszka. 1996. Using information labeling to influence the market for quality in food products. American Journal of Agricultural Economics. 29: 47–54.

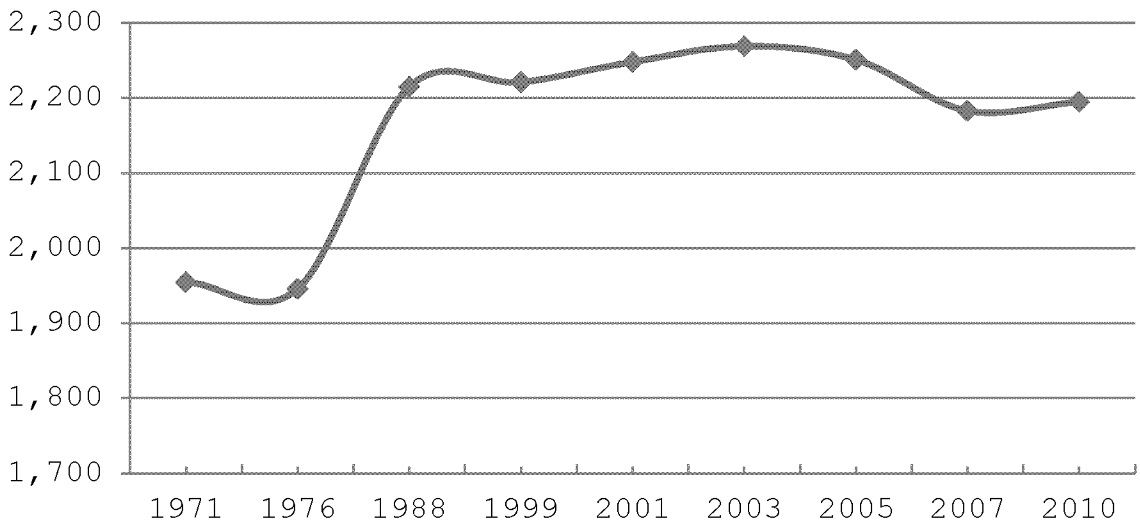
[41] NHANES. 2013. ''Questionnaires, Datasets, and Related Documentation'' Centers for Disease Control and Prevention. Accessed on 5/6/2014. *http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm* NHANES.

[42] Todd, J. 2014. Changes in eating patterns and diet quality among working-age adults, 2005–2010. U.S. Department of Agriculture, Economic Research Service. ERR–161. Todd 2014.

[43] Choiniere, C.J. and A. Lando. 2008. '', FDA 2008 Health and Diet Survey-Consumer Behavior Research'' Accessed on 5/6/2014. < *http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm193895.htm.*>

As is shown on Graph 1, from 1971—2010, mean energy intake increased by 240 kcal/day [44] although recent reports suggest overweight and obesity has leveled-off nationally and even declined in certain groups.[45] During this period, an emphasis on health aspects such as ''low in sodium'' or ''low in fat'' led consumers to disregard other pertinent health information, *e.g.,* calorie count, sugars and serving size, leading to overconsumption.[46] Between 1970 and 2005, sugars and sweeteners available for consumption increased by 19 percent. This increase in supply enabled an increase in consumption such that by 2004, the daily sugar intake for men and women averaged 25.4 tsp (406 kcal) and 18.3 tsp (292 kcal) respectively.[47] From 2007–2010, children and adults consumed more than double the amount of recommended added sugars, with lower income individuals consuming more added sugars than higher income individuals.[48] For perspective, the 2015–2020 Dietary Guidelines for Americans recommends less than 10 percent of calories per day from added sugars combined, yet added sugars alone contributed an average of 16 percent of the total calories in American diets. The increase in caloric density worsened the negative health impacts associated with overconsumption. Updating nutrition facts and serving size labels so as to take into consideration current consumption patterns, dietary recommendations, and scientific evidence will help producers credibly communicate hard to distinguish product attributes as well as aid current and future label-users overcome the issues presented above.

Graph 1 -- Mean Daily Energy Intake (kcals)



Source: Ford, E.S. and W.H. Dietz. 2013. Trends in energy intake among adults in the United States: findings from NHANES. American Journal Clinical Nutrition. 97: p848-53.

Of those U.S. adults who rarely or never use Nutrition Facts labels, over 31 million of them are overweight or obese; conditions linked to increased incidence of coronary heart disease, stroke, type 2 diabetes, cancer, and high blood pressure. For perspective, overweight and obese individuals spend 10 and 43 percent more money on health care as compared to normal weight individuals, respectively.[49] Overall annual medical expenditure caused by overweight or obesity has been estimated to account for between 5 and 7 percent of national medical expenditures [50] and is projected to increase to 17 percent by 2030.[51] With regard to health care providers, obesity accounts for 8.5 percent of Medicare spending, 12 percent of Medicaid spending, and 13 percent of private payer spending.[52]

A daily energy surplus of 50–100 kcals will lead to overweight and

[44] Ford, E.S. and W. H. Dietz. 2013. Trends in energy intake among adults in the United States: finding from NHANES. American Journal of Clinical Nutrition. 97: 848–853. Ford and Dietz, 2013.

[45] Fryar, C, Carroll, M., Ogden, C. 2014. Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, 1960–162 Through 2011–2012. CDC National Center for Health Statistics. *http://www.cdc.gov/nchs/data/hestat/obesity_adult_11_12/obesity_adult_11_12.htm.*

[46] Chandon, P. 2013. How package design and packaged-based marketing claims lead to overeating. Applied Economic Perspectives and Policy. 35: 7–31.

[47] Johnson, R.K., L.J. Appel, M. Brands, B.V. Howard, M. Lefevre, R.H. Lustig, F. Sacks, L.M. Steffen, and J. Wylie-Rosett. 2009. Dietary sugars intake and cardiovascular health a scientific statement from the American Heart Association. Circulation. 1012–1020.

[48] Biing-Hwan Lin and Rosanna Mentzer Morrison. 2014. ERS's Food Consumption and Nutrient Intake Data-Tool for Assessing Americans' Diets. USDA Economic Research Service. *https://www.ers.usda.gov/amber-waves/2014/october/erss-food-consumption-and-nutrient-intake-data-tools-for-assessing-americans-diets/.*

[49] Tsai, A.G., D.F. Williamson, and H.A. Glick. 2010. Direct medical cost of overweight and obesity in the USA: A quantitative systematic review. Obesity Reviews. 12: 50–61. Tsai et al. 2010.

[50] Tsai, A.G., D.F. Williamson, and H.A. Glick. 2010. Direct medical cost of overweight and obesity in the USA: A quantitative systematic review. Obesity Reviews. 12: 50–61. Tsai et al. 2010.

[51] Wang, Y.C., K.M, T.Marsh, S.L. Gortmaker, and M. Brown. 2011. Health and economic burden of the projected obesity trends in the USA and the UK. The Lancet. 378: 815–825 Wang 2011.

[52] Finkelstein, E.A., J.G. Trogdon, J.W. Cohen, and W.Dietz. 2009. Annual medical spending attributable to obesity: Payer and service-specific estimates. Health Affairs Web Exclusive. 33:11.

obesity.[53] Thus, the 92–279 kcal difference in kcals consumed at home between those who rarely or never read labels as compared to those who at least sometimes read labels is understood to be significant, Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home. When asked why they did not use nutritional labels, approximately 10 percent of overweight respondents exclusively had issues related to readability and comprehensibility: The print is too small, they would not know what to look for, or they do not have enough time. Addressing these design limitations would provide consumers with information that will convey relevant nutrition information.

These modest reductions are known to lead to significant benefits in the form of weight loss, health improvements, and reduced medical expenditures.[54] These issues can be addressed by altering the design and content of nutritional and serving size labels, *e.g.,* reducing the variance between food labels by more closely aligning FSIS's requirements with FDA's, providing a calorie count for the entire package and or utilizing a dual column layout when appropriate, along with increasing and bolding the font size for the most salient information.

In total, the USDA and FDA regulate roughly 50,000 [55] and 740,000 [56] labels. The proposed rule reduces the amount of inconsistent information across FSIS and FDA products by more closely aligning nutrition labeling requirements with FDA's final changes, which ensures that food nutrition information is consistent across food products. This proposed rule allows nutrition labeling to more accurately reflect current dietary guidelines and is more easily understood by consumers. As will be detailed in the following sections, the magnitude of the sum of public health benefits brought about by even a small change in consumer behavior because of the information provided by the label warrants the proposed rule.

Baseline

FSIS estimates that there are roughly 50,000 different retail nutrition labels for meat or poultry products, roughly 25 percent of which are private labels (store brand). The Agency estimates that FSIS products are produced by 3,307 establishments, of which, 3,125 are considered either small or very small establishments. The number of labels and establishments is based on Information Resources, Incorporated (IRI) scanner data [57] and the Small Business Administration's (SBA's) business size classifications.

There are almost 50 million adults who rarely or never use the Nutrition Facts label. Of this population, nearly 32 million are overweight, are obese, or have hypertension, Table 11 and 12. FSIS estimated this proposed rule would impact a portion of these consumers by increasing the usability of nutrition labeling which will, in turn, improve their health and welfare.

Expected Costs of the Proposed Rule

Quantitative costs for the proposed rule include relabeling, recordkeeping, and reformulation costs. FSIS anticipates allowing a 24-month compliance period with a 36-month compliance for small businesses,[58] consistent with FDA's final rules (81 FR 33742 and 81 FR 34000). On December 1, 2014, FSIS issued a final rule that established January 1, 2018, as the uniform compliance date for new meat and poultry product labeling regulations that are issued between January 1, 2015 and December 31, 2016 (79 FR 71007). However, according to the uniform compliance date final rule, if any food labeling regulation involves special circumstances that justify a compliance date other than the uniform compliance date, FSIS will determine an appropriate compliance date and will publish that compliance date in the rulemaking (79 FR 71008). FSIS is proposing not to use the uniform compliance date for a final rule resulting from this proposed rule because, depending on when the final rule is published, the use of the uniform compliance date may result in a compliance period of less than 24 months.

The combined expected annualized costs equal $10.8 million annualized at a 3 percent rate over 20 years. The one-time costs, staggered over the first three years, are $165,540,072. In addition, consumers will incur costs associated with learning how to use new labels, which is a form of qualitative costs. What follows are details for each of the quantitative costs.

Relabeling Costs

To estimate the costs associated with relabeling products under USDA jurisdiction, this analysis utilized the 2014 FDA Labeling Cost Model [59] and Information Resources, Inc. (IRI) scanner data. The cost of relabeling depends on the number of labels required to change, whether or not the change can be coordinated with another label update, and the type of label change (extensive, major or minor). To determine the number of FSIS regulated labels in the retail market, we relied on IRI scanner data. Overall, there are 56,905 labels in the retail market under FSIS jurisdiction (14,056 private and 42,849 branded), though some are exempt from nutrition labeling per 9 CFR 317.400 and 381.500. To find the number of labels that are exempt, we utilized data from IRI and the National Meat Case Study. Data from IRI estimates 30.64 percent (3,619 private and 13,806 branded labels) of meat and poultry products are fresh in the retail market, thus possibly eligible for a labeling exemption. Of these products, approximately 39 percent do not have

[53] Finkelstein, E.A., C.J. Ruhm, and K.M. Kosal. 2005. Economic causes and consequences of obesity. Annual Review of Public Health. 26. 239–257. and Johnson, R. K., L.J. Appel, M. Brands, B.V. Howard, M. Lefevre, R.H. Lustig, F. Sacks, L.M. Steffen, and J. Wylie-Rosett. 2009. Dietary sugars intake and cardiovascular health a scientific statement from the American Heart Association. Circulation: 1012–1020.

[54] Dall, T.M., V.L. Fulgoni III, Y. Zhang, K.J. Reimers, P.T. Packard, and J.D. Astwood. 2009. Potential health benefits and medical cost savings from calorie, sodium, and saturated fat reductions in the American diet. American Journal of Health Promotion. 23. 412–422 and Sturm, R. 2002 The effects of obesity, smoking, and drinking on medical problems and costs. Health Risks and Costs. 21: 245–253.

[55] IRI (2012). InfoScan data. Information Resources, Inc. (IRI).

[56] Nutrition Facts/Serving Sizes Combined PRIA for Docket No. FDA–2012–N–1210 and Docket No. FDA–2004–N–0258. Available at: *http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/UCM385669.pdf.*

[57] Any opinions, findings, recommendations, or conclusions are those of the authors and do not necessarily reflect the views of the Economic Research Service, U.S. Department of Agriculture. The analysis, findings, and conclusions expressed in this paper also should not be attributed to either Nielsen or Information Resources, Inc. (IRI). This research was conducted in collaboration with USDA under a Third Party Agreement with IRI.

[58] Small Businesses are based on the Small Business Administration (SBA) size standards. The SBA defines a small business in NAICS code 311611—Animal (except Poultry) Slaughter and NAICS code 311612—Meat Processed from Carcasses as having less than 1,000 employees. A business in NAICS code 311615—Poultry Processing has a small business standard of less than 1,250 employees and NAICS code Seafood Product Preparation and Packaging has a less than 750-employee standard.

United States Small Business Administration (SBA), Table of Small Business Standards Matched to North American Industry Classification System Codes. Effective February 26, 2016. Available at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

[59] RTI International. ''2014 FDA Labeling Cost Model.'' Prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela C. Coglaiti, and Shawn A. Karns. Contract No. HHSF–223–2011–10005B, Task Order 20, August 2015.

nutrition labeling.[60] Therefore, we estimate there are 50,110 FSIS labels with nutrition labeling; 12,645 private (14,056 − (3,619 × 39%)) and 37,465 branded (42,849 − (13,806 × 39%)). See Table 2 below for details.

TABLE 2—TOTAL NUMBER OF FSIS UPCS WITH NUTRITION FACTS LABELS

Type of label	Total FSIS labels	Number of UPCs exempt from NFL	Total FSIS UPCs with NFL
Branded	42,849	5,384	37,465
Private	14,056	1,411	12,645
Total	56,905	6,795	50,110

Using SBA's small business definition of small business and IRI scanner data, FSIS estimates 53.6 percent of UPCs are from small businesses and 46.4 percent of UPCs are from large. The 26,859 UPCs (53.6 percent of 50,110) from small manufacturers have 36 months to comply with the proposed regulations and the 23,251 (46.4 percent of 50,110) from large manufacturers will have 24 months to comply. In total, there are 6,778 private labels (12,645 × 53.6%) and 20,081 branded labels (37,465 × 53.6%) for small businesses, and 5,867 private labels (12,645 × 46.4%) and 17,384 branded labels (37,465 × 46.4%) for large businesses. The Small Business Administration (SBA) defines a small business in NAICS code 311611—Animal (except Poultry) Slaughter and NAICS code 311612—Meat Processed from Carcasses as having less than 1,000 employees.[61] A business in NAICS code 311615—Poultry Processing has a small business standard of less than 1,250 employees and NAICS code Seafood Product Preparation and Packaging has a less than 750-employee standard.[62]

To adjust for inflation in the 2014 FDA Labeling Cost Model, we updated the wage rates using the most current (2015) wages and applied a benefits and overhead factor of two to estimate the total cost per type of label change. The cost estimates in 2015 U.S. Dollars (USD) are $572 per label (with a range of $141 to $1,620) for minor coordinated changes and $3,887 per label (with a range of $1,842 to $7,741) for minor uncoordinated changes (FDA Labeling Cost Model, 2014). The cost estimates in 2015 USD are $1,152 per label (with a range of $296 and $3,204) for major coordinated changes and $9,401 per label (with a range of $5,125 to $17,400) for major uncoordinated changes. The cost estimate in 2015 USD is $13,858 per label (with a range of $7,038 and $25,399) for both coordinated and uncoordinated extensive changes.

Based on FDA's Labeling Cost Model, the majority of the label changes required by the proposed rule are considered minor. Minor changes are categorized as alterations that do not require the entire label to be redesigned, *e.g.,* changing a single color or updating the ingredient list. In contrast, a major change requires completely redesigning a label, *e.g.,* changing multiple colors or modifying the front of the package. An extensive change is a major format change requiring a modification to the product packaging to accommodate labeling information. An example of an extensive change is increasing the package surface area.

Over 24 percent of the labels will undergo a major change; 22.8 percent (11,432/50,110) for the dual column and 1.6 percent (805/50,110) for removing a front of package (FOP) health or nutrient claim in response to changes in the DVs, RACCs, or the definition of dietary fiber, Table 3. The estimate of products requiring a dual column label was determined using IRI scanner data and identifying packaged products containing between 200 to 300 percent of the RACC. From this group, packaged products that required further processing before consuming or that are traditionally eaten in combination with other products, such as raw meat, poultry, and condiments, were excluded as they are exempted from the dual column labeling requirements. Alterations of health and nutrient claims were dependent on updates in Daily Values, RACCs, or the definition of dietary fiber.

Extensive changes are changes for products that may increase their package size to continue to make a health or nutrient content claim in response to the change in definition of a single-serving container. The proposed rule requires products that have RACCs of 100 g or larger and are packaged such that they contain more than 150 percent but less than 200 percent of the RACC to be defined as a single-serving container. Using IRI scanner data, we identified the UPCs with RACCs over 100 g that contain more than 150 percent but less than 200 percent of the RACC and that make a health or nutrient content claim. Based on these criteria, we estimate 13 UPCs may have an extensive change due to increasing the package size to continue to make a health or nutrient content claim. See Table 3 below for details.

TABLE 3—NUMBER OF LABEL CHANGES BY TYPE OF LABEL CHANGES

Type of change	Description of change	Number of UPCs
Major	Dual Column Label	11,432
	FOP claim and RACC, Daily Value, or fiber change	805
Extensive	Over 100 g RACC and FOP claim	13
Minor	Total Minor Change	37,860

[60] National Cattlemen's Beef Association, 2010. A Snapshot of Today's Retail Meat Case, 2010 National Meat Case Study Executive Summary. Available here: *http://www.beefretail.org/CMDocs/BeefRetail/research/2010NationalMeatCaseStudy.pdf.*

[61] United States Small Business Administration (SBA), Table of Small Business Standards Matched to North American Industry Classification System Codes. Effective February 26, 2016. Available at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

[62] United States Small Business Administration (SBA), Table of Small Business Standards Matched to North American Industry Classification System Codes. Effective February 26, 2016. Available at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

TABLE 3—NUMBER OF LABEL CHANGES BY TYPE OF LABEL CHANGES—Continued

Type of change	Description of change	Number of UPCs
Total Number of NFL under USDA Jurisdiction		50,110

As shown in Table 4—Label Changes That Can Be Coordinated with a Planned Change, private (store brand) labels change less frequently than branded labels. Allowing a producer to coordinate a required label change with a planned change saves costs associated with recordkeeping, labor, and materials. As such, under a 24 month compliance period for large businesses, changes to all branded labels will be coordinated with another planned label change. However, for private (store brand) labels only 26 percent will be coordinated with another change, and 74 percent will be uncoordinated. Allowing small businesses 36 months to comply, all branded products can coordinate a change and 57 percent of private labels can coordinate the label changes, Table 4—Label Changes That Can Be Coordinated with a Planned Change. As a result, the mid-point annualized cost at a 3 percent discount rate over 20 years for updating all of the labels under USDA jurisdiction is estimated to equal $4,484,734, with an average per label one-time cost of $1,371, Table 5. The total one-time cost, staggered over the total 36-month compliance period, is $68,723,156 with a range of $26,933,776 to $159,581,369.

TABLE 4—LABEL CHANGES THAT CAN BE COORDINATED WITH A PLANNED CHANGE

Compliance period (months)	Branded (percent)	Private label (percent)	Weighted average [1] (percent)
12	11	5	10
18	37	15	32
24	100	26	82
30	100	40	85
36	100	57	89
42	100	100	100

[1] Based on IRI data analysis, 25% of FSIS labels are private and 75% are branded.
Source: August 2015, "2014 FDA Labeling Cost Model".

TABLE 5—ALTERNATIVE 2—LABELING COSTS

[24 Month for large, 36 months for small]

	Small		Large		Costs		
	Private	Branded	Private	Branded	Lower	Mean	Upper
Total Number of Labels	6,778	20,081	5,867	17,384			
Coordinated Change:							
Major	943	4,904	373	4,245	$3,097,640	$12,055,680	$33,529,860
Minor	2,919	15,172	1,153	13,134	4,565,298	18,520,216	52,452,360
Uncoordinated Change:							
Extensive	2	5	1	5	91,494	180,154	330,187
Major	712	0	1,060	0	9,081,500	16,658,572	30,832,800
Minor	2,202	0	3,280	0	10,097,844	21,308,534	42,436,162
Total Cost					26,933,776	68,723,156	159,581,369
Annualized Cost (3% DR, 20 Year)					1,757,644	4,484,734	10,413,956
Annualized Cost (7% DR, 20 Year)					2,376,035	6,062,598	14,077,899
Average Per label one time cost					537	1,371	3,184.62
Per label Annualized Cost (3% DR, 20 Year)					35	89	208
Per label Annualized Cost (7% DR, 20 Year)					47	121	281

Recordkeeping Cost

This proposed rule requires that under certain circumstances manufacturers must maintain additional records to verify the amount of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid in products. Thus, if adopted, manufacturers will be required to maintain records sufficient to verify the label declaration for these nutrients. Examples of appropriate retained records include nutrient database analyses, nutrient database calculation based on recipes or formulations, batch records, or any other information a manufacturer retains which verify the nutrient content in the final product.

We assume that manufacturers currently have records for added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid. However, the proposed changes will require manufacturers to maintain these records and verify as needed. Thus, the recordkeeping cost is the initial time burden for meat and poultry product manufacturers to maintain these records to verify the amount of such nutrients in a food and to make such records available to appropriate regulatory officials upon request. From IRI scanner data, we estimate there are roughly 3,307 manufacturers making products regulated by FSIS. The declaration of Vitamin E and folate/folic acid is not mandatory unless accompanied with a nutrient claim. However, consistent with FDA's Final RIA, FSIS estimates each manufacturer would incur six hours of recordkeeping burden, one hour for each nutrient, resulting in 19,842 recordkeeping hours for the industry as a whole. This estimate is likely an overestimate as not all manufacturers will need to keep records for added sugars, dietary fiber, soluble fiber, vitamin E, and folate/folic acid. According to the Bureau of Labor Statistics, Occupational Employment and Wages, the median hourly wage of an operations manager is $46.99[63] with a range of $31.13 to 73.21 at the 25th and 75th percentile. In addition to the base wage, FSIS increased this cost by 100 percent to account for benefits and overhead. Consequently, FSIS assumed a mid-point total hourly compensation rate of $93.98 ($46.99 × 2) with a range of $62.26 (31.13 × 2) to $146.42 (73.21 × 2). The total recordkeeping costs, discounted over 20 years using a 3 percent discount rate are an estimated $121,690 with a range of $80,617 to $189,592.

TABLE 6—ESTIMATED RECORDKEEPING BURDEN

Type of declaration	Total annual recordkeeping burden hours	Cost (in 2015 USD)		
		Lower	Mid	Upper
Added Sugars	3,307	$205,894	$310,792	$484,211
Dietary Fiber	3,307	205,894	310,792	484,211
Soluble Fiber	3,307	205,894	310,792	484,211
Insoluble Fiber	3,307	205,894	310,792	484,211
Vitamin E	3,307	205,894	310,792	484,211
Folate/Folic Acid	3,307	205,894	310,792	484,211
Total	19,842	1,235,363	1,864,751	2,905,266
Annualized 3%, 20 years		80,617	121,690	189,592
Annualized 7%, 20 years		108,981	164,504	256,296
Median hourly wage for operations manager				93.98
25 percentile wage estimate				62.26
75 percentile wage estimate				146.42

Reformulation Costs

The proposed rule could motivate food manufacturers to reformulate their products. Food manufacturers may reformulate their products due to the increased visibility of added sugars or to maintain a health or nutrient content claim driven by a change in the Daily Values or RACC and changes in the definition of dietary fiber. We estimate reformulation costs associated with each group in the sections below. Note that we do not anticipate reformulation costs for mandating *trans* fat labeling because *trans* fat in meat and poultry products are usually naturally occurring.

Consistent with FDA, the Agency estimated costs using the 2014 FDA Reformulation Cost Model.[64] The model accounts for variations in food product complexity, company size, compliance period, reformulation types and activities. Consistent with FDA, the Agency estimated the cost of reformulation for a minor nonfunctional ingredient at all complexity levels, (low, medium and high) at all company size levels, (small, medium and large). As defined by the reformulation model, small businesses have less than $1 million in annual sales, medium businesses have between $1–500 million in annual sales, and large businesses have over $500 million in sales. The reformulation model estimates all private label brands are medium businesses and branded products are small, medium or large, depending on the type of product or brand.

The compliance period used in our estimate is 24 months for all businesses, as an estimate for a 36-month compliance period for a small business is not available in the model. The model only estimates the cost for small businesses at the 12 or 24-month compliance period and at the 12, 24 or 36 month for large businesses. Therefore, the reformulation cost estimates is an overestimate.

To adjust for inflation in the 2014 Reformulation model, we adjusted the wage rates using the most current (2015) Consumer Price Index for All Urban Consumers and applied a benefits and overhead factor of two to estimate the total cost per formula. The cost per formula ranges from $4,723 to $361,371 for a high complexity product, $2,898 to $361,371 for a medium complexity product, and $2,264 to $338,918 for a low complexity product. The cost varies by the size of company, with large and medium businesses having higher costs per formula than small businesses.

Number of Product Reformulations for Added Sugars Declaration

The proposed rule emphasizes the amount of sugar in a product by requiring a label to declare both the amount of ''Total Sugar'' and ''Added Sugars'' with a Daily Reference Value (DRV) for added sugars of 10 percent of calories.[65] Manufacturers may decide to reformulate products in light of these

[63] Bureau of Labor Statistics, Occupational Employment and Wages, May 2015. Mean hourly wage for 11–1021 General and Operations Managers. Accessed May 26, 2016. available at: *http://www.bls.gov/oes/current/oes111021.htm#(1).*

[64] RTI International. ''Reformulation Cost Model.'' Prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela Coglaiti, Shawn Karns, and Catherine Viator. Contract No. HHSF–223–2011–10005B, Task Order 20, August 2015.

[65] 50 grams for children and adults 4 years of age and older and 25 grams for children 1 through 3 years of age.

new requirements. This model uses IRI data to identify those USDA regulated products that exceed the proposed DRV for added sugars. Based on this proposed provision, FSIS regulates roughly 12,080 products where sugar contributes to more than 10 percent of the calories. Reformulation costs are based on the formula counts, not individual product labels. Many of these products have the same formula. For example, while there is one original Slim Jim formula, there is a plethora of products, *e.g.,* in different sizes. Therefore, the FDA's Reformulation Cost Model was used to determine the number of formulas from the number of products. We found 10,518 formulas associated with these 12,080 products with high sugar content.

FSIS does not estimate that manufacturers would reformulate all 10,518 products because reformulation is voluntary and can be quite expensive. We assume 7.5 to 9 percent (8.25%) of all formulas with high sugar content will reformulate, which is consistent with FDA's assumptions.[66] Table 7 below summarizes the total formulas that may reformulate for added sugars.

TABLE 7—TOTAL FORMULAS THAT MAY REFORMULATE FOR ADDED SUGARS DECLARATION

Complexity formulas	Branded (small)	Branded (medium)	Branded (large)	Private (medium)	Total formulas
High	93	205	87	213	598
Medium	83	86	21	51	241
Low	7	8	2	12	29

Number of Product Reformulations to Maintain Health and Nutrient Content Claims

The proposed rule would disqualify some products from bearing a health or nutrient claim as a result of changes in the RACC categories, changes in Daily Values for certain vitamins and minerals, and modifications to the definition of fiber to exclude certain isolated and synthetic fibers from the definition. As a result, manufacturers of these products would either have to remove the claim from the product's label or reformulate in order to continue to make the claim.[67]

To determine the reformulation cost related to RACC changes, the Agency used IRI scanner data and identified 62 products with new or changing RACC categories with a health or nutrient claim (*e.g.,* ''good source of . . .,'' ''low cholesterol,'' etc.). To determine the reformulation cost of Daily Value (DV) changes, we used IRI scanner data and identified 12 products with claims for the proposed vitamins and mineral DV changes (*e.g.,* ''good source of Vitamin C''). For the fiber claims, we refined the IRI scanner data and identified 731 products containing a synthetic or isolated fiber with a fiber claim. As noted above, reformulation costs are by formula counts, not by individual labels. We used FDA's Reformulation Cost Model to determine the number of formulas from the number of products. This work identified 53 formulas for RACC changes, 11 formulas for DV changes, and 654 formulas for new fiber definition. FSIS assumed that manufacturers will elect to reformulate 50 percent of their products and to remove the claim from the other 50 percent. Therefore, 365 formulas will incur reformulation costs: 30 formulas for RACC, 6 formulas for Daily Value and 329 formulas for fiber. The estimates may vary due to rounding in the business size and complexity categories. See Table 8 below for summary of the formulas that may reformulate due to the new fiber definition, or for changes in the Daily Vales or RACC.

TABLE 8—TOTAL FORMULAS THAT MAY REFORMULATE FOR NEW FIBER DEFINITION, DV, OR RACC

Complexity formulas	Branded (small)	Branded (medium)	Branded (large)	Private (medium)	Total formulas
High	56	127	59	103	345
Medium	4	6	4	6	20

Total Reformulation Cost for Sugars Declaration and To Maintain Health and Nutrient Content Claims

The mean one-time cost for reformulation is $77,294,020, with an average per formula one-time cost of $77,009. The annualized cost at a 3 percent discount rate over 20 years for reformulation is $6,196,385, with a range of $2,908,387 to $10,019,460. One-time reformulation costs are $94,952,165 with a range of $44,567,540 to $153,536,199. See Table 9 below for a summary of the estimated reformulation cost in 2015 dollars.

TABLE 9—ALTERNATIVE 2—REFORMULATION COST

	Lower	Mid	Upper
High Complexity Formulas	$36,295,355	$77,294,020	$124,785,011

[66] Regulatory Impact Analysis for Final Rules on ''Food labeling: Revision of the Nutrition and Supplement Facts Labels''. Docket No. FDA–2012–N–1210 and ''Food Labeling: Serving Sizes of Foods that can Reasonably be consumed at One Eating Occasion: Dual-Column Labeling: Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints: and Technical Amendments'' Docket No. FDA–2004–N–0258., page 70, available at: *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM506797.pdf.*

[67] To illustrate, consider these examples:

1. Reformulate due to DV change—A Beef Tomato Sauce with 12 mgs of vitamin C makes a ''High in Vitamin C'' claim since it meets the claim requirement of 20 percent or more of the Vitamin C RDI per RACC. By increasing the Vitamin C RDI from 60 mg to 90 mg, the product can no longer make the claim.

2. Reformulate due to New Fiber definition—A product with mostly synthetic fiber is making an ''excellent source of fiber'' fiber since certain synthetic and isolated fibers are included in the fiber definition. By removing some synthetic fibers from the fiber definition, the product can no longer make the claim.

TABLE 9—ALTERNATIVE 2—REFORMULATION COST—Continued

	Lower	Mid	Upper
Med Complexity Formulas	7,488,995	15,983,483	25,998,357
Low Complexity Formulas	783,190	1,674,662	2,752,831
Total Cost	44,567,540	94,952,165	153,536,199
Annualized Cost (3% DR, 20 Year)	2,908,387	6,196,385	10,019,460
Annualized Cost (7% DR, 20 Year)	3,931,645	8,376,460	13,544,608
Average Per formula one time cost	36,146	77,009	124,522
Per formula Annualized Cost (3% DR, 20 Year)	2,359	5,025	8,126
Per formula Annualized Cost (7% DR, 20 Year)	3,189	6,794	10,985

Quantitative Benefits of the Proposed Rule

By ensuring that recommendations are based on current dietary guidelines and making the most salient information prominent, the proposed rule will benefit the nearly 186 million Americans who frequently or sometimes use nutritional facts and serving size labels. However, this Preliminary Regulatory Impact Analysis (PRIA) limits the quantitative benefits to the medical costs savings for overweight or hypertensive adults who report not using or rarely using Nutrition Facts labels that are expected to experience health benefits with increased label use and modified diet. The annual present value of benefits at a 3 percent discount rate over 20 years is estimated at $36,894,007. A detailed description of this analysis follows.

As noted in the Need for Rule section above, a significant portion of U.S. citizens are overweight, obese, or hypertensive. Such conditions afflict individuals and society with poorer health and higher medical expenditures. It is well established that improved nutrition reduces overweight, obesity, and hypertension rates, which in turn reduces medical expenses.[68] Based on the NHANES analysis, using and understanding the Nutrition Facts label is linked to healthier diets. If finalized, this proposed rule will improve nutritional labels by updating and simplifying the information found on them. The frequency of label usage will increase as improved, and simpler to understand information will be available to the consumer, which will, in turn, promote consumption of healthier diets, *e.g.,* lower caloric or sodium consumption.

In this analysis, quantified benefits are a measure of expected health improvements resulting from increased label-use, causing diet modification for some overweight and hypertensive adults. The benefits analysis can be broken down into a series of steps. The first step is determining the baseline caloric and sodium intake for consumers by label-use. The second step is estimating the number of consumers who could potentially change their behavior from increased label-use because of this rule. The third step is estimating the change in diet from increased label-use. The final step is measuring the medical cost savings benefit using the Dall et al. (2009), Nutrition Impact Model, which links the health benefits and medical cost savings from reductions in caloric and sodium intake. A description of each step in the benefits analysis is given in this section.

Benefits Analysis: Baseline Caloric and Sodium Intake for Consumers by Label-Use

The first step in this analysis is to determine the baseline relationship between caloric and sodium intake with label-use. To determine this relationship, FSIS used NHANES data to correlate use of nutritional and serving size labels with caloric and sodium intake. NHANES is a continuous CDC survey with data released in two-year segments. This analysis included data from the 2009–2010 survey. NHANES collects detailed information through questionnaires, dietary recall, and a physical exam. In the Flexible Consumer Behavior Survey (FCBS) section of NHANES, respondents provided information on how frequently they used nutritional and serving size information found on food labels. Also, respondents who reported rarely or never using labels provided reasons for not doing so.

In the dietary recall component, respondents report everything they ate or drank, and where the food was obtained, for two days (two 24 hour periods). Food obtained from a store or catalog was identified as food at home (FAH). This analysis excluded calories consumed away from home, as these foods typically do not include a Nutrition Facts label. Weights were applied to the dataset to account for the survey design (including oversampling of certain groups), survey non-response, and post stratification so that the population totals represent the U.S. Census civilian non-institutionalized adult population.

The baseline links degree of label use, ranging from always to never, with average caloric, sugar and sodium intake, Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home. While data limitations prevent establishing causation between label use and behavior, the two are inversely correlated. Revealed in Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home, Nutrition Facts label use has an inverse relationship with total caloric, sugar and sodium intake. Based on this information, this analysis assumes if an average consumer who ''never'' used the Nutrition Facts label began to rarely read labels, they would reduce their daily caloric intake by 187 kcals. For most overweight or obese individuals, a stable daily reduction of 187 kcals would lead to weight loss and corresponding reductions in medical expenditures.[69] Like caloric and sodium intake, sugar consumption is greater for

[68] Campos, A., J. Doxey, and D. Hammond. 2011. Nutrition labels on pre-packaged foods: a systematic review. Public Health Nutrition. 14: 1496–1506;, Dall, T.M., V.L. Fulgoni III, Y. Zhang, K.J. Reimers, P.T. Packard, and J.D. Astwood. 2009. Potential health benefits and medical cost savings from calorie, sodium, and saturated fat reductions in the American diet. American Journal of Health Promotion. 23: 412–422;, Mokdad, A.H., J.S. Marks, D.F. Stroup, and J.L. Gerberdin. 2004. Actual causes of death in the U.S., 2000. American Medical Association. 291: 1238–1245; and Young, L.R. and M. Nestle. 2002. The contribution of expanding portion sizes to the US obesity epidemic. American Journal of Public Health. 83: 717–724.

[69] Dall et al. 2009—''With the 100-kcal reduction, for example, the number of obese adults would decline by more than 34 million. Many obese adults would move into the overweight category, with a net decrease of overweight adults of close to 37 million . . . The prevalence of chronic conditions associated with excess weight would decline such that national medical expenditures would be approximately $58 billion lower than current spending levels.''

individuals that use nutrition information less.

Further, we find as nutritional label usage increases, not only is the average caloric intake reduced, but also the portion of calories from sugar is reduced. For consumers that ''never'' use the Nutrition Facts label, calories from sugar account for 27 percent of their total at home consumption.[70] In contrast, for consumers that most frequently use the Nutrition Facts label, calories from sugar account for 23 percent of their total at home consumption.[71] Overall, the less an individual uses nutritional information, the more sugar accounts for total caloric intake.

Benefits Analysis: Estimating the Number of Consumers Who Will Potentially Change Their Behavior

This study monetizes the health benefits derived from adults:

—Who report rarely or never reading Nutrition Facts labels;
—Who are overweight or hypertensive;
—Whose reasons for not reading labels will be addressed by the proposed rule;
—Who are expected to change their behavior.

For caloric reduction benefits, we only include overweight individuals who are maintaining or losing weight. This is because the Nutrition Impact Model assumed that all overweight adults are at weight equilibrium and not gaining weight. The overweight and gaining weight adults may not experience weight loss from a small reduction in caloric intake and therefore will not obtain the medical cost savings from weight loss as calculated in the Nutrition Impact Model. The caloric reduction benefits from the model is calculated by a constant reduction in caloric intake below the Estimated Energy Requirement[72] (EER) (*i.e.* a level of caloric intake below that required to maintain current body weight) for a given weight, age, height and gender and physical activity level (PAL) for overweight adults. It takes about four years until a new weight equilibrium is reached where the EER equals the new daily caloric intake. Utilizing NHANES dietary recall data, most adults (72.8 percent[73]) are consuming at or below their EER. Although NHANES dietary recall data is self-reported and individuals, especially overweight or obese individuals, sometimes underreport caloric intake in these types of surveys[74 75], the dietary recall component of NHANES is used in reporting for the Dietary Guidelines for Americans and many other official government documents. Also, this finding is consistent with recent reports in which prevalence of obesity and overweight have stabilized and in some population groups have reduced in recent years.[76 77] Therefore, this analysis measures the benefit of caloric reduction among overweight adult consumers maintaining or losing weight.

NHANES data identified the number of overweight adults who are maintaining or losing weight that never or rarely use labels, Table 8. An overweight adult maintaining or losing weight has a Body Mass Index (BMI) of 25 or over, aged 16 years or older and consumes calories equal to or less than their Estimated Energy Requirement, EER.[78] Based on NHANES data, 60 percent (9,501,972) of users who never read labels are either overweight or obese. Conversely, 64 percent (21,611,037) of label-users who rarely read labels are overweight or obese, Table 11. To find the number of overweight individuals maintaining or losing weight, we relied on NHANES data and the Institute of Medicine (IOM) EER calculation. Below are the IOM calculations:

For adult males:

$$EER = 662 - (9.53 \times age) + PAL \times (15.91 \times weight + 539.6 \times height)$$

For adult females:

$$EER = 354 - (6.91 \times age) + PAL \times (9.36 \times weight + 726 \times height)$$

For a conservative estimate, the IOM PAL coefficient associated with sedentary activity estimated individuals EER (1.0 for men and women). All other components of the IOM EER calculation (gender, age, weight, height) were derived from NHANES 2009–2010 and calculated using SAS.[79] The overweight individuals with a kcal intake at or less than their EER are maintaining or losing weight. The analysis found approximately 57.5 percent of these overweight rarely label-users are maintaining or losing weight, while 55.7 percent of overweight never label-users are maintaining or losing weight. In total, there are 12,428,680 rarely label-users and 5,293,397 never label-users that are overweight and maintaining or losing weight, Table 11.

Although the same person can experience health costs savings from both caloric and sodium reduction, it may overestimate benefits if using both the caloric and sodium reduction models. Therefore, to avoid double counting for the sodium reduction benefits, the analysis excluded the population benefiting from caloric reduction, overweight rarely and never label-users maintaining or losing weight. The sodium reduction analysis only includes hypertensive individuals who are normal weight or overweight and gaining weight. An estimated 461,384 and 118,705 normal weight hypertensive adults rarely or never use labels, respectively. In addition, an estimated 563,394 rarely and 551,856 never adult label-users are overweight and gaining weight with hypertension. In total, there are 1,024,778 rarely and 670,561 never hypertensive label-users who are normal weight or overweight and gaining weight, Table 12.

While the proposed changes will help many normal weight, non-hypertensive consumers use labels to maintain healthy diets, this analysis does not quantify these benefits.

Identifying the reasons overweight or hypertensive consumers do not read nutritional and serving size information is another important factor in estimating

[70] Per Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home, consumers that ''never'' use the Nutrition Facts panel consume 1,741 kcal and 122 grams of sugar from foods at home each day. A gram of sugar = 3.87 calories. ((122mg*3.87)/1,741)

[71] Per Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home, consumers that ''Always or Most of the Time'' use the Nutrition Facts panel consume 1,439 kcal and 85 grams of sugar from foods at home each day. A gram of sugar = 3.87 calories. ((85mg*3.87)/1,439)

[72] For adult males: $EER = 662 - (9.53 \times age) + PAL \times (15.91 \times weight + 539.6 \times height)$;

For adult females: $EER = 354 - (6.91 \times age) + PAL \times (9.36 \times weight + 726 \times height)$.

[73] The IOM PAL (1.11 for men and 1.12 for women) associated with low physical activity was utilized in estimating individuals EER. All other components of the IOM EER calculation (gender, age, weight, height) were derived from NHANES 2009–2010.

[74] Archer E, Hand GA, Blair SN (2013) Correction: Validity of U.S. Nutritional Surveillance: National Health and Nutrition Examination Survey Caloric Energy Intake Data, 1971–2010. PLoS ONE 8(10): *http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0076632.*

[75] Champagne C, et al, (2002) Energy Intake and Energy Expenditure: A controlled Study Comparing Dietitians and Non-dietitians, Journal of the American Dietetic Association, Available at: *http://www.sciencedirect.com/science/article/pii/S0002822302903160.*

[76] Ogden C.L., Carroll M.D., Kit B.K., Flegal K.M. Prevalence of obesity in the United States, 2009–2010. NCHS data brief, no 82. Hyattsville, MD: National Center for Health Statistics. 2012.

[77] Flegal K.M., Carroll M.D., Kit B.K., Ogden C.L. Prevalence of Obesity and Trends in the Distribution of Body Mass Index Among U.S. Adults, 1999–2010. *JAMA.* 2012;307(5):491–497. doi:10.1001/jama.2012.39.

[78] For adult males: $EER = 662 - (9.53 \times age) + PAL \times (15.91 \times weight + 539.6 \times height)$;

For adult females: $EER = 354 - (6.91 \times age) + PAL \times (9.36 \times weight + 726 \times height)$.

[79] SAS version 9.2 Cary, NC, 2011 *http://www.sas.com/technologies/analytics/statistics/stat/index.html.*

increased label use. NHANES respondents that rarely or never read nutrition information were able to select multiple reasons for not reading labels. Responses provided for not reading labels were mixed, Table 10. Many of the reasons for not reading labels are not addressed by this proposed rule and will not lead to increased label use: *i.e.* ''I can't read English well'' or ''I usually buy food that I'm used to, so I don't feel the need to check labels.'' The proposed rule is intended to make the most important information more prominent and the entire label quicker to read, reducing the time spent gathering information on the label. As such, only those overweight or hypertensive consumers who exclusively selected a combination of ''the print is too small,'' ''I won't know what to look for,'' and ''I don't have time'' reasons for not reading labels were considered in the mid-point benefits estimate. That group constitutes approximately 10 percent. Of this group, approximately 1 percent exclusively replied ''the print is too small,'' approximately 2 percent exclusively replied ''I won't know what to look for,'' approximately 3 percent exclusively replied ''I don't have time,'' and approximately 4 percent gave a combination of these reasons for not using labels, Table 10. Excluded from the mid-point benefits estimate were consumers who reported not using labels because for a variety of reasons, they expressed little to no interest in the information, or because they could not read English. As such, this analysis assumes that only 10 percent of overweight/hypertensive rarely/never users will increase their label use as a mid-point estimate, Table 11 and 12.

For the lower bound estimate, only those overweight or hypertensive consumers who exclusively gave ''the print is too small for me to read'' reason for not reading labels were considered (1 percent) as print size is directly changed by the regulation. The lower bound estimate excludes everyone who did not exclusively give ''the print is too small for me to read'' as a reason for not reading labels, 99 percent of consumers.

For the upper bound estimate, only those overweight or hypertensive consumers who selected one or more of the following reasons for not reading labels were considered: ''the print is too small,'' ''I won't know what to look for,'' and ''I don't have time''. This group constitutes approximately 44 percent. The upper bound estimate includes consumers who gave the three above reasons and does not exclude anyone if they gave other reasons for not using labels.

TABLE 10—REASONS OVERWEIGHT RARELY AND NEVER USERS DO NOT USE LABELS

Reasons for not reading labels	Total response with overlap [1] (%)	Exclusive response [2] (%)	Exclusive group, no overlap [3] (%)	Total responses from exclusive group w/overlap [4] (%)
Targeted Population				
The print is too small for me to read	16	1	10	44
I won't know what to look for even if I read the labels	20	2		
I don't have time	24	3		
Other				
I usually buy foods that I'm used to, so I don't feel that I need to check labels	53	7		
I buy what I or my family like, I don't care about the labels	51	5		
I have a good diet so there is no need to check	12	1		
I'm satisfied with my health so there is no need for me to check	25	2		
I don't think food labels are important to me	15	2		
I can't read English well	8	2		
Other/Refused/Don't know	14	8		

[1] Total Response with Overlap includes the percentage of NHANES respondents who gave this reason for rarely or never using food labels.

[2] Exclusive Response includes the percentage of respondents who only gave this reason for rarely or never using food labels. The lower-bound estimate is 1% for consumers who exclusively gave "the print is too small for me to read" reason.

[3] Exclusive Group No Overlap includes the percentage of NHANES respondents who only gave some combination of 3 reasons that are addressed by the rule: "The Print is too small for me to read," "I won't know what to look for even if I read the labels" and or "I don't have time". This is the mid-point estimate.

[4] Total Responses from Exclusive Group with Overlap includes the percentage of NHANES respondents who gave some combination of 3 reasons that are addressed by the rule: "The Print is too small for me to read," "I won't know what to look for" and "I don't have time". This is the upper-bound estimate.

Source: NHANES. 2013. ''Questionnaires, Datasets, and Related Documentation'' Centers for Disease Control and Prevention. Accessed on 1/23/2014. *http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.*

Increasing label use does not necessarily lead to a change in behavior. Our analysis further refines the benefits analysis by estimating only a portion of the overweight or hypertensive rarely/never label-users increasing their label use will potentially change their diet. This estimate was derived from data in the FDA 2008 Health and Diet Survey. In 2008, FDA asked consumers ''In the last two weeks, can you remember an instance where your decision to buy or use a food product was changed because you read the nutrition label?'' and 49 percent of respondents said yes.[80] As such, this analysis assumes only 49 percent of overweight/hypertensive consumers who increase label use will potentially change their behavior, Table 11 and 12. As a mid-point estimate, there are 868,382 overweight users maintaining or losing weight that could potentially increase label use and reduce their caloric intake (1,772,208 * 49%). This estimate ranges from 86,838 (177,221 * 49%) to 3,820,880 (7,797,714 * 49%) for the lower and upper bound, Table 11. As a mid-point estimate, there

[80] Choiniere, C.J. and A. Lando. 2008. ''FDA 2008 Health and Diet Survey—Consumer Behavior Research'' Accessed on 5/6/2014. <*http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm193895.htm*>.

are 83,072 hypertensive normal weight or overweight and gaining weight individuals that could potentially increase their label use and reduce their sodium intake (169,534 * 49%). This estimate ranges from 8,307 (16,953 * 49%) to 365,515 (745,949 * 49%) for the lower and upper bound, Table 12.

TABLE 11—CALCULATING THE TARGETED POPULATION FOR CALORIC REDUCTION BENEFITS

	Rarely	Never	Totals
Start with all users	33,653,297	15,807,324	49,460,621
Reduce to only:			
Overweight Users	21,611,037	9,501,972	31,113,009
Overweight users maintaining or losing weight	12,428,680	5,293,397	17,722,077
Lower bound population (1% of users)	124,287	52,934	177,221
Mid-point population (10% of users)	1,242,868	529,340	1,772,208
Upper bound population (44% of users)	5,468,619	2,329,095	7,797,714
Lower bound population expected to change behavior (49% of lower bound pop.)	60,901	25,938	86,838
Mid-point population expected to change behavior (49% of mid-point pop.)	609,005	259,376	868,382
Upper bound population expected to change behavior (49% of upper bound pop.)	2,679,623	1,141,257	3,820,880

Source: NHANES. 2013. "Questionnaires, Datasets, and Related Documentation" Centers for Disease Control and Prevention. Accessed on 1/23/2014. *http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.*

TABLE 12—CALCULATING THE TARGETED POPULATION FOR SODIUM REDUCTION BENEFITS

	Rarely	Never	Totals
Start with all users	33,653,297	15,807,324	49,460,621
Reduce to only hypertensive users:			
Normal weight	461,384	118,705	580,089
Overweight and gaining weight	563,394	551,856	1,115,250
Total hypertensive normal weight or overweight and gaining weight	1,024,778	670,561	1,695,339
Lower bound population (1% of users)	10,248	6,706	16,953
Target Population (10% of users)	102,478	67,056	169,534
Upper bound population (44% of users)	450,902	295,047	745,949
Lower bound population expected to change behavior (49% of lower bound pop.)	5,022	3,286	8,307
Mid-point population expected to change behavior (49% of mid-point pop.)	50,214	32,857	83,072
Upper bound population expected to change behavior (49% of upper bound pop.)	220,942	144,573	365,515

Source: NHANES. 2013. "Questionnaires, Datasets, and Related Documentation" Centers for Disease Control and Prevention. Accessed on 1/23/2014. *http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.*

Benefits Analysis: Estimating Changes in Diet

FSIS assumed that the population expected to change its behavior will do so by moderately increasing its label-use from either never to rarely or rarely to sometimes. The expected diet change is the difference in caloric and sodium intake between each user group. Accordingly, the mid-point estimate of 259,376 overweight consumers who never use the Nutrition Facts label could potentially begin to rarely use labels and reduce their daily caloric intake by 187 kcals (1,741 − 1,554). The mid-point estimate of 609,005 overweight consumers who rarely use the Nutrition Facts label could potentially begin to use labels sometimes and reduce their caloric intake by 92 kcal (1,554 − 1,462). The same formula is followed for the normal weight consumers with hypertension resulting in a 87 mg daily sodium reduction for the 32,857 former never label-users and 104 mg reduction for 50,214 former rarely label-users.

Benefits Analysis: Estimate the Economic Benefits of Caloric and Sodium Reduction

To quantify the medical cost savings from reductions in caloric and sodium intake, FSIS used the Nutrition Impact Model developed by Tim Dall et al. (2009). The Nutrition Impact Model estimates the potential health benefits of weight loss by reducing daily caloric intake for overweight adults.

The Nutrition Impact Model also estimates the benefits of sodium reduction in adults with hypertension. The model combines these benefits to estimate national medical costs savings from changes in dietary habits among the general adult population. The model concludes modest to aggressive changes in diet can improve health and reduce annual national medical expenditures by $60 to $120 billion.

The Nutrition Impact Model used scientific reports and peer-reviewed literature to quantify the relationships between dietary change, body mass index, and blood pressure (Systolic BP/Diastolic BP) and between these same factors and disease risk. By modeling the reduction in health conditions associated with long-term improved nutritional intake, the model can measure the potential health conditions averted by reducing daily caloric and sodium intake in the American diet. For example, weight loss can improve or prevent many diseases risks such as cancer and diabetes, resulting in a medical savings. The benefits of caloric reductions in overweight adults is measured by the medical savings of reductions in the following health conditions; arthritis, asthma, cancer, cerebrovascular disease, congestive heart failure, coronary heart disease, diabetes, esophagus/stomach disease, gallbladder disease, gynecological conditions, kidney/urinary disease, other cardiovascular disease, and sleep apnea. The benefits of sodium reductions are measured by the medical savings of reductions in hypertension cases. Some health conditions are jointly attributed to multiple risk factors.

Caloric Reduction Benefits

For caloric reductions benefits, the Nutrition Impact Model begins to calculate the benefits starting in the fourth year of diet as weight loss is more significant in the first few years then stabilizes in year four with little additional weight loss. As discussed in the Nutrition Impact Model, if the total overweight and obese population (139 million people in 2007) reduced their daily caloric intake by 100 kcal, many obese adults would move into the overweight category while many overweight adults would move into the normal weight category. In turn, the prevalence of chronic health conditions associated with excess weight would be reduced. There would be 1.7 million fewer cases of coronary heart disease and 1.5 million fewer cases of type 2 diabetes in a given year. Overall, a 100 kcal reduction in the diets of all U.S. overweight adults (139 million) will lead to $58.4 billion in national medical costs savings annually, or $420 ($58.4B/139M) per overweight adult after a period of four years. Also, the Nutrition Impact Model concludes that if the overweight and obese population reduced its daily caloric intake by 500-kcal, almost the entire U.S. adult population would stabilize at normal weight levels with national medical savings at $110.5 billion, or $795 per overweight person.

As displayed in Table 13, our analysis expects potentially 259,376 overweight adults to reduce their total caloric intake by 187 kcal and 609,005 adults to reduce their total caloric intake by 92 kcal as the mid-point estimate. The Nutrition Impact Model estimates a 92 kcal reduction could potentially result in $55 billion of annual medical savings after 4 years or $395.68 ($55B/139M) dollars per person. For a 187 kcal reduction, the potential annual medical savings is $84 billion or $575.54 ($84B/139M) per person after four years. Table 13 provides details of the distribution of increased label users, associated reductions in calories, and potential savings.

Recognizing that individuals will benefit from both improved FDA and FSIS labels, this analysis took additional steps to distill out benefits specific to FSIS products with Nutrition Facts labeling. First, our analysis scaled down the estimate by only including the average caloric and sodium intake of FSIS products for adults. Using Table 1B—Mean Intake of Energy and Mean Contribution (KCAL) of Various Foods among U.S. Population by Age from the National Cancer Institute,[81] we estimate about 397 of the 2,199 daily calorie consumption (18.1 percent) from adults are derived from USDA products affected by this rulemaking.[82] These products include all chicken and chicken mixed dishes, beef and beef mixed dishes, burgers, sausages, franks, bacon and ribs and some pizzas, pasta dishes, and eggs and egg mixed dishes.

In addition, although the analysis only incorporates sodium and caloric intake from food at home, some meat and poultry products are exempt from nutrition labeling, and therefore removed from the benefits analysis. As discussed in the cost section above, we estimate approximately 11.95 percent (30.64% * 39%) of food-at-home meat and poultry products are exempt from nutrition labeling. Therefore, our analysis further scales back the benefits estimate first by removing 81.9 percent for the kcal intake of FDA products and second by removing 11.95 percent for the FSIS products exempt from nutrition labeling. This results in the mid-point annual benefits of $79,173,871 (496M * (100% − 81.9%) * (100% − 11.95%)) for caloric reduction. The lower bound estimate is $7,917,474 and upper bound estimate is $348,365,416, Table 13.

TABLE 13—ANNUAL MEDICAL SAVINGS FROM REDUCING CALORIC INTAKE ^

User type	Lower bound number of users	Mid-point number of users	Upper bound number of users	Potential savings per person	Lower bound total potential savings	Mid-point total potential savings	Upper bound total potential savings
Sometimes	60,901	609,005	2,679,623	$395.68	$24,097,308	$240,971,098	$1,060,273,229
Rarely	25,938	259,376	1,141,257	575.54	14,928,357	149,281,263	656,839,054
Annual benefits after 4 years ($ 2007)					39,025,665	390,252,361	1,717,112,283
Annual benefits after 4 years ($ 2015) *					49,679,672	496,791,256	2,185,883,936
Benefits from USDA products ($ 2015)					7,917,474	79,173,871	348,365,416

^ It is expected to take 4 years for the medical benefits from a reduction in calories to be experienced.
[2] CPI–U for Medical Care of 1.273% was used to adjust for inflation (2007–2015).

Sodium Reduction Benefits

While the benefits of caloric reduction weight-loss are measured at year four in the Nutrition Impact Model, sodium reduction benefits are experienced right away. In most individuals, blood pressure is reduced within days to weeks of reducing sodium intake.[83] Therefore, the potential benefits are estimated in the first year for increased label use for adults with hypertension. The Nutrition Impact Model estimates 1.5 million fewer cases of hypertension with a potential annual savings of $2.3 billion if adults with hypertension reduced their daily sodium intake by 400 mg.

As displayed in Table 14, our mid-point estimate expects 32,857 adults with hypertension to reduce their sodium intake by 87 mg for food at home, and 50,214 adults with hypertension to reduce their sodium intake by 104 mg for food at home. The Nutrition Impact Model estimates a 104 mg daily sodium reduction for all adults with hypertension results in $1.17B dollars of annual medical savings, or $27.86 ($1.17B/42M) dollars per person. For an 87 mg daily sodium reduction for all adults with hypertension, the potential annual medical savings are $1.11B, or $26.43 ($1.11B/42M) per person.

As calculated with the caloric benefits, our analysis scaled down the estimate for sodium reduction benefits by only incorporating the average sodium intake of FSIS products with labeling for adults. Using Table 1B—Mean Intake of Sodium, Mean Intake of Energy, and Mean Sodium Contribution

[81] Sources of Energy among the U.S. Population, 2005–06. Applied Research Program Web site. National Cancer Institute. *http://appliedresearch.cancer.gov/diet/foodsources/energy/*. Table 1B. Updated April 11, 2014. Accessed June 21, 2014.

[82] FDA estimated 353 of 2,157 calories (16.4 percent) an average American consumes daily come from USDA products in FDAs Nutrition Facts/Serving Sizes Combined PRIA. This differs from our estimate by age, group and food product category. FDA used the average kcal intake for all age groups, including children (2,157) and our estimate used the average kcal for adults age 19 plus (2,199). Also, we assumed half of pizzas and pasta dishes were USDA products and FDA did not. FDA included cold cuts, which was not included in the 30 most common food groups in adult diets.

[83] He F.J., Li J., and G.A. MacGregor. 2013. Effect of longer-term modest salt reduction on blood pressure. Cochrane Database of Systematic Reviews. Issue 4. Art. No,: CD004937. DOI: 10.1002/14651858.CD004937. pub2.

(mg) of Various Foods Among US Population, by Age, NHANES 2005–06,[84] we estimate about 965 of the 3,535 daily sodium consumption (27.3% percent) from adults are derived from USDA products. These products include all chicken and chicken mixed dishes, beef and beef mixed dishes, burgers, cold cuts, sausages, franks, bacon and ribs and some pizzas, pasta dishes, and eggs and egg mixed dishes.

In addition, as discussed in the caloric reduction benefits section above, we scaled back the potential benefits by 11.95 percent for the food-at-home FSIS products that are exempt from nutrition labeling. Overall, our benefits estimate scales back the benefits by removing 72.7 percent for the sodium intake of FDA products and removing 11.95 percent for the FSIS products exempt from nutrition labeling, resulting in the mid-point annual benefits estimate of $693,815 ($2.9M*(100%–72.7%) * (100%–11.95%)) for sodium reduction. The lower bound estimate is $69,389 and upper bound estimate is $3,052,804, Table 14.

TABLE 14—ANNUAL MEDICAL SAVINGS FROM REDUCING SODIUM INTAKE ^

User type	Lower bound number of users	Mid-point number of users	Upper bound number of users	Potential savings per person	Lower bound total potential savings	Mid-point total potential savings	Upper bound total potential savings
Sometimes	5,022	50,214	220,942	$27.86	$139,913	$1,398,962	$6,155,444
Rarely	3,286	32,857	144,573	26.43	86,849	868,411	3,821,064
Annual benefits after 4 years ($ 2007)					226,762	2,267,373	9,976,508
Annual benefits after 4 years ($ 2015) *					288,668	2,886,366	12,700,095
Benefits from USDA products ($ 2015)					69,389	693,815	3,052,804

^ It is expected to take 4 years for the medical benefits from a reduction in calories to be experienced.
[2] CPI–U for Medical Care of 1.273% was used to adjust for inflation (2007–2015).

Summary of Potential Benefits Over 20 Years With a 24 Month Compliance Period for Large and 36 Month Compliance Period for Small Businesses

The welfare gains from caloric and sodium reduction estimated above reflect the full annual potential impact of the regulation without adjusting for the potential lag between reaching a particular weight and experiencing the associated health outcomes and medical cost savings. However, industry would need time to modify labels under the new regulations. Table 15 uses the FDA Cost Label model[85] to estimate the frequency of label changes in twelve-month increments. As shown in Table 4—Label Changes That Can Be Coordinated with a Planned Change, only 10 percent of all labels will be updated by the end of the first year and 82 percent by the end of the second year. After 24 months, all large manufacturers are in compliance and 82 percent of small businesses are in compliance. Based on IRI scanner data and SBA small business standards, 53.6 percent of FSIS labels are from small businesses and 46.4 percent are from Large. Therefore, after 24 months, 90.35 percent of FSIS's Nutrition Facts labels are updated ((100% of Large * 46.4% of labels) + (82% of Small * 53.6% of Labels)). After 36 months, 100 percent of FSIS's nutrition facts labels are updated.

To arrive at the present value estimate of potential benefits, FSIS multiplied the percentage of label changes in each 12 month period by the annual potential benefits estimate. The percentage of label changes estimates the percentage of updated labels at a given time: 10 percent after 12 months, 90.35 percent after 24 months, and 100 percent after 36 or more months. Again, the Nutrition Impact Model estimates benefits immediately for reductions in sodium intake and at year four for reductions in caloric intake. Therefore, benefits for caloric reduction start four years after the labels update while benefits for sodium reduction are realized as the labels are updated. For example, as is shown in Table 4—Label Changes That Can Be Coordinated with a Planned Change, 12 months after publication of the final rule, an estimated 10 percent of FSIS labels are changed, resulting in 10 percent of the annual sodium benefits and no quantified benefits for the caloric intake reductions. After 24 months, 90.35 percent of Nutrition Facts labels are updated, resulting in 90.35 percent of the annual sodium benefits and no quantified benefits for the caloric intake reductions. The benefits in year 6 are a product of 100 percent of the sodium reduction benefits and 10 percent of the caloric reduction benefits as four years have passed since 10 percent of the labels were updated. Not until year seven are the full annual sodium and caloric reduction mid-point benefits without latency applied.

FSIS could not determine the weight-level-to-health outcome latency for each health condition included in the Nutrition Impact Model. But, to try and account for this latency, FSIS assumed a uniform health impacts time pattern between present age and age 80 and a uniform age distribution between age 18 and 79 to determine weighting factors that could be applied to the benefits estimates from the Nutrition Impact Model to calculate the present and annualized benefits. FSIS multiplied average weighting factors of 0.665 (3 percent discount rate) and 0.458 (7 percent discount rate) by the present value annual benefit from caloric and sodium reduction to estimate the total annual health impact for each year. FSIS is requesting comment on accounting for latency between weight change and health outcomes.

The mid-point present value, discounted at 3 percent rate is $549 million and $239 million with a 7 percent discount rate. The mid-point annual benefit is $37 million at a 3 percent discount rate and $23 million at 7 percent. The lower bound estimate is $3,689,445 and upper bound estimate is $162,333,818 at a 3 percent discount rate, Table 15.

[84] Sources of Energy among the U.S. Population, 2005–06. Applied Research Program Web site. National Cancer Institute. *http://appliedresearch.cancer.gov/diet/foodsources/energy/*. Table 1B. Updated April 11, 2014. Accessed June 21, 2014.

[85] RTI International. ''2014 FDA Labeling Cost Model.'' Prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela C. Coglaiti, and Shawn A. Karns. Contract No. HHSF–223–2011–10005B, Task Order 20, August 2015.

TABLE 15—PRESENT VALUE OF BENEFITS OVER 20 YEARS GIVEN A 24 MONTH COMPLIANCE PERIOD FOR LARGE AND 36 MONTH COMPLIANCE PERIOD FOR SMALL BUSINESSES

Year	Lower bound benefits from caloric and sodium reduction	Mid-point benefits from caloric and sodium reductions	Upper bound benefits from caloric and sodium reduction
NPV 3%	$54,889,631	$548,889,659	$2,415,117,294
NPV 7%	23,880,540	238,802,476	1,050,732,115
Annual PV 3%	3,689,445	36,894,007	162,333,818
Annual PV 7%	2,254,154	22,541,264	99,181,679

Uncertainty in the Quantitative Benefits Analysis

The ramifications of the proposed rule are not expected to have a significant impact on the food market. As a mid-point estimate, we estimate potentially 609,005 adults would potentially reduce their caloric intake by 92 kcals, and 259,376 adults will potentially reduce their caloric intake by 187 kcals for FDA and FSIS regulated products. Additionally, as a mid-point estimate, we estimate potentially 50,214 adults would potentially reduce their sodium intake by 104 mg and 32,857 adults would potentially reduce sodium intake by 87 mg for FDA and FSIS regulated products. Only a small portion of the caloric and sodium intake are from meat or poultry products as only 18 percent of all caloric intake is from FSIS products. Further still, this small change in diet may lead to increased consumption of lower calorie or lower sodium products, including food products reformulated in response to the changes on the label. Therefore, we estimate the market impact will distribute across all food markets with minimal impact on meat and poultry markets. The benefits analysis for the proposed rule may underestimate the full consumer welfare gain for several reasons. This analysis only includes the potential medical savings for the overweight and hypertension population that sparsely uses labels. The analysis does not account for benefits in diet modifications for children under the age of 16 or most people of normal weight. Though, we can expect the diet behavior of adults to transfer to their children under the age of 16. Normal weight consumers and consumers currently using labels when buying food may modify their diet and benefit from the new content and design on the Nutrition Facts label. The analysis only includes benefits from caloric and sodium reductions leading to averted health conditions associated with hypertension, overweight and obesity. Many major health conditions are associated with obesity; therefore the medical savings benefit for calorie reduction weight-loss is substantial in overweight and obese individuals. However, other modifications to the label, such as updates to RACCs and Daily Values for added sugars, nutrients and minerals, may help consumers adjust their diet and improve their personal welfare. Modifications such as the dual column labels will simplify the calculation for total nutrients in an entire package, which may contribute to a healthful diet. Additionally, health benefits from caloric reduction do occur before four years, and health benefits may continue to increase over time; however the Nutrition Impact Model begins to calculate the benefits from caloric reductions starting at year four. FSIS has no means to quantify these benefits. Further, there may be indirect benefits to reducing caloric and sodium intake through improved lifestyle, wages, or productivity that are not measured in this benefits estimate. Therefore, the resulting potential benefits estimate should be interpreted as an underestimate of overall benefits.

However, data supporting the benefits analysis is from national consumer surveys where results are on self-reported behavior changes, which could potentially overstate actual results. In addition, the consumers in our quantitative benefits estimate may lose utility associated with consuming products high in sugar, calories and sodium.[86] Furthermore, as noted earlier in the analysis, the available estimates of the relationship between label use and calorie and sodium intake generally establish only correlation, but the way they are used to develop benefits estimates reflects an assumption of causation. Therefore, in some instances, the analysis may overestimate the welfare gains.

[86] Ashley, Elizabeth M., Clark Nardinelli and Rosemarie A. Lavaty. ''Estimating the Benefits of Public Health Policies that Reduce Harmful Consumption.'' *Health Economics* 24(5): 617–624. May 2015. *http://onlinelibrary.wiley.com/doi/10.1002/hec.3040/full.*

Qualitative Benefits

FSIS believes there are several additional benefits associated with the proposed changes which are hard to quantify. To start, the millions of normal weight not hypertensive users who currently use nutritional information will benefit from the clearer label format. Additionally, the proposed changes would harmonize the labels between FDA and USDA products, reducing producer administration costs. Further still, the proposed changes could potentially simplify the communication of hard to distinguish, but sought after, product attributes benefiting both producers and consumers.

The mandatory declaration of *trans* fat, added sugars, vitamin D and potassium and other changes on the Nutrition Facts label will assist consumers in making informed choices and maintaining healthy dietary practices. Consumers can better determine which products are suitable for their personal preference and dietary needs. The more up-to-date information included on the Nutrition Facts label better reflects the current recommendations for American diets, allowing consumers to make informed decisions leading to an increase in consumer welfare.

Small businesses will benefit from the additional 12-month compliance period. Allowing small businesses additional time to comply reduces costs of relabeling, reformulation and recordkeeping and allows additional time to understand and implement the proposed regulations.

Also, the Agency believes that the public would be better served by having the regulations governing nutrition labeling consolidated in one part of title 9. Rather than searching through two separate parts of title 9—317 and 381—to find the nutrition labeling regulations, interested parties would only have to survey one, 9 CFR part 413, to be able to apply nutrition panels to their meat and poultry products.

Alternative Regulatory Approaches

Four alternatives, Table 16, are considered for the proposed serving size and Nutrition Facts label proposed rule.

- Alternative 1: Take no regulatory action by continuing with the existing labeling requirements.
- Alternative 2: The proposed rule, giving large manufacturers a 24-month compliance period and small manufacturers 36-months.
- Alternative 3: The proposed rule, giving manufacturers a 42-month compliance period.
- Alternative 4: The proposed rule, giving all manufacturers 24-months to comply.
- Alternative 5: The proposed rule, giving large manufacturers a 12-month compliance period and small manufactures 24-months.

TABLE 16—COMPARISON OF THE CONSIDERED ALTERNATIVES

Considered Alternative	Benefits [1]	Costs [1]	Net benefits [1]
1—Take No Action.	Zero	Zero	Zero.
2—The Proposed Rule—24-month compliance large, 36-month compliance small.	About 1 million consumers would increase their label use, leading to roughly $36.9 million in health benefits. Small businesses benefit from the additional compliance time.	Costs equal $10.8 million. Relabeling FSIS products will be coordinated and uncoordinated and is estimated to cost industry $4.5 million. Recordkeeping costs are estimated at $121,690. Reformulation is expected to cost industry $6.2 million.	In addition to the $26.1 million in net benefits, the proposed rule would harmonize USDA and FDA labels and give small businesses additional compliance time.
3—42-month Compliance Period.	The extended compliance period delays the speed at which an estimated 1 million consumers would increase their label use. This delay reduces health benefits to $36.4 million.	Costs equal $7.8 million. The extended compliance period reduces labeling costs to $2.3 million by allowing all coordinated changes. Recordkeeping costs remain at $121,690. Reformulation costs are expected to cost $5.3 million. Consumers and producers would incur costs because FSIS and FDA labels would be inconsistent.	Net benefits are $28.6 million. In comparison to alternative 2, benefits are reduced 1.4 percent, and costs are reduced 27.9 percent. However, alternative 3's compliance period is longer than alternative 2's, delaying benefits.
4—24-month Compliance Period.	About 1 million consumers would increase their label use leading to roughly $37.2 million in health benefits.	Costs equal to $11.4 million. Small businesses do not have additional time to comply, increasing labeling costs to $5.1 million for the additional uncoordinated changes. In addition, reformulation is expected to increase to $6.2 million. Recordkeeping costs remain at $121,690. Consumers and producers would incur costs because FSIS and FDA labels would be inconsistent.	Net benefits are $25.8 million, 1 percent lower than alternative 2's. While benefits are $288,829 higher than alternative 2's, costs are $619,687 higher. The increase in benefits may be reduced due to confusion between inconsistent FSIS and FDA labels.
5—12-month compliance large, 24-month compliance small.	Updates to the labels for FDA and FSIS products have the same compliance date. About 1 million consumers would increase their label use leading to roughly $38.5 million in health benefits.	Costs equal to $17.4 million, the highest of all alternatives. Labeling costs increase to $8.5 million for the coordinated and uncoordinated changes. Recordkeeping costs remain at $121,690. Reformulation costs are expected to cost $8.8 million. In addition, both consumers and producers would incur costs because USDA and FDA labels would be inconsistent.	Net benefits are $21.1 million, almost 20 percent lower than alternative 2's. While benefits are 4 percent higher than alternative 2's, costs are 61 percent higher. Qualitative benefits are consistency between FSIS and FDA labels.

[1] All quantified benefits and costs are annualized at 3 percent over 20 years.

Alternative 1—Take No Regulatory Action by Continuing With the Existing Labeling

Both producers and consumers will be worse off absent the proposed action. While ''no action'' means the 3,307 manufacturers with roughly 50,000 products under USDA jurisdiction would continue to be regulated in the same manner as they currently are, the market will be impacted in several costly ways.

First, no action would create inconsistencies between USDA and FDA labels. As such, the manufacturers that produce products regulated by both USDA and FDA will have to operate under two differentiated procedures, *e.g.,* maintaining multiple label formats, recording different product attributes, and utilizing differing RACCs for products with similar uses. This would increase administration costs for producers and make label use more difficult for consumers, decreasing their benefit.[87]

Second, if the USDA were to take ''no action,'' the Agency would fail to address the health problems related to diet by making it more difficult for consumers to heed dietary guidelines. Third, the ''no action'' would fail to make any improvements to address the problems that prohibit millions of consumers from using labels: The print being too small, not knowing what to look for, or not having enough time. The targeted population of nearly 32 million overweight or hypertensive adults, whom rarely or never use the Nutrition Facts label, would continue to not read the labels and continue with high sodium or calorie diets. In combination, these impacts would hinder producers vying to compete based on hard to

[87] Bialkova, S. and H. Trijp. 2010. What determines consumer attention to nutrition labels? Food Quality and Preference. 21 1042–1051 and Campos, A., J. Doxey, and D. Hammond. 2011. Nutrition labels on pre-packaged foods: a systematic review. Public Health Nutrition. 14: 1496–1506. Bialkova and Trijp, 2010 and Campos et al., 2011.

distinguish health and nutritional attributes, reducing market competition, and would do nothing to address the nation's overweight and obesity epidemic.

Alternative 2—The Proposed Rule, Giving Large Manufacturers a 24-Month Compliance Period and Small Manufacturers 36-Months

Alternative 2, the proposed rule, addresses many of the current nutritional and serving size labels' short comings by applying the changes proposed in the preamble with a 24-month compliance period for large and 36-month for small, consistent with FDA's compliance period. While industry will incur costs associated with relabeling, recordkeeping, and reformulation, consumers will benefit from an increase in information which may lead to improved health. The estimated net benefits are $26.1 million. The proposed costs and benefits associated with this alternative are detailed in Expected Costs of the Proposed Rule and Quantitative Benefits of the Proposed Rule sections of this PRIA.

Alternative 3—The Proposed Rule, Giving Manufacturers a 42 Month Compliance Period

Alternative 3 would apply the changes detailed in the preamble but extends the compliance period to 42 months. Compared to alternative 2, this alternative reduces costs while holding benefits nearly constant. As shown in Table 4—Label Changes That Can Be Coordinated with a Planned Change, a 42-month compliance period would provide industry sufficient time to coordinate all required label changes, subsequently reducing annualized relabeling costs by about $2.1 million, as compared to alternative 2. Recordkeeping costs would remain the same as alternative 2 and annualized reformulation costs would be reduced by about $1 million.

Health benefits would be delayed by extending the compliance period. Annual benefits at a 3 percent discount rate under alternative 3 are estimated to be $36.4 million, which is roughly $500,000 less than alternative 2's estimated annual benefits. However, a 42-month compliance period would result in delayed label updates, and extend inconsistencies between USDA and FDA labels for an additional 18 months compared to alternative 2.

Also, extending the compliance period would require a further exception to current uniform compliance guidelines[88] set by the Agency. Consistent with FDA's uniform compliance dates for food labels, USDA sets uniform compliance dates in 2-year increments to enhance the industry's ability to make orderly adjustments to new labeling requirements without unduly exposing consumers to outdated labels. Further, cost estimates may be understated as producers who market FDA-regulated and FSIS related products may voluntarily adopt the FDA timetable and not use the additional compliance period allotted.

Relabeling Costs

Alternative 3 applies FDA's 2014 Labeling Cost Model to estimate the cost of relabeling roughly 50,000 food labels under a 42-month compliance period. In this scenario both branded and private (store brand) label changes can be coordinated, reducing the average one time per label cost from $1,371 to $717, Table 17. In sum, extending the compliance period reduces the average annualized relabeling costs to $2.3 million, assuming a 3 percent discount rate over 20 years.

TABLE 17—ALTERNATIVE 3—LABELING COSTS

[42 Month]

	Private	Branded	Costs		
			Lower	Mid	Upper
Total Number of Labels	12,645	37,465			
Coordinated Change:					
Major	3,088	9,149	$3,622,152	$14,097,024	$39,207,348
Minor	9,554	28,306	5,338,260	21,655,920	61,333,200
Uncoordinated Change:					
Extensive	3	10	91,494	180,154	330,187
Total Cost			9,051,906	35,933,098	100,870,735
Annualized Cost (3% DR, 20 Year)			590,709	2,344,921	6,582,619
Annualized Cost (7% DR, 20 Year)			798,538	3,169,935	8,898,583
Average Per label one time cost			181	717	2,013
Per label Annualized Cost (3% DR, 20 Year)			12	47	131
Per label Annualized Cost (7% DR, 20 Year)			16	63	178

Recordkeeping Costs

Alternative 3 does not alter the recordkeeping requirements as presented in the Expected Cost section above. As such, we assume the recordkeeping costs associated under alternative 3 are equal to those under alternative 2.

Reformulation Costs

Extending the compliance period reduces the cost for product reformulation. However, the longest compliance period covered in the 2014 Reformulation Cost Model is 36 months for large and 24 months for small businesses. As such, the reformulation costs associated with alternative 3 are based on a 24 month compliance period for small and 36 month compliance

[88] Uniform Compliance Date for Food Labeling Regulations, 79 FR 71007 (2014). Depending on the Alternative 2 final publication date, Alternative 2 may not deviate from the uniform compliance date, except for small businesses as they have an additional 12 months to comply.

period for large. Therefore, the reformulation costs are under estimated for this alterative.

TABLE 18—ALTERNATIVE 3—REFORMULATION COST

[42 months]

	Lower	Mid	Upper
High	$30,918,175	$65,967,997	$107,198,289
Med	6,568,245	14,044,083	22,986,932
Low	714,402	1,529,728	2,526,885
Total Cost	38,200,822	81,541,808	132,712,106
Annualized Cost (3% DR, 20 Year)	2,492,908	5,321,253	8,660,522
Annualized Cost (7% DR, 20 Year)	3,369,988	7,193,430	11,707,555
Average Per formula one time cost	30,982	66,133	107,634
Per formula Annualized Cost (3% DR, 10 Year)	2,022	4,316	7,024
Per formula Annualized Cost (7% DR, 10 Year)	2,733	5,834	9,495

Quantitative Benefits

Again, the present value of health benefits was derived by multiplying the percentage of label changes in each 12 month period by annual health benefits. The prolonged compliance period reduces the rate labels are updated, which in turn reduces the rate at which consumers are exposed to updated labels and overall benefits. As is shown on Table 19, the expected difference in annual health benefits between alternative 2 and alternative 3 is about $0.5 million. Alternative 3 has the benefit of saving roughly $3 million annually from reductions in labeling and reformulation costs, $2.1 million of which is derived from reductions in labeling costs.

TABLE 19—COMPARISON OF ALTERNATIVES 2 AND 3

	Alternative 2			Alternative 3		
	Benefits	Costs [1]	Net benefits	Benefits	Costs [1]	Net benefits
Annual PV[2] 3%	$36,894,007	$10,802,809	$26,091,198	$36,382,559	$7,787,864	$28,594,695
Annual PV 7%	22,541,264	14,603,562	7,937,702	22,154,586	10,527,869	11,626,717

[1] Costs include relabeling, recordkeeping, and reformulation costs.
[2] Present Value (PV) is the current worth of a future sum of money or stream of cash flows given a specified rate of return.

Qualitative Benefits

Alternative 3 is expected to have the same type of qualitative benefits as alternative 2, but their realization is delayed. Labels would not be harmonized as soon as alternative 2, resulting in confusion between USDA and FDA labels. Producers who market FDA-regulated products also may voluntarily adopt the FDA timetable and update their labels prior to the 42-month compliance period.

Alternative 4—The Proposed Rule, Giving All Manufacturers 24 Months To Comply

Under this alternative, all manufacturers are given a 24 month compliance period. This alternative does not give small businesses additional time to comply and is inconsistent with FDA's compliance period.

Relabeling Costs

Under alternative 4, small and large businesses are given 24 months to comply with the proposed changes. Under a 24-month compliance period, all branded labels and 26 percent of private labels will incur a coordinated label change while 74 percent of private labels will incur an uncoordinated label change, Table 20.

TABLE 20—ALTERNATIVE 4—LABELING COSTS

[24 Month compliance period]

	Private	Branded	Costs		
			Lower	Mean	Upper
Total Number of Labels	12,645	37,465			
Coordinated Change:					
Major	803	9,149	$2,945,792	$11,464,704	$31,886,208
Minor	2,484	28,306	4,341,390	17,611,880	49,879,800
Uncoordinated Change:					
Major	2,285		11,710,625	21,481,285	39,759,000
Minor	7,070		13,022,940	27,481,090	54,728,870
Extensive	3	10	91,494	180,154	330,187
Total Cost			32,112,241	78,219,113	176,584,065
Annualized Cost (3% DR, 20 Year)			2,095,580	5,104,420	11,523,517
Annualized Cost (7% DR, 20 Year)			2,832,868	6,900,309	15,577,838

TABLE 20—ALTERNATIVE 4—LABELING COSTS—Continued

[24 Month compliance period]

	Private	Branded	Costs		
			Lower	Mean	Upper
Average Per label one time cost			641	1,561	3,524.00
Per label Annualized Cost (3% DR, 20 Year)			42	102	230
Per label Annualized Cost (7% DR, 20 Year)			57	138	311

Recordkeeping Costs

Compared to alternative 2, alternative 4 does not alter the recordkeeping requirements. As such, we assume the recordkeeping costs associated under alternative 4 are equal to those under alternative 2.

Reformulation Costs

Reducing the compliance period for small businesses increases the cost for product reformulation. However, the longest compliance period covered in the 2014 Reformulation Cost Model for small businesses is 24 months. Therefore, the reformulation cost for alternative 2 and alternative 3 are both estimated on a 24 month compliance period for both large and small businesses. Alternative 2 overestimated reformulation cost since this alternative is based on a 24 month compliance period for large and 36 months for small businesses and alternative 4 reformulation cost is most accurate given the compliance period is 24 months for large and small businesses.

TABLE 9—ALTERNATIVE 2—REFORMULATION COST

	Lower	Mid	Upper
High Complexity Formulas	$36,295,355	$77,294,020	$124,785,011
Med Complexity Formulas	7,488,995	15,983,483	25,998,357
Low Complexity Formulas	783,190	1,674,662	2,752,831
Total Cost	4,567,540	94,952,165	153,536,199
Annualized Cost (3% DR, 20 Year)	2,908,387	6,196,385	10,019,460
Annualized Cost (7% DR, 20 Year)	3,931,645	8,376,460	13,544,608
Average Per formula one time cost	36,146	77,009	124,522
Per formula Annualized Cost (3% DR, 20 Year)	2,359	5,025	8,126
Per formula Annualized Cost (7% DR, 20 Year)	3,189	6,794	10,985

Quantitative Benefits

The reduced compliance period increases the rate labels are updated, which in turn increases the rate at which consumers are exposed to updated labels, resulting in earlier and higher consumer welfare benefits. Again, the present value of health benefits was calculated by multiplying the percentage of label changes in each 12 month period by annual health benefits. As is shown in Table 22, the expected difference in annual health benefits between alternative 2 and alternative 4 is about $288,829. Alternative 4 increases the annual labeling cost by over $0.6 million annually. Overall, the net benefit decreases by $330,858 under alternative 4.

TABLE 22—COMPARISON OF ALTERNATIVES 2 AND 4

	Alternative 2			Alternative 4		
	Benefits	Costs [1]	Net Benefits	Benefits	Costs [1]	Net Benefits
Annual PV[2] 3%	$36,894,007	$10,802,809	$26,091,198	$37,182,836	$11,422,496	$25,760,340
Annual PV 7%	22,541,264	14,603,562	7,937,702	22,763,888	15,441,274	7,322,614

[1] Costs include relabeling, recordkeeping, and reformulation costs.
[2] Present Value (PV) is the current worth of a future sum of money or stream of cash flows given a specified rate of return.

Qualitative Benefits

Alternative 4 may benefit consumers from the potential reformulation of products to reduce added sugars. Also, alternative 4 would still benefit the public by consolidating nutrition labeling regulations to one location; however, it would result in inconsistencies between products regulated by either the FDA or USDA. These inconsistencies would likely increase confusion amongst both producers and consumers, reducing overall benefits.

Alternative 5—The Proposed Rule, Giving Large Manufacturers 12-Month Compliance Period and Small 24-Month Compliance

Alternative 5 more closely aligns the compliance date with FDA labels. Sharing the same compliance date with FDA products allows for harmonized labels across agencies. However, FSIS labels will have a shorter time to comply than FDA by sharing the same compliance date. FDA is giving a 24-month compliance period for large businesses and 36 months for small businesses to comply, the same compliance period as alternative 2. Also, compared to alternative 2, this alternative greatly increases costs while holding benefits nearly constant. For these reasons, this is not our preferred alternative. The sections below outline the costs and benefits for this alternative.

Relabeling Costs

Alternative 5 applies FDA's 2014 Labeling Cost Model to estimate the cost of relabeling roughly 50,000 food labels under a 12-month compliance period for large manufacturers and 24 months for small. Reducing the compliance period increases the number of uncoordinated changes, resulting in higher labeling costs. For a 12-month compliance period, only 11 percent of branded and 5 percent of private labels will have a coordinated change. For a 24-month compliance period, only 26 percent of private brands will have a coordinated change. The average one-time per label cost increases from $1,371 to $2,591, Table 23.

TABLE 23—ALTERNATIVE 5—LABELING COSTS

[12 month for large, 24 months for small]

	Small	Large	Costs		
			Lower	Mean	Upper
Total Number of Labels	26,859	23,251			
Coordinated Change:					
Major	5,334	1,828	$2,119,952	$8,250,624	$22,947,048
Minor	16,504	5,656	3,124,560	12,675,520	35,899,200
Uncoordinated Change:					
Extensive	7	6	91,494	180,154	330,187
Major	1,225	3,850	26,008,391	47,708,270	88,301,659
Minor	3,789	11,911	28,919,400	61,025,900	121,533,700
Total Cost			60,263,797	129,840,468	269,011,794
Annualized Cost (3% DR, 20 Year)			3,932,693	8,473,125	17,555,163
Annualized Cost (7% DR, 20 Year)			5,316,333	11,454,226	23,731,598
Average Per label one time cost			1,203	2,591	5,368.43
Per label Annualized Cost (3% DR, 20 Year)			78	169	350
Per label Annualized Cost (7% DR, 20 Year)			106	229	474

Recordkeeping Costs

Alternative 5 does not alter the recordkeeping requirements as presented in the Expected Cost section above. As such, we assume the recordkeeping costs associated under alternative 5 are equal to those under alternative 2.

Reformulation Costs

Reducing the compliance period increases the cost for product reformulation. However, the longest compliance period covered in the 2014 Reformulation Cost Model for a small business is 24 months. Therefore, the reformulation cost for small and medium businesses in alternative 2 is based on a 24 month compliance period, resulting in an overestimate of cost in alternative 2. Even with the overestimation in alternative 2 reformulation cost, the one-time cost for reformulation increases by $40.2 million with alternative 5, with an average per formula cost increasing from $77,009 to $109,638, Table 24. The increase is attributed to the 12-month compliance period for large manufacturers.

TABLE 24—ALTERNATIVE 5—REFORMULATION COST

[12 month large, 24 months small]

	Lower	Mid	Upper
High Complexity Formulas	$52,426,895	$111,272,089	$177,545,177
Med Complexity Formulas	10,251,245	21,801,633	35,032,632
Low Complexity Formulas	989,550	2,109,464	3,430,665
Total Cost	63,667,690	135,183,186	216,008,474
Annualized Cost (3% DR, 20 Year)	4,154,824	8,821,780	14,096,274
Annualized Cost (7% DR, 20 Year)	5,616,616	11,925,548	19,055,768
Average Per formula one time cost	51,636	109,638	175,189
Per formula Annualized Cost (3% DR, 20 Year)	3,370	7,155	11,433
Per formula Annualized Cost (7% DR, 20 Year)	4,555	9,672	15,455

Quantitative Benefits

By reducing the compliance period, labels are updated faster, resulting in earlier consumer welfare benefits. Again, the present value of health benefits was derived by multiplying the percentage of label changes in each 12-month period by annual health benefits. Alternative 5 proposed a 12-month compliance period for large and 24 month compliance period for small. Based on IRI scanner data and SBA small business standards, 53.6 percent of labels are from small businesses and 46.4 percent are from Large. Utilizing these proportions and Table 4—Label Changes That Can Be Coordinated with a Planned Change, we estimate that after 12 months, 50.76 percent of FSIS's Nutrition Facts labels are updated ((100% of Large * 46.4% of labels) + (10% of Small * 53.6% of Labels)). After 24 months, 100 percent of FSIS's nutrition facts labels are updated.

As shown in Table 25, the expected increase in annual health benefits between alternative 2 and alternative 5 is about $1.6 million. However, alternative 5 increases cost by $6.6

million annually, of which $4 million is derived from increases in labeling costs.

TABLE 25—COMPARISON OF ALTERNATIVES 2 AND 5

	Alternative 2			Alternative 5		
	Benefits	Costs [1]	Net Benefits	Benefits	Costs [1]	Net Benefits
Annual PV 3%	$36,894,007	$10,802,809	$26,091,198	$38,470,229	$17,416,595	$21,053,634
Annual PV 7%	22,541,264	14,603,562	7,937,702	23,794,722	23,544,278	250,444

[1] Costs include relabeling, recordkeeping, and reformulation costs.
[2] Present Value (PV) is the current worth of a future sum of money or stream of cash flows given a specified rate of return.

Qualitative Benefits

Alternative 5 is expected to have similar qualitative benefits as alternative 2, with the additional benefit of harmonized labels between FSIS and FDA. Assuming FSIS has a one-year lag from FDA's final rule (81 FR 33742 and 81 FR 34000), under this alternative, USDA and FDA labels will have the same compliance date, resulting in less confusion over similar food products.

IV. Regulatory Flexibility Act

The FSIS Administrator made a preliminary determination that this proposed rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). This determination was made because small businesses only account for 50 percent of the Nutrition Facts Labels and are given an additional 12 months to comply, reducing the costs of the proposed regulations.

All manufacturers are required to update labels if this proposed rule is finalized. FSIS considered other alternatives and the preferred alternative gives small businesses an additional 12 months to comply with the regulations to reduce the impact on small businesses. The additional compliance time reduces the burden and cost for small business and is consistent with FDA's compliance period.

On the basis of IRI scanner data, FSIS estimates that 3,307 manufacturers produce roughly 50,000 different retail labels with nutrition labeling for meat or poultry products. Using SBA's small business definition [89] and IRI scanner data, FSIS estimates 3,125 small manufacturers would be affected by the proposed rule. The small FSIS manufacturers produce 26,859 labels (53.6 percent of 50,110) as shown in Table 5—Alternative 2—Labeling Costs (24 Month for Large, 36 Months for Small). Note that the disproportionately large percentage of labels from the 182 large manufacturers is attributable to the fact that they typically produce more labeled products per manufacturer than small manufacturers.

The average one-time cost per label change is $1,208 or $79 annualized over 10 years at a 3-percent discount rate for small businesses. The annualized costs at a 3-percent discount rate for all labels changes from small retail manufacturers is $2,116,554 with an average cost of $677 ($2.1M/3,125) per small business. Relabeling costs for small businesses are less than half ($2.1M out of $4.5M) of the total annualized cost at a 3-percent discount rate (Table 5—Alternative 2—Labeling Costs (24 Month for Large, 36 Months for Small)). These estimates in Table 5 include small business relabeling costs from minor, major, extensive coordinated and uncoordinated changes for a 36-month compliance period.

V. Paperwork Requirements

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this proposed rule have been submitted for approval to OMB.

Title: Revision of the Nutrition Facts Labels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed.

Type of Collection: New.

Abstract: The proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA. The provisions include burden for recordkeeping, annual reporting, and third-party disclosure for the declaration of Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Vitamin E, and Folate/Folic Acid. The likely respondents to this information collection are manufacturers of FSIS retail food products containing Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Vitamin E, and Folate/Folic Acid.

Proposed Recordkeeping and Annual Record Reporting Requirements

Under this proposed rule manufacturers must maintain additional records for Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Dietary Fiber, Vitamin E, and Folate/Folic Acid. Manufacturers are also required to provide these records to the inspector or any duly authorized representative of the Agency upon request.[90]

FSIS believes the new records required from this proposed rule are records that responsible manufacturers use and retain as a normal part of business. Thus, the recordkeeping burden consists of the time required to identify and assemble the records for copying and holding and the reporting burden consists of the time required to assemble and provide records to the appropriate FSIS officials. FSIS estimates one hour of recordkeeping and one hour of recordkeeping burden for each newly required nutrient per manufacturer. If the rule is finalized as proposed, the declaration for added sugars, dietary fiber, soluble fiber, and insoluble fiber would be mandatory and 3,307 manufacturers for FSIS products would incur this burden. The declaration of Vitamin E and folate/folic acid is not mandatory unless accompanied with a nutrient claim. However, we estimate that roughly all 3,307 FSIS manufacturers will incur a one hour recordkeeping burden for the mandatory components and one hour record burden for vitamin E and folic acid. As shown in Table 26, the initial recordkeeping and reporting burden for covered respondents is 39,684 hours.

[90] Proposed 9 CFR 413.309(h)(8).

TABLE 27—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Type of declaration	Number of respondents	Hours of recordkeeping burden per respondent	Hours of reporting burden per respondent	Total burden hours
Added Sugars	3,307	1	1	6,614
Dietary Fiber	3,307	1	1	6,614
Soluble Fiber	3,307	1	1	6,614
Insoluble Fiber	3,307	1	1	6,614
Vitamin E	3,307	1	1	6,614
Folate/Folic Acid	3,307	1	1	6,614
Total initial hours	....	....	....	39,684

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for added sugars, dietary fiber, and soluble and insoluble fiber. Manufacturers will only need to keep records for products with both added and naturally occurring sugars and products with non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber.
[3] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for vitamin E and folate/folic acid. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Third Party Disclosures Burden for Manufacturers

FSIS estimated that the burden associated with the proposed changes would be a one-time burden for the food manufacturers to revise the nutrition labels. We estimate the one-time third party disclosure burden would be approximately two hours. Each label would require a respondent one hour of review to determine how to bring it into compliance with the proposed requirements. FSIS estimated each label redesign would require one additional hour per label, for a total of two hours per unique label for each respondent. Based on estimates from IRI scanner data, there are 50,110 unique nutrition labels under FSIS jurisdiction. Therefore, the estimated burden for this collection of information is 200,440 hours for respondents as shown in Table 27.

TABLE 28—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE

Action	Number of labels	Average time burden per disclosure	Total hours
Reviewing Labels	50,110	2	100,220
Label Redesign	50,110	2	100,220
Total hours	....	....	200,440

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Summary of Burden for Paperwork Reduction Act Section

Estimate of Burden: FSIS estimates that it would take 2.00 hours per respondent for recordkeeping and record reporting. FSIS also estimates it will take a respondent 2 hours per label to review and redesign the label.

Respondents: Manufacturers of FSIS products at the retail level.

Estimated Number of respondents: 3,307.

Estimated Number of FSIS labels: 50,110.

Estimated Number of Responses per Respondent: about 73 hours.

Estimated Total Annual Burden on Respondents: 241,411 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6065, South Building, Washington, DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to both Gina Kouba, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB.

VI. E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to government information and services, and for other purposes.

VII. Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

VIII. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

IX. USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf*, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410.

Fax: (202) 690–7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

X. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register* .

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe* . Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

XI. Proposed Regulatory Amendments

List of Subjects

9 CFR Parts 301 and 304

Meat inspection.

9 CFR Part 316

Food labeling, Food packaging, Meat inspection.

9 CFR Part 317

Food labeling, Food packaging, Meat inspection, Nutrition, Reporting and recordkeeping.

9 CFR Part 318

Food additives, Food packaging, Laboratories, Meat inspection, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 319

Food grades and standards, Food labeling, Frozen foods, Meat inspection, Oils and fats.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping.

9 CFR Part 327

Food labeling, Food packaging, Imports, Meat inspection.

9 CFR Part 362

Meat inspection, Poultry and poultry products, Reporting and recordkeeping.

9 CFR Part 381

Administrative practice and procedure, Animal diseases, Crime, Exports, Food grades and standards, Food labeling, Food packaging, Government employees, Grant programs—agriculture, Imports, Intergovernmental relations, Laboratories, Meat inspection, Nutrition, Polychlorinated biphenyls (PCB's), Poultry and poultry products, Reporting and recordkeeping requirements, Seizures and forfeitures, Signs and symbols, Technical assistance, Transportation.

9 CFR Parts 412 and 413

Food labeling, Food packaging, Meat inspection, Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR Chapter III as follows:

PART 301—TERMINOLOGY; ADULTERATION AND MISBRANDING STANDARDS

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 U.S.C. 138–138i, 450, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

■ 2. Amend § 301.2 by revising paragraph (10) under the definition of ''Misbranded'' to read as follows:

§ 301.2 Definitions.

* * * * *

(10) 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 is required by the regulations in part 317 of this subchapter and part 413 of subchapter E.

* * * * *

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

■ 3. The authority citation for part 304 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 4. Amend § 304.2 by revising paragraph (b) to read as follows:

§ 304.2 Information to be furnished; grant or refusal of inspection.

* * * * *

(b) The Administrator is authorized to grant inspection upon his or her determination that the applicant and the establishment are eligible therefor and to refuse to grant inspection at any establishment if he or she determines that it does not meet the requirements of this part or the regulations in parts 305, 307, and part 416, §§ 416.1 through 416.6 of this chapter, or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations in parts 316 and 317 of this subchapter and part 412 of subchapter E. Any application for inspection may be refused in accordance with the rules of practice in part 500 of this chapter.

* * * * *

PART 316—MARKING PRODUCTS AND THEIR CONTAINERS

■ 5. The authority citation for part 316 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

■ 6. Amend paragraph (b) of § 316.8 by replacing the phrase ''this part and part 317 of this subchapter'' with ''this part, part 317 of this subchapter, and part 413 of subchapter E.''

■ 7. Amend paragraph (e) of § 316.11 by adding the phrase ''and part 413 of subchapter E'' after ''in part 317 of this subchapter''.

■ 8. Amend paragraph (b) of § 316.13 by adding the phrase ''and part 413 of subchapter E'' after ''part 317 of this subchapter''.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

■ 9. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 10. Amend § 317.16 by replacing the phrase ''this part 317'' with ''this part 317 or part 413 of subchapter E''.

Subpart B—[Removed and Reserved]

■ 11. Remove and reserve subpart B, consisting of §§ 317.300 through 317.400.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

■ 12. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 13. Amend paragraph (b) of § 318.10 by replacing the phrase ''part 317 of the regulations in this subchapter'' with ''part 412 of subchapter E''.

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

■ 14. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 15. Amend paragraph (a) of § 319.1 by adding the phrase ''and part 413 of subchapter E'' after ''part 317 of this subchapter''.

■ 16. Amend § 319.10 by revising paragraph (a) to read as follows:

§ 319.10 Requirements for substitute standardized meat food products named by use of an expressed nutrition content claim and a standardized term.

(a) *Description.* The meat food products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 413.313(d), for a standardized product defined in this part and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in part 413 of subchapter E. The expressed nutrient content claim shall comply with the requirements of § 413.313 and with the requirements of part 413, which define the particular nutrient content claim that is used. The meat food product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

* * * * *

■ 17. Amend paragraph (b) of § 319.10 by replacing the reference to ''§ 317.313(d)(1) and (2)'' with ''§ 413.313(d)(1) and (2)''.

PART 320—RECORDS, REGISTRATION, AND REPORTS

■ 18. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.

■ 19. Amend § 320.1 by revising paragraph (b)(8) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(8) Records of nutrition labeling as required by part 413 of subchapter E.

* * * * *

PART 327—IMPORTED PRODUCTS

■ 20. The authority citation for part 327 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 21. Amend § 327.15 by revising paragraph (b) to read as follows:

§ 327.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

* * * * *

(b) All labeling used with an outside container of foreign product must be approved in accordance with part 317 of this subchapter and parts 412 and 413 of subchapter E.

* * * * *

PART 362—VOLUNTARY POULTRY INSPECTION REGULATIONS

■ 22. The authority citation for part 362 continues to read as follows:

Authority: 7 U.S.C. 1622; 7 CFR 2.18(g) and (i) and 2.53.

■ 23. Amend paragraph (a) of § 362.2 by replacing ''Part 381'' with ''parts 381 and 413.''

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 24. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

§ 381.172 [Amended]

■ 25. Amend § 381.172 by revising paragraphs (a) and (b) to read as follows:

(a) *Description.* The poultry products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 413.313(d), for a standardized product defined in this subpart and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in this subpart. The expressed nutrient content claim shall comply with the requirements of § 413.313 and with the requirements in part 413 which define the particular nutrient content claim that is used. The poultry product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties, and shelf-life, of the poultry product shall be similar to those of the standardized poultry product produced under subpart P of this part. If there is a significant difference in a performance characteristic that materially limits the use of the product compared to the use of the standardized product defined in subpart P of this part, the label shall include a statement in accordance with § 413.313(d)(1) and (2) that informs the consumer of such differences (*e.g.,* if appropriate, ''not recommended for frozen storage'' or ''not suitable for roller grilling''). Deviations from the ingredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

* * * * *

■ 26. Amend § 381.175 by revising paragraph (b)(5) to read as follows:

§ 381.175 Required records to be kept.

* * * * *

(b) * * *

(5) Records of nutrition labeling as required by part 413.

* * * * *

Subpart Y—[Removed and Reserved]

■ 27. Remove and reserve subpart Y, consisting of §§ 381.400 through 381.500.

PART 412—LABEL APPROVAL

■ 28. The authority citation for part 412 continues to read as follows:

Authority: 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

■ 29. Amend § 412.2 by revising paragraph (a)(1) to read as follows:

§ 412.2 Approval of generic labels.

(a)(1) An official establishment, or an establishment certified under a foreign inspection system in accordance with part 327, or part 381, subpart T of this chapter, is authorized to use generically approved labels, as defined in paragraph (b) of this section, and thus is free to use such labels without submitting them to the Food Safety and Inspection Service for approval, provided the label, in accordance with this section, displays all mandatory features in a prominent manner in compliance with parts 317, 381, and 413 and is not otherwise false or misleading in any particular.

* * * * *

■ 30. Add part 413 to subchapter E to read as follows:

PART 413—NUTRITION LABELING

Sec.

413.1–413.299 [Reserved]
413.300 Nutrition labeling of meat, meat food products, and poultry products.
413.301 Required nutrition labeling of ground or chopped products.
413.302 Location of nutrition information.
413.303–413.307 [Reserved]
413.308 Labeling of products with number of servings.
413.309 Nutrition label content.
413.310–413.311 [Reserved]
413.312 Reference amounts customarily consumed per eating occasion.
413.313 Nutrient content claims; general principles.
413.314–413.343 [Reserved]
413.344 Identification of major cuts of meat products and poultry products.
413.345 Nutrition labeling of single-ingredient, raw meat or poultry products that are not ground or chopped products described in § 413.301.
413.346–413.353 [Reserved]
413.354 Nutrient content claims for ''good source,'' ''high,'' and ''more''.
413.355 [Reserved]
413.356 Nutrient content claims for ''light'' or ''lite''.
413.357–413.359 [Reserved]
413.360 Nutrient content claims for calorie content.
413.361 Nutrient content claims for the sodium content.
413.362 Nutrient content claims for fat, fatty acids, and cholesterol content.
413.363 Nutrient content claims for ''healthy''.
413.364–413.368 [Reserved]
413.369 Labeling applications for nutrient content claims.
413.370–413.379 [Reserved]
413.380 Label statements relating to usefulness in reducing or maintaining body weight.
413.381–413.399 [Reserved]
413.400 Exemptions from nutrition labeling.

Authority: 21 U.S.C. 451–470, 601–695; 7 CFR 2.7, 2.18, 2.53.

§ 413.300 Nutrition labeling of meat, meat food products, and poultry products.

(a) Nutrition labeling must be provided for all meat, meat food products, and poultry products intended for human consumption and offered for sale, except single-ingredient, raw meat or poultry products that are not ground or chopped meat or poultry products described in § 413.301 and are not major cuts of single-ingredient, raw meat or poultry products identified in § 413.344, unless the product is exempted under § 413.400. Nutrition labeling must be provided for the major cuts of single-ingredient, raw meat or poultry products identified in § 413.344, either in accordance with the provisions of § 413.309 for nutrition labels, or in accordance with the provisions of § 413.345 for point-of-purchase materials, except as exempted under § 413.400. For all other products for which nutrition labeling is required, including ground or chopped meat or poultry products described in § 413.301, nutrition labeling must be provided in accordance with the provisions of § 413.309, except as exempted under § 413.400.

(b) Nutrition labeling may be provided for single-ingredient, raw meat or poultry products that are not ground or chopped meat or poultry products described in § 413.301 and that are not major cuts of single-ingredient, raw meat or poultry products identified in § 413.344, either in accordance with the provisions of § 413.309 for nutrition labels, or in accordance with the provisions of § 413.345 for point-of-purchase materials.

§ 413.301 Required nutrition labeling of ground or chopped products.

(a) Nutrition labels must be provided for all ground or chopped products (livestock species or kind) and hamburger with or without added seasonings (including, but not limited to, ground beef, ground beef patties, ground sirloin, ground pork, ground lamb, ground chicken, ground turkey, and (kind) burgers) that are intended for human consumption and offered for sale, in accordance with the provisions of § 413.309, except as exempted under § 413.400.

(b) [Reserved]

§ 413.302 Location of nutrition information.

(a) Nutrition information on a label of a packaged product shall appear on the label's principal display panel or on the information panel, except as provided in paragraphs (b) and (c) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

(c) Products in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required information may use any alternate panel that can be readily seen by consumers for the nutrition information. In determining the sufficiency of available space for the nutrition information, the space needed for vignettes, designs, and other nonmandatory label information on the principal display panel may be considered.

§§ 413.303–413.307 [Reserved]

§ 413.308 Labeling of products with number of servings.

The label of any package of a product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 317.2(h)(10) or § 381.121(c)(7).

§ 413.309 Nutrition label content.

(a) All nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(b)(1) The term ''serving'' or ''serving size'' means an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the product. When the product is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(8), (b)(12), and (b)(14) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, serving size declared on a product label shall be determined from the ''Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply'' (Reference Amounts) that appear in § 413.312(b) using the procedures described in this paragraph (b). For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, ''for sale only through the _______program'' (fill in the blank with the name of the appropriate weight-control program, *e.g.,* Smith's Weight Control), on the principal display panel. However, the Reference Amounts in § 413.312(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrition claims.

(3) The declaration of nutrient and food component content shall be on the basis of the product ''as packaged'' for all products, except that single-ingredient, raw products that are not ground or chopped products described in § 413.301 may be declared on the basis of the product ''as consumed''. For single-ingredient, raw products that are not ground or chopped products described in § 413.301, if data are based on the product 'as consumed,' the data must be presented in accordance with § 413.345(d). In addition to the required declaration on the basis of ''as packaged'' for products other than single-ingredient, raw products that are not ground or chopped products described in § 413.301, the declaration may also be made on the basis of ''as consumed,'' provided that preparation and cooking instructions are clearly stated.

(4) For products in discrete units (*e.g.,* hot dogs, chicken wings, and individually packaged products within a multi-serving package), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (*e.g.,* beef fritters and barbecue sauce, chicken wings and barbecue sauce), the serving size shall be declared as follows:

(i) If a unit weighs 50 percent or less of the Reference Amount, the serving size shall be the number of whole units that most closely approximates the Reference Amount for the product category.

(ii) If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may declare one unit or two units as the serving size.

(iii) If a unit weighs 67 percent or more but less than 200 percent of the Reference Amount, the serving size shall be one unit.

(iv) If a unit weighs at least 200 percent and up to and including 300 percent of the applicable reference amount, the serving size shall be the amount that approximates the reference amount. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving size, the manufacturer shall provide a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per individual unit. The first column would be based on the serving size for the product and the second column would be based on the individual unit. The exemptions in paragraphs (b)(16)(i)(A), (B), and (C) of this section apply to this provision.

(v) For products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (*e.g.,* beef fritters and barbecue sauce, chicken wings and barbecue sauce), the serving size may be the number of discrete units represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product as determined in § 413.312(c).

(vi) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (*i.e.,* are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(vii) The serving size for products that naturally vary in size (*e.g.,* chicken breast, poultry parts, pork chop) may be the amount in ounces that most closely approximates the reference amount for the product category. Manufacturers shall adhere to the requirements in paragraph (b)(7)(iii) of this section for expressing the serving size in ounces.

(5) For products in large discrete units that are usually divided for consumption (*e.g.,* pizza, pan of poultry lasagna), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (*e.g.* pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually divided for consumption, the serving size shall be the fractional slice of the ready-to-eat product (*e.g.,* 1/8 quiche, 1/4 pizza) that most closely approximates the Reference Amount for the product category. The serving size may be the fraction of the package used to make the Reference Amount for the unprepared product determined in § 413.312(d) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount of the combined product determined in § 413.312(c). In expressing the fractional slice, manufacturers shall use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be generated by further division by 2 or 3.

(6) For nondiscrete bulk products (*e.g.,* whole roast beef, marinated beef tenderloin, large can of chili, whole turkey, turkey breast, ground poultry), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (*e.g.,* roast beef and gravy, turkey breast and gravy), the serving size shall be the amount in household measure that most closely approximates the Reference Amount for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the

combined product determined in § 413.312(c).

(7) For labeling purposes, the term ''common household measure'' or ''common household unit'' means cup, tablespoon, teaspoon, piece, slice, fraction (*e.g.,* ¼ pizza), ounce (oz), or other common household equipment used to package food products (*e.g.,* jar or tray). In expressing serving size in household measures, except as specified in paragraphs (b)(7)(iv), (v), and (vi) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in ¼- or ⅓-cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 2 tablespoons (tbsp), 1, 1⅓, 1½, or 1½ tbsp for quantities less than 2 tbsp but greater than or equal to 1 tbsp, and teaspoons in whole number of teaspoons for quantities less than 1 tbsp but greater than or equal to 1 teaspoon (tsp), and in ¼-tsp increments for quantities less than 1 tsp.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce increments most closely approximating the Reference Amount with rounding indicated by the use of the term ''about'' (*e.g.,* about 2.5 ounces).

(iv) A description of the individual container or package shall be used for single-serving containers and for individually packaged products within multi-serving containers (*e.g.,* can, box, package, meal, or dinner). A description of the individual unit shall be used for other products in discrete units (*e.g.,* chop, slice, link, or patty).

(v) For unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (*e.g.,* pizza kit), the fraction or portion of the package may be used.

(vi) For products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (*e.g.,* ham with a glaze packet, chicken wings with a glaze packet), the nutrition information may be declared for each component or as a composite. The serving size shall be provided in accordance with the provisions of paragraphs (b)(4), (b)(5), and (b)(6) of this section, whichever is applicable.

(vii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, and 1 oz in weight means 28 grams (g).

(viii) When a serving size, determined from the Reference Amount in § 413.312(b) and the procedures described in this section, falls exactly half way between two serving sizes (*e.g.,* 2.5 tbsp), manufacturers shall round the serving size up to the next incremental size.

(8) A product that is packaged and sold individually that contains less than 200 percent of the applicable reference amount must be considered to be a single-serving container, and the entire content of the product must be labeled as one serving. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving, for a product that is packaged and sold individually that contains more than 150 percent and less than 200 percent of the applicable reference amount, the Nutrition Facts label may voluntarily provide, to the left of the column that provides nutrition information per container (*i.e.,* per serving), an additional column that lists the quantitative amounts and percent Daily Values per common household measure that most closely approximates the reference amount.

(9) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(8) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams), except for single-serving containers.

(i) For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to paragraph (b)(11) of this section. However, if a manufacturer voluntarily provides the metric quantity on products that can be sold as single servings, then the numerical value provided as part of the serving size declaration must be identical to the metric quantity declaration provided as part of the net quantity of contents statement.

(ii) The gram or milliliter quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g (mL). The gram (mL) quantity between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL) and the g (mL) quantity less than 2 g (mL) should be expressed in 0.1-g (mL) increments.

(iii) In addition, serving size may be declared in ounce, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, *e.g.,* 1 slice (28 g/1 oz) for sliced bologna or for sliced chicken roll. The ounce quantity equivalent to the metric quantity should be expressed in 0.1-oz increments.

(iv) If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce.

(v) For products that only require the addition of water or another ingredient that contains insignificant amounts of nutrients in the amount added and that are prepared in such a way that there are no significant changes to the nutrient profile, the amount of the finished product may be declared in parentheses at the end of the serving size declaration (*e.g.,* ½ cup (120g) concentrated soup (makes 1 cup prepared)).

(10) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section.

(i) The number of servings must be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings must be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term ''about'' (*e.g.,* about 2 servings; about 3.5 servings).

(ii) When the serving size is required to be expressed on a drained solids basis and the number of servings varies because of a natural variation in unit size (*e.g.,* pickled pigs feet), the manufacturer may state the typical number of servings per container (*e.g.,* usually 5 servings).

(iii) For random weight products, manufacturers may declare ''varied'' for the number of servings per container provided the nutrition information is based on the reference amount expressed in the appropriate household measure based on the hierarchy described in paragraph (b)(7) of this section. Random weight products are foods such as meat roasts or whole turkeys that are sold as random weights that vary in size, such that the net contents for different containers would vary. The manufacturer may provide the typical number of servings in parentheses following the ''varied'' statement (*e.g.,* varied (approximately 8 servings per pound)).

(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (*i.e.,* are labeled appropriately for individual sale as single-serving containers), the number of servings shall be the number of individual packages within the total package.

(v) For packages containing several individually packaged multi-serving units, the number of servings shall be determined by multiplying the number of individual multi-serving units in the total package by the number of servings in each individual unit. The declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw products that are not ground or chopped products described in § 413.301, including those that have been previously frozen.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of single-ingredient, raw products that are not ground or chopped products described in § 413.301 and products that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed. Declaration of the nutrient and food component content of products that are packed in liquid which is not customarily consumed shall be based on the drained solids.

(12) The serving size for meal-type products and main-dish products as defined in § 413.313(l) and § 413.313(m) in single-serving containers will be the entire edible content of the package. Serving size for meal-type products and main-dish products in multi-serve containers will be based on the reference amount applicable to the product in § 413.312(b) if the product is listed in § 413.312(b). Serving size for meal-type products and main-dish products in multi-serve containers that are not listed in § 413.312(b) will be based on the reference amount according to § 413.312(c), (d), and (e).

(13) Another column of figures may be used to declare the nutrient and food component information in the same format as required by § 413.309(e).

(i) Per 100 grams, 100 milliliters, or 1 ounce of the product as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in is more than one unit.

(14) If a product consists of assortments of meat, meat food products, or poultry products (*e.g.,* variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(15) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare nutrition information on the basis of the product as consumed in the format required in paragraph (e) of this section (*e.g.,* a cream soup mix may be labeled with the percent Daily Value and quantitative amounts for the dry mix alone (per serving), and the percent Daily Value and quantitative amounts for the serving of the final soup when prepared (*e.g.,* per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided,* that the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(16)(i) Products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 percent of the applicable reference amount must provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values for the entire package, as well as a column listing the quantitative amounts and percent Daily Values for a serving that is less than the entire package (*i.e.,* the serving size derived from the reference amount). The first column would be based on the serving size for the product and the second column would be based on the entire contents of the package.

(A) This provision does not apply to products that meet the requirements to use the tabular display for small packages in paragraph (g)(1)(i)(A) of this section or to products that meet the requirements to use the linear format in paragraph (g)(1)(i)(B) of this section.

(B) This provision does not apply to products that require further preparation and provide an additional column of nutrition information under paragraph (e) of this section, to products that are commonly consumed in combination with another food and provide an additional column of nutrition information under paragraph (e) of this section, to products that provide an additional column of nutrition information for two or more groups for which RDIs are established (*e.g.,* both infants through 12 months and children 1 through 3 years of age), or to random-weight products covered under paragraph (b)(10)(iii) of this section.

(ii) When a nutrient content claim or health claim is made on the label of a product that uses a dual column in accordance with paragraph (b) of this section, the claim must be followed by a statement that sets forth the basis on which the claim is made, except that the statement is not required for products when the nutrient that is the subject of the claim meets the criteria for the claim based on the reference amount for the product and the entire container or the unit amount. When a nutrient content claim is made, the statement must express that the claim refers to the amount of the nutrient per serving (*e.g.,* ''good source of calcium per serving'' or ''per X [insert unit] serving'' or per reference amount (*e.g.,* ''good source of calcium per [insert reference amount (*e.g.,* per 8 ounces)]), as required based on § 413.313(p). When a health claim is made, the statement shall be ''A serving of ____ ounces of this product conforms to such a diet.''

(c) The declaration of nutrition information on the label and in labeling of a meat or meat food product or poultry product shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of the amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraphs (f) or (g) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraphs (d) or (e) of this section.

(1) ''Calories, total,'' ''Total calories,'' or ''Calories'': A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parenthesis immediately following the statement of the caloric content.

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (*i.e.,* before rounding) of food components (*e.g.,* fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (*i.e.,* the Atwater method) given in Table

13, USDA Handbook No. 74 (slightly revised, 1973);

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9–11;

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate (less the amount of non-digestible carbohydrates and sugar alcohols), and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9–11. A general factor of 2 calories per gram for soluble non-digestible carbohydrates shall be used. The general factors for caloric value of sugar alcohols provided in paragraph (c)(1)(i)(F) of this section shall be used;

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of 21 CFR, or by other means, as appropriate;

(E) Using bomb calorimetry data subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised, 1973) p. 10; or

(F) Using the following general factors for caloric value of sugar alcohols: Isomalt—2.0 calories per gram, lactitol—2.0 calories per gram, xylitol—2.4 calories per gram, maltitol—2.1 calories per gram, sorbitol—2.6 calories per gram, hydrogenated starch hydrolysates—3.0 calories per gram, mannitol—1.6 calories per gram, and erythritol—0 calories per gram.

(ii) ''Calories from saturated fat'' or ''Calories from saturated'' (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section per serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories as provided in paragraph (d)(5) of this section.

(2) ''Fat, total'' or ''Total fat'': A statement of the number of grams of total fat per serving defined as total lipid fatty acids and expressed as triglycerides where fatty acids are aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group. Amounts shall be expressed to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) ''Saturated fat'' or ''Saturated'': A statement of the number of grams of saturated fat per serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat per serving if no claims are made about fat, fatty acid, or cholesterol content, and if ''calories from saturated fat'' is not declared. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(A) [Reserved]

(B) [Reserved]

(ii) ''*Trans* Fat'' or ''*Trans*'': A statement of the number of grams of *trans* fat in a serving, defined as the sum of all unsaturated fatty acids that contain one or more isolated (*i.e.,* nonconjugated) double bonds in a *trans* configuration. The word ''*trans*'' may be italicized to indicate its Latin origin. *Trans* fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero.

(iii) ''Polyunsaturated fat'' or ''Polyunsaturated'' (VOLUNTARY): A statement of the number of grams of polyunsaturated fat per serving defined as cis, cis-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 413.362(b)(1) for a claim for ''fat free,'' label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iv) ''Monounsaturated fat'' or ''Monounsaturated'' (VOLUNTARY): A statement of the number of grams of monounsaturated fat per serving defined as cis-monounsaturated fatty acids may be declared voluntarily, except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 413.362(b)(1) for a claim for ''fat free,'' label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) ''Cholesterol'': A statement of the cholesterol content per serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams of cholesterol per serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. If the product contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as ''less than 5 milligrams.''

(4) ''Sodium'': A statement of the number of milligrams of sodium per serving expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) ''Fluoride'' (VOLUNTARY): A statement of the number of milligrams of fluoride in a specified serving of food may be declared voluntarily, except that when a claim is made about fluoride content, label declaration shall be required. Fluoride content shall be expressed as zero when the serving contains less than 0.1 milligrams of fluoride, to the nearest 0.1-milligram increment when the serving contains less than or equal to 0.8 milligrams of fluoride, and the nearest 0.2 milligram-increment when a serving contains more than 0.8 milligrams of fluoride.

(6) ''Carbohydrate, total'' or ''Total carbohydrate'': A statement of the number of grams of total carbohydrate per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, or, if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. This calculation method is described in USDA Handbook No. 74 (slightly revised, 1973), pp. 2–3.

(i) ''Dietary fiber'': A statement of the number of grams of total dietary fiber per serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required, or, alternatively, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required, and as a result not declared, the statement ''Not a significant source of dietary fiber'' shall be placed at the bottom of the table of nutrient values in the same type size. The following isolated or synthetic non-digestible carbohydrate(s) have been determined by FDA to have physiological effects that are beneficial to human health and, therefore, shall be included in the calculation of the amount of dietary fiber: [beta]-glucan soluble fiber (as described in 21 CFR 101.81(c)(2)(ii)(A)), psyllium husk (as described in 21 CFR 101.81(c)(2)(ii)(A)(6)), cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. The manufacturer must make and keep records in accordance with paragraphs (h) of this section to verify the declared amount of dietary fiber in the label and labeling of food when a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food.

(A) ''Soluble fiber'' (VOLUNTARY): A statement of the number of grams of soluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must maintain records in accordance with paragraph (h)(8) of this section to verify the declared amount of soluble fiber in the label and labeling of food when a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) ''Insoluble fiber'' (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must make and keep records in accordance with paragraph (h)(8) of this section to verify the declared amount of insoluble fiber in the label and labeling of food when a mixture of insoluble and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) ''Total Sugars'': A statement of the number of grams of sugars per serving, except that the label declaration of sugars content is not required for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Total sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Total sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) ''Added Sugars'': A statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. If a statement of the added sugars content is not required and, as a result, not declared, the statement ''Not a significant source of added sugars'' shall be placed at the bottom of the table of nutrient values in the same type size. Added sugars are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. Added sugars content shall be indented under Total Sugars and shall be prefaced with the word ''Includes'' followed by the amount (in grams) ''Added Sugars'' (''Includes 'X' g Added Sugars''). It shall be expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When a mixture of naturally occurring and added sugars is present in the food, and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation and/or non-enzymatic browning, the manufacturer must maintain records in accordance with paragraph (h)(8) of this section to verify the declared amount of added sugars in the label and labeling of food.

(iv) ''Sugar alcohol'' (VOLUNTARY): A statement of the number of grams of sugar alcohols per serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol, total sugars, or added sugars when sugar alcohols are present in the product, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (*e.g.,* mannitol or xylitol) or is generally recognized as safe (*e.g.,* sorbitol). In lieu of the term ''sugar alcohol,'' the name of the specific sugar alcohol (*e.g.,* ''xylitol'') present in the product may be used in the nutrition label, provided that only one sugar alcohol is present in the product. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) ''Protein'': A statement of the number of grams of protein per serving, expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in products represented or

purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a product represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement ''not a significant source of protein,'' or a listing aligned under the column headed ''%Daily Value'' of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as percent of Daily Value. When the protein quality in a product as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a product represented or purported to be specifically for infants through 12 months, the statement ''not a significant source of protein'' shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with § 413.309(h), except when the procedure for a specific food requires a specific factor other than 6.25, that factor shall be used.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be specifically for infants through 12 months of age or children 1 through 3 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed ''%Daily Value,'' and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the product is represented or purported to be specifically for infants through 12 months and the protein quality value is less than 40 percent of the reference standard.

(ii) The ''corrected amount of protein (grams) per serving'' for products represented or purported to be for adults and children 1 or more years of age is equal to the actual amount of protein (grams) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in ''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' except that when official AOAC procedures described in paragraph (c)(7) of this section require a specific factor other than 6.25, that specific factor shall be used.

For products represented or purported to be specifically for infants through 12 months, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject product's protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, a value of 11 grams of protein shall be the RDI for infants through 12 months, a value of 13 grams shall be the DRV for children 1 through 3 years of age, and a value of 71 grams of protein shall be the RDI for pregnant women and lactating women.

(8) Vitamins and minerals: The requirements related to including a statement of the amount per serving of vitamins and minerals are described in this paragraph (c)(8).

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d) through (g) of this section, products represented or purported to be specifically for infants through 12 months, children 1 through 3 years, pregnant women and lactating women shall use the RDIs that are specified for the intended group. For products represented or purported to be specifically for both infants through 12 months and children 1 through 3 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants through 12 months and for children 1 through 3 years of age. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. The percent Daily Value based on the RDI values for pregnant women and lactating women shall be declared on food represented or purported to be specifically for pregnant women and lactating women. All other products shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a quantitative amount by weight and percent of the RDI shall include vitamin D, calcium, iron, and potassium in that order, for infants through 12 months, children 1 through 3 years of age, pregnant women, lactating women, and adults and children 4 or more years of age. The declaration of folic acid shall be included as a quantitative amount by weight when added or a claim is made about the nutrient. The declaration of vitamins and minerals in a food as a quantitative amount by weight and percent of the RDI, may include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section. The declaration of vitamins and minerals shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section as a statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as a percent of the Daily Value, when they are added, or when a claim is made about them, unless otherwise stated as quantitative amount by weight and percent of the Daily Value. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling and the vitamins and minerals are:

(A) Required or permitted in a standardized food (*e.g.,* thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (*i.e.,* component) in another product; or

(B) Included in a product solely for technological purposes and declared only in the ingredients statement. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Quantitative amounts and percentages of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients) or ''Contains <2 percent of the Daily Value of this (these) nutrients.'' Alternatively, except as provided for in paragraph (f) of this section, if vitamin D, calcium, iron, or potassium is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement ''Not a significant source of ____ (listing the vitamins or minerals omitted)'' is placed at the bottom of the table of nutrient values. Either statement shall be in the same type size as nutrients that are indented. The quantitative amounts of vitamins and minerals, excluding sodium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in paragraph (c)(8)(iv) of this section, except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (*e.g.,* the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram).

(iv) The following RDIs, nomenclature, and units of measure are established for the following vitamins and minerals which are essential in human nutrition:

Nutrient	Unit of measure	RDI			
		Adults and children ≥4 years	Infants[1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin A	Micrograms RAE[2] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Vitamin D	Micrograms (mcg)[3]	20	10	15	15
Vitamin E	Milligrams (mg)[4]	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE[5] (mg)	16	4	6	18
Vitamin B_6	Milligrams (mg)	1.7	0.3	0.5	2.0
Folate[6]	Micrograms DFE[7] (mcg)	400	80	150	600
Vitamin B_{12}	Micrograms (mcg)	2.4	0.5	0.9	2.8
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorus	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1,500	2,300
Potassium	Milligrams (mg)	*4,700*	*700*	*3,000*	*5,100*
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	*N/A*	*11*	*N/A*	[8] *71*

[1] RDIs are based on dietary reference intake recommendations for infants through 12 months of age.
[2] RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 micrograms supplemental β-carotene, 12 micrograms β-carotene, or 24 micrograms α-carotene, or 24 micrograms β-cryptoxanthin.
[3] The amount of vitamin D may, but is not required to, be expressed in international units (IU), in additional to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.
[4] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*-α-tocopherol.
[5] NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan.
[6] ''Folate'' and ''Folic Acid'' must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.
[7] DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally-occurring folate = 0.6 mcg folic acid.
[8] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women.

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

Calories—Energy

Vitamin C—Ascorbic acid

Thiamin—Vitamin B_1

Riboflavin—Vitamin B_2

(vi) A statement of the percent of vitamin A that is present as *beta*-carotene may be declared voluntarily. When the vitamins and minerals are listed in a single column, the statement shall be indented under the information on vitamin A. When vitamins and minerals are arrayed horizontally, the statement of percent shall be presented in parenthesis following the declaration of vitamin A and the percent of Daily Value of vitamin A in the product (*e.g.,* ''Percent Daily Value: Vitamin A 50 (90 percent as beta-carotene)''). When declared, the percentages shall be expressed in the same increments as are provided for vitamins and minerals in paragraph (c)(8)(iii) of this section.

(vii) When the amount of folate is declared in the labeling of a product the nutrient name ''folate'' shall be listed for products containing folate (natural folate, and/or synthetic folate), folic acid, or a mixture of folate and folic acid. The name of the synthetic form of the nutrient ''folic acid'', when added or a claim is made about the nutrient, shall be included in parentheses after this declaration with the amount of folic acid. The declaration must be folate in mcg DFE (when expressed as a quantitative amount by weight) and the percent Daily Value based on folate in mcg DFE, or may be expressed as folate and the percent DV based on folate in mcg DFE. When declared, folic acid must be in parentheses, mcg of folic acid as shown in paragraph (d)(12) of this section in the display that illustrates voluntary declaration of nutrition information.

(9) The following DRVs, nomenclature, and units of measure are established for the following food components:

Food component	Unit of measurement	DRV			
		Adults and children ≥4 years	Infants through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Fat	Grams (g)	[1] 78	30	[2] 39	[1] 78
Saturated fatty acids	Grams (g)	[1] 20	N/A	[2] 10	[1] 20
Cholesterol	Milligrams (mg)	300	N/A	300	300
Total carbohydrate	Grams (g)	[1] 275	95	[2] 150	[1] 275
Sodium	Milligrams (mg)	2,300	N/A	1,500	2,300
Dietary fiber	Grams (g)	[1] 28	N/A	[2] 14	[1] 28
Protein	Grams (g)	[1] 50	N/A	[2] 13	N/A
Added Sugars	Grams (g)	[1] 50	N/A	[2] 25	[1] 50

[1] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women.

[2] Based on the reference caloric intake of 1,000 calories for children 1 through 3 years of age.

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on products in the following format, as shown in paragraph (d)(12) of this section, except on foods where the horizontal display is permitted as provided for in paragraph (d)(11) of this section, on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those food products on which the simplified format is permitted to be used as provided for in paragraph (f) of this section, on foods for infants through 12 months of age and children 1 through 3 years of age as provided for in § 413.400(c), and on foods in small or intermediate-sized packages as provided for in paragraph (g) of this section.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (*i.e.,* space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section, and

(D) Letters should never touch.

(iii) Information required in paragraphs (d)(7) and (d)(8) of this section shall be in type size no smaller than 8 point. Information required in paragraph (d)(5) of this section for the ''Calories'' declaration shall be highlighted in bold or extra bold and shall be in a type size no smaller than 16 point except the type size for this information required in the tabular displays as shown in paragraphs (d)(11)(iii), (e)(6)(ii), and (g)(1)(i)(A) of this section, and the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section shall be in a type size no smaller than 10 point. The numeric amount for the information required in paragraph (d)(5) of this section shall also be highlighted in bold or extra bold type and shall be in a type size no smaller than 22 point, except the type size for this information required for the tabular display for small packages as shown in paragraph (g)(1)(i)(A) of this section, and for the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section no smaller than 14 point. The information required in paragraph (d)(9) of this section shall be in a type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall be in a type size no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(3)(ii), (d)(4), and (d)(6) of this section (*i.e.,* ''Nutrition Facts,'' ''Serving Size,'' ''Amount per serving,'' and ''% Daily Value*''), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (*i.e.,* ''Calories,'' ''Total Fat,'' ''Cholesterol,'' ''Sodium,'' ''Total Carbohydrate'' and ''Protein''), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted in bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate ''Nutrition Facts'' from the servings per container statement required in paragraph (d)(3)(i) of this section, and shall separate each nutrient and its corresponding percent of Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent of Daily Value above and below it, as shown in paragraph (d)(12) of this section.

(2) The information shall be presented under the identifying heading of ''Nutrition Facts'' which shall be set in a type size no smaller than all other print size in the nutrition label except for the numerical information for ''Calories'' required in paragraph (d)(5) of this section, and except for labels presented according to the format provided for in paragraphs (d)(11)(iii),

(d)(13)(ii), (e)(6)(ii), (g)(1)(i)(A) and (g)(1)(i)(B) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section, as shown in paragraph (d)(12) of this section.

(3) Information on servings per container and serving size shall immediately follow the heading as shown in paragraph (d)(12) of this section. Such information shall include:

(i) ''____ servings per container'': The number of servings per container, except that this statement is not required on single-serving containers as defined in paragraph (b)(8) of this section or on single-ingredient, raw products that are not ground or chopped products described in § 413.301. The information required in this paragraph shall be located immediately after the ''Nutrition Facts'' heading and shall be in a type size no smaller than 10 point, except the type size for this information shall be no smaller than 9 point in the tabular display for small packages as shown in paragraph (g)(1)(i)(A) of this section and the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section. For the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section, the actual number of servings may be listed after the servings per container declaration.

(ii) ''Serving size'': A statement of the serving size as specified in paragraph (b)(9) of this section shall immediately follow the ''____ servings per container'' declaration. The information required in this paragraph shall be highlighted in bold or extra bold and be in a type size no smaller than 10 point except the type size shall be no smaller than 9 point for this information in the tabular displays as shown in paragraphs (d)(11) and (e)(6)(ii) of this section, the tabular display for small packages as shown in (g)(1)(i)(A) of this section, and the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section. The serving size amount must be right justified if adequate space is available. If the ''Serving size'' declaration does not fit in the allocated space a type size of no smaller than 8 point may be used on packages of any size.

(4) A subheading ''Amount per serving'' shall be separated from serving size information by a bar as shown in paragraph (d)(12) of this section, except this information is not required for the dual column formats shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section. ''Per____'' (*e.g.,* per ½ a burrito)'' is required for dual column formats.

(5) Information on calories shall immediately follow the subheading ''Amount per serving'' and shall be declared in one line. If ''Calories from saturated fat'' is declared, it shall be indented under ''Calories'' and shall be in a type size no smaller than 8 point.

(6) The column heading ''% Daily Value,'' followed by an asterisk (*e.g.,* ''% Daily Value*''), shall be separated from information on calories by a bar as shown in paragraph (d)(12) of this section. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column headings ''Percent Daily Value,'' ''Percent DV,'' or ''% DV'' may be substituted for ''% Daily Value.''

(7) Except as provided for in paragraph (g)(1)(i)(B) of this section, and except as permitted by § 413.400(d)(2), nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except for folic acid in conventional food and voluntarily declared vitamins and minerals expressed as a statement of the amount per serving calculated as a percent of the RDI and expressed as a percent Daily Value, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a ''g'' for grams or ''mg'' for milligrams, or ''mcg'' for micrograms as shown in paragraph (d)(12) of this section. The symbol ''<'' may be used in place of ''less than''.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading ''% Daily Value'' established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (*i.e.,* before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (*i.e.,* %).

(8) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and shall be arrayed vertically as shown in paragraph (d)(12) of this section (*e.g.,* Vitamin D 2 mcg 10%, Calcium 260 mg 20%, Iron 8 mg 45%, Potassium 235 mg 6%) or may be listed horizontally. When listed horizontally in two columns, vitamin D and calcium should be listed on the first line and iron and potassium should be listed on the second line as shown in paragraph (d)(12) of this section in the side-by-side display. When more than four vitamins and minerals are declared voluntarily as shown in paragraph (d)(12) of this section in the label which illustrates the mandatory plus voluntary provisions of paragraph (d) of this section, they may be declared vertically with percentage listed under the column headed ''% Daily Value.''

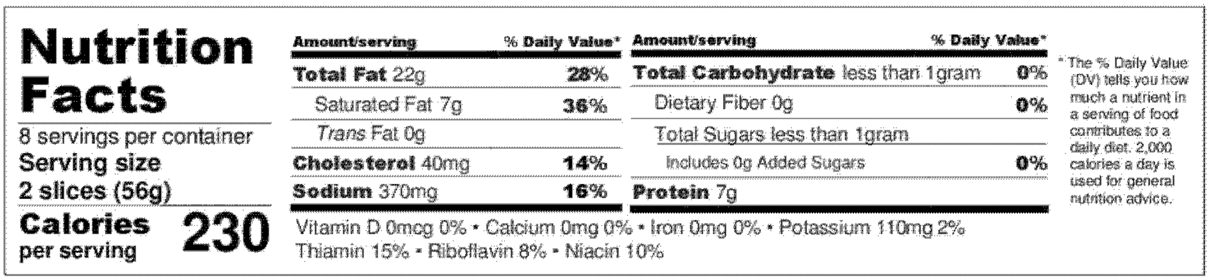
(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from the list by a bar, except that the footnote may be omitted from foods that can use the terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietarily insignificant source of calories'' on the label or in the labeling of foods as defined in 9 CFR 413.360(b). The first sentence of the footnote: ''The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet'' may be used on foods than can use the terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietarily insignificant source of calories'' on the label or in the labeling of foods as defined in 9 CFR 413.360(b). The footnote shall state: ''*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.'' If the food product is represented or purported to be for children 1 through 3 years of age, the second sentence of the footnote shall substitute ''1,000 calories'' for ''2,000 calories''.

(10) Caloric conversion information on a per gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph (d)(9), separated from that information by a hairline. This information may be presented horizontally (*i.e.* ''Calories per gram: Fat 9, Carbohydrate 4, Protein 4'') or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraph (d)(9) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of potassium is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the nutrients and the percent of DV information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (*i.e.,* approximately 3 inches) to accommodate the required components of the nutrition label up to and including the mandatory declaration of potassium, the nutrition label may be presented in a horizontal display as shown in the following sample label.



(12) The following sample labels illustrate the mandatory provisions and mandatory plus voluntary provisions of paragraph (d) of this section and the side-by-side display:

Nutrition Facts

8 servings per container
Serving size **1 cup (245g)**

Amount per serving	
Calories	**60**
	% Daily Value*
Total Fat 1.5g	**2%**
Saturated Fat 0.5g	**0%**
Trans Fat 0g	
Cholesterol 10mg	**4%**
Sodium 560mg	**24%**
Total Carbohydrate 9g	**3%**
Dietary Fiber 0g	**0%**
Total Sugars less than 1gram	
Includes 0g Added Sugars	**0%**
Protein 2g	
Vitamin D 0mcg	0%
Calcium 0mcg	0%
Iron 0.5mcg	2%
Potassium 0mcg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to daily diet. 2,000 calories a day is used for general nutrition advice.

Nutrition Facts

17 servings per container
Serving size **3/4 cup (28g)**

Amount per serving	
Calories	**140**
	% Daily Value*
Total Fat 1.5g	**2%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Polyunsaturated Fat 0.5g	
Monounsaturated Fat 0.5g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 22g	**8%**
Dietary Fiber 2g	**7%**
Soluble Fiber <1g	
Insoluble Fiber 1g	
Total Sugars 9g	
Includes 8g Added Sugars	**16%**
Protein 9g	**18%**
Vitamin D 2mcg (80 IU)	10%
Calcium 130mg	10%
Iron 4.5mg	25%
Potassium 115mg	2%
Vitamin A 90mcg	10%
Vitamin C 9mg	10%
Thiamin 0.3mg	25%
Riboflavin 0.3mg	25%
Niacin 4mg	25%
Vitamin B_6 0.4mg	25%
Folate 200mcg DFE (120mcg folic acid)	50%
Vitamin B_{12} 0.6mcg	25%
Phosphorus 100mg	8%
Magnesium 25mg	6%
Zinc 3mg	25%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(13)(i) Nutrition labeling on the outer label of packages of products that contain two or more products in the same packages (*e.g.,* variety packs) or of packages that are used interchangeably for the same type of food (*e.g.,* meat salad containers, poultry salad containers) may use an aggregate display.

(ii) Aggregate displays shall comply with format requirements of paragraph (d) of this section to the maximum extent possible, except that the identity of each food shall be specified to the right of the ''Nutrition Facts'' heading, and both the quantitative amount by weight (*i.e.,* g/mg/mcg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food. The following sample label illustrates an aggregate display.

Nutrition Facts	**Smoked Beef Sausage**		**Smoked Pork Sausage**		**Smoked Turkey Sausage**	
8 servings per container **Serving size 1 link**	(84g		(84g)		(84g)	
Amount per serving **Calories**	**340**		**260**		**130**	
	% Daily Value*		**% Daily Value***		**% Daily Value***	
Total Fat	32g	**41%**	24g	**31%**	7g	**9%**
Saturated Fat	13g	**65%**	8g	**40%**	3g	**15%**
Trans Fat	0.5g		0g		0g	
Cholesterol	70mg	**23%**	50mg	**17%**	45mg	**15%**
Sodium	700mg	**30%**	700mg	**30%**	1000mg	**43%**
Total Carbohydrate	0g	**0%**	0g	**0%**	0g	**0%**
Dietary Fiber	0g	**0%**	0g	**0%**	0g	**0%**
Total Sugars	0g		1g		3g	
Includes Added Sugars	0g	**0%**	1g	**2%**	3g	**6%**
Protein	13g		10g		13g	
Vitamin D	0.5mc	2%	0.9mcg	4%	0mcg	0%
Calcium	0mg	0%	0mg	0%	0mg	0%
Iron	1.3mg	8%	0.5mg	2%	8mg	45%
Potassium	200mg	4%	410mg	8%	170mg	4%
Vitamin A		2%		0%		4%
Vitamin C		0%		0%		2%
Thiamin		0%		15%		8%
Riboflavin		8%		15%		8%
Niacin		15%		15%		20%
Vitamin B_6		10%		10%		20%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice

(14) When nutrition labeling appears in a second language, the nutrition information may be presented in a separate nutrition label for each language or in one nutrition label with the information in the second language following that in English. Numeric characters that are identical in both languages need not be repeated (*e.g.,* ''Protein/Proteinas 2 g''). All required information must be included in both languages.

(e) Nutrition information may be presented for two or more forms of the same product (*e.g.,* both ''as purchased'' and ''as prepared'') or for common combinations of foods as provided for in paragraph (b) of this section, for different units (*e.g.,* per nugget or per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDIs are established (*e.g.,* both infants through 12 months of age and children 1 through 3 years of age) as shown in paragraph (c)(8)(i) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the serving size information there shall be two or more column headings accurately describing the amount per serving size of the form of the same product (*e.g.,* ''raw'' and ''roasted''), the combinations of foods, the units, or the RDI groups that are being declared as shown in paragraph (e)(5) of this section.

(2) The quantitative information by weight as required in paragraph (d)(7)(i) and the information required in (d)(7)(ii) of this section shall be presented for the form of the product as packaged and for any other form of the product (*e.g.,* ''as prepared'' or combined with another ingredient as shown in paragraph (e)(5) of this section) but may be on the basis of 'as consumed' for single-ingredient, raw products that are not ground or chopped products described in § 413.301, and according to the label serving size based on the Reference Amount in § 413.312(b).

(3) When the dual labeling is presented for two or more forms of the same food, for combinations of food, for different units, or for two or more groups for which RDIs are established, quantitative information by weight and the percent Daily Value shall be presented in two columns and the columns shall be separated by vertical lines as shown in paragraph (e)(5) of this section.

(4) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, potassium as shown in paragraph (e)(5) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

Nutrition Facts

8 servings per container
Serving Size 4oz (112g, about 84g braised)

	Per raw portion		Per braised portion	
Calories	**220**		**210**	
		% DV*		% DV*
Total Fat	17g	**22%**	16g	**21%**
Saturated Fat	5g	**25%**	5g	**25%**
Trans Fat	0g		0g	
Cholesterol	60mg	**20%**	80mg	**27%**
Sodium	1360mg	**59%**	830mg	**36%**
Total Carb.	0g	**0%**	0g	**0%**
Dietary Fiber	0g	**0%**	0g	**0%**
Total Sugars	0g		0g	
Incl. Added Sugars	0g	**0%**	0g	**0%**
Protein	17g		15g	
Vitamin D	0mcg	0%	0mcg	0%
Calcium	0mg	0%	0mg	0%
Iron	1.9mg	10%	1.6mg	8%
Potassium	330mg	8%	120mg	2%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice

(6) When dual labeling is presented for a food on a per serving basis and per container basis as required in paragraph (b)(16)(i) of this section or on a per serving basis and per unit basis as required in paragraph (b)(4)(iv) of this section, the quantitative information by weight as required in (d)(7)(i) and the percent Daily Value as required in paragraph (d)(7)(ii) shall be presented in two columns, and the columns shall be separated by vertical lines as shown in the displays in paragraph (e)(6)(i) of this section.

(i) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, and potassium as shown in the following sample labels.

Nutrition Facts

12 servings per container
Serving Size 1/2 burrito (139g)

	Per 1/2 burrito		Per 1 burrito	
Calories	**330**		**660**	
		% DV*		% DV*
Total Fat	13g	**17%**	27g	**35%**
Saturated Fat	4g	**20%**	8g	**40%**
Trans Fat	0g		0.5g	
Cholesterol	10mg	**3%**	20mg	**7%**
Sodium	820mg	**36%**	1630mg	**71%**
Total Carb.	43g	**16%**	86g	**43%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	4g		8g	
Incl. Added Sugars	1g	**2%**	2g	**4%**
Protein	10g		20g	
Vitamin D	0mcg	0%	0mcg	0%
Calcium	40mg	4%	80mg	6%
Iron	2mg	10%	4mg	20%
Potassium	190mg	4%	380mg	8%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice

Nutrition Facts

About 2 servings per container
Serving Size 1 cup (243g)

	Per serving		Per container	
Calories	**100**		**210**	
		% DV*		% DV*
Total Fat	3g	**4%**	6g	**8%**
Saturated Fat	1.5g	**8%**	3g	**15%**
Trans Fat	0g		0g	
Cholesterol	12mg	**4%**	26mg	**9%**
Sodium	740mg	**32%**	1620mg	**70%**
Total Carb.	10g	**4%**	21g	**8%**
Dietary Fiber	2g	**7%**	4g	**14%**
Total Sugars	1g		2g	
Incl. Added Sugars	0g	**0%**	0g	**0%**
Protein	8g		16g	
Vitamin D	0mcg	**0%**	0mcg	0%
Calcium	27mg	**2%**	58mg	4%
Iron	0.9mg	**6%**	1.9mg	10%
Potassium	280mg	**6%**	620mg	15%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice

(ii) The following sample label illustrates the provisions of paragraphs (b)(4)(iv) and (b)(16)(i) of this section for labels that use the dual column format in the horizontal display.

Nutrition Facts

2 servings per container
Serving size 1 cup (255g)

Calories
220 per serving | **440** per container

	Per serving	% DV*	Per container	% DV*		Per serving	% DV*	Per container	% DV*
Total Fat	5g	**6%**	10g	**13%**	**Total Carb.**	35g	**13%**	70g	**25%**
Saturated Fat	2g	**10%**	4g	**20%**	Dietary Fiber	6g	**21%**	12g	**43%**
Trans Fat	0g		0g		Total Sugars	7g		14g	
Cholesterol	15mg	**5%**	30mg	**10%**	Incl. Added Sugars	4g	**8%**	8g	**16%**
Sodium	240mg	**10%**	480mg	**21%**	**Protein**	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%	Iron	1mg	6%	2mg	10%
Calcium	200mg	15%	400mg	30%	Potassium	470mg	10%	940mg	20%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(f)(1) The declaration of nutrition information may be presented in the simplified format as set forth herein when any required nutrients, other than the core nutrients (*i.e.,* calories, total fat, sodium, total carbohydrate, and protein), are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, total sugars, added sugars, and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, sodium, total carbohydrate, and protein;

(ii) Any of the following that are present in more than insignificant amounts: saturated fat, *trans* fat, cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and potassium; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added in fortified or fabricated foods.

(3) Other nutrients that are naturally present in the product in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) Any required nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the columnar listing, provided that the following statement is included at the bottom of the nutrition label, ''Not a significant source of ____.'' The blank shall be filled in with the appropriate nutrient or food component. Alternatively, amounts of vitamins and minerals present in insignificant amounts may be declared by the use of an asterisk (or symbol) that is placed at the bottom of the table of nutrient values and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).''

(5) Except as provided for in paragraph (g) of this section and in § 413.400(c) and (d), nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required, and an asterisk shall be placed at the bottom of the label followed by the statement ''%DV = %Daily Value'' when ''Daily Value'' is not spelled out in the heading, as shown in the following example that illustrates the simplified display

Nutrition Facts

64 servings per container
Serving size 1 tbsp (14g)

Amount per serving
Calories 130

	% DV*
Total Fat 14g	**18%**
Saturated Fat 2g	**10%**
Trans Fat 2g	
Polyunsaturated Fat 4g	
Monounsaturated Fat 6g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and potassium

* %DV = %Daily Value

(g) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) of this section and § 413.302(a) by one or more of the following means:

(1)(i) Presenting the required nutrition information in a tabular or linear fashion, rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the package shape or size will not accommodate a tabular display.

(A) The following sample label illustrates the tabular display for small packages.

Nutrition Facts	Amount/serving	% DV*	Amount/serving	% DV*
5 servings per container	**Total Fat** 2g	**3%**	**Total Carb.** 15g	**5%**
Serving size 1/6 cup (28g)	Sat. Fat 1g	**5%**	Fiber 0g	**0%**
	Trans Fat 0.5g		Total Sugars 14g	
	Cholesterol 10mg	**3%**	Incl. 13g Added Sugars	**26%**
Calories per serving 90	**Sodium** 200mg	**9%**	**Protein** 3g	
	Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%			

(B) The following sample label illustrates the linear display.

Nutrition Facts Serv. size: 1 package,
Amount per serving: **Calories 140, Total Fat** 12g (15% DV), Sat. Fat 5g (25% DV), *Trans Fat* 0g, **Cholest.** 30mg (10% DV), **Sodium** 500mg (22% DV), **Total Carb.** 0g (0% DV), Fiber 0g (0% DV), Total Sugars 0g (Incl. 0g Added Sugars, 0% DV), **Protein** 6g, Vit. D (0% DV), Calcium (0% DV), Iron (2% DV), Potassium (2% DV).

(2) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
Calories from saturated fat—Sat fat cal
Saturated fat—Sat fat
Monounsaturated fat—Monounsat fat
Polyunsaturated fat—Polyunsat fat
Cholesterol—Cholest

Total carbohydrate—Total carb. This abbreviation can also be used on dual column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii).

Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
Vitamin—Vit
Potassium—Potas

Includes—Incl. This abbreviation can also be used on dual column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section

(3) Omitting the footnote statement and placing another asterisk at the bottom of the label followed by the statement ''%DV=%Daily Value.''

(4) Presenting the required nutrition information on any other label panel.

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the ''Chemistry Laboratory Guidebook,'' or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 2016 edition of the ''Official Methods of Analysis'' of the AOAC International, unless a particular method of analysis is specified in § 413.309(c), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. When a nutrient is naturally occurring (indigenous) in a food or an ingredient that is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements, except that when an exogenous source of the nutrient is also added to the final food product, the total amount of the nutrient in the final food product (indigenous and exogenous) is subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, polyunsaturated or monounsaturated fat shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) or 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)) unless it meets the following requirements:

(i) When a vitamin, mineral, protein, or dietary fiber meets the definition of a Class I nutrient, the nutrient content of the composite must be formulated to be at least equal to the value for that nutrient declared on the label.

(ii) When a vitamin, mineral, protein, total carbohydrate, polyunsaturated or monounsaturated fat, dietary fiber meets the definition of a Class II nutrient, the nutrient content of the composite must be at least equal to 80 percent of the value for that nutrient declared on the label. Provided, that no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that product at the level involved.

(5) A product with a label declaration of calories, total sugars, added sugars (when the only source of sugars in the food is added sugars), total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) or 4(h) of the Poultry Products Inspection

Act (21 U.S.C. 453(h)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. Provided, that no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of vitamins, minerals, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugar alcohols, polyunsaturated or monounsaturated fat may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, added sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of the serving size.

(8) The management of the official establishment or establishment certified under a foreign inspection system, in accordance with parts 327 and 381, subpart T, of this chapter must maintain records in accordance with parts 320 and 381, subpart Q, of this chapter to support the validity of nutrient declarations contained on product labels including the records in subparagraphs (h)(8)(i)–(vii) of this section for documenting the amount of dietary fiber, soluble fiber, insoluble fiber, added sugars, tocopherol, folate, and folic acid. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(i) When a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food, a manufacturer must maintain records of the amount of non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(ii) When a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must maintain records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iii) When a mixture of insoluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must maintain records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iv) When a mixture of naturally occurring and added sugars is present in the food, a manufacturer must maintain records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient).

(v) When the amount of sugars added to food products is reduced through the process of yeast-leavening, non-enzymatic browning or fermentation, manufacturers must:

(A) Maintain records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after the process of non-enzymatic browning, yeast-leavening, fermentation, or the manufacture of reaction flavors and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning or fermentation; or

(B) Maintain records of the amount of added sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label; or

(C) Submit a request to FSIS to use an alternative means of compliance. The request must provide scientific data or other information for why the amount of added sugars in a serving of product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning and/or fermentation. A significant reduction would be where reduction in added sugars after non-enzymatic browning or fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within good manufacturing practice under § 413.309(h)(6). In addition, the scientific data or other information must include the reason that the manufacturer is unable to determine a reasonable approximation of the amount of added sugars in a serving of their finished product and a description of the process that they used to come to that conclusion.

(vi) When a mixture of *all rac*-α-tocopherol and *RRR*-α-tocopherol is present in a food, manufacturers must maintain records of the amount of *all rac*-α-tocopherol added to the food and *RRR*-α-tocopherol in the finished food.

(vii) When a mixture of folate and folic acid is present in a food, manufacturers must maintain records of the amount of synthetic folate and/or folic acid added to the food and the amount of naturally-occurring folate in the finished food.

(9) The compliance provisions set forth in paragraph (h)(1) through (8) of this section shall not apply to single-ingredient, raw products that are not ground or chopped products described in § 413.301, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its released form, the USDA National Nutrient Database for Standard Reference as provided in § 413.345(e) and (f).

(i) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the office of the FSIS Docket Clerk, Room 8–164A, Patriots Plaza 3, 355 E Street SW., Washington, DC, and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA), call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(1) AOAC Reseller. Techstreet, 6300 Interfirst Dr., Ann Arbor, MI 48108, Toll free in United States: 1–800–699–9277, Outside United States: 1–734–780–8000, Fax: 1–734–780–2046, *www.techstreet.com, techstreet.service@thomsonreuters.com*. FSIS does not endorse any particular reseller and notes that other resellers also may have the reference for sale.

(i) ''Official Methods of Analysis of the AOAC INTERNATIONAL,'' 20th Edition, Volumes 1 and 2, 2016.

(ii) [Reserved]

(2) Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO), Publications Division, Viale delle Terme di Caracalla, 00100 Rome, Italy.

(i) FAO Food and Nutrition Paper 51,''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' Rome, 1991. *http://*

apps.who.int/iris/bitstream/10665/38133/1/9251030979_eng.pdf.

(ii) [Reserved]

(3) United States Department of Agriculture (USDA), Agricultural Research Service, Washington, DC, Nutrient Data Laboratory, Bldg. 005, Room 105 BARC—West, Beltsville, MD 20705, 301–504–0630. *http://www.ars.usda.gov/News/docs.htm?docid=9447*.

(i) USDA Handbook No. 74, Energy Value of Foods—basis and derivation, by A. L. Merrill and B. K. Watt, (slightly revised, 1973) *http://www.ars.usda.gov/SP2UserFiles/Place/80400525/Data/Classics/ah74.pdf*.

(ii) [Reserved]

§§ 413.310–413.311 [Reserved]

§ 413.312 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amounts), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants through 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for use by an infant through 12 months of age or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (*e.g.,* a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (*e.g.,* ground beef), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1—MEAT AND POULTRY PRODUCT REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: FOODS FOR INFANTS AND YOUNG CHILDREN 1 THROUGH 3 YEARS OF AGE [1 2 3]

Product category	Reference amount (g)	Label statement [4]
Infant and Toddler Foods:		
Dinner Dry Mix	15	__tbsp(s) (__g); cup(s) (__g).
Dinner, ready-to-serve, strained type	110	__cup(s) (__g);__cup(s) (mL).
Dinner, soups, ready-to-serve, junior type	110	__cup(s) (__g); cup(s) (__mL).
Dinner, stew or soup, ready-to-serve young children	170	__cup(s) (__g); cup(s) (__mL).
Plain meats, plain poultry, meat sticks, poultry sticks, ready to serve	55	2 oz (56g); __link(s) (__g).

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture and updated by the U.S. Department of Agriculture based on data from the National Health and Nutrition Examination Survey, 2003–2004, 2005–2006, and 2007–2008 conducted by the Centers for Disease Control and Prevention, in the U.S. Department of Health and Human Services.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (*e.g.,* heat and serve, brown and serve). If not listed separately, the Reference Amount for the unprepared form (*e.g.,* dehydrated cereal) is the amount required to make one Reference Amount of the prepared form. Prepared means prepared for consumption (*e.g.,* ready to serve).

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by the regulation.

[4] The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (*e.g.,* patty for patties, link for links, etc.).

TABLE 2—MEAT AND POULTRY PRODUCT REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1 2 3 4 5]

Product category	Reference amount	Reference amount	Label statement [6]
	Ready-to-serve	Ready-to-cook	
Egg mixtures with meat or poultry; *e.g.,* western style omelet, soufflé, egg foo young.	110 g	n/a	4 oz (112g); __piece(s) (__g).
Lard, margarine, shortening	1 tbsp	n/a	1 tbsp (__g).
Salad and potato toppers; *e.g.,* bacon bits, poultry bacon bits.	7 g	n/a	__tbsp (__g).
Bacon; *e.g.,* bacon, beef breakfast strips, pork breakfast strips, pork rinds, pork back fat.	15 g	54 g = bacon, pork rinds, pork back fat; 30 g = meat breakfast strips.	__piece(s) (__g) __pieces pan fried (__g).
Poultry bacon, poultry breakfast strips	15 g	26 g = poultry bacon; 18 g = poultry breakfast strips.	__piece(s) (__g); __pieces pan fried (__g).
Dried meat or poultry products; *e.g.,* jerky, dried beef or poultry, Parma ham, meat or poultry sausage products with a moisture/protein ratio of less than 2:1; *e.g.,* pepperoni.	30 g	n/a	__piece(s) (__g); __slice(s) (__g); 2 oz (28g).
Snacks; *e.g.,* meat or poultry snack food sticks	30 g	n/a	__piece(s) (__g); 2 oz (28g).
Luncheon products, luncheon meat, bologna, poultry bologna, Canadian style bacon, poultry Canadian style bacon, meat or poultry pattie crumbles, blood pudding, meat or poultry luncheon loaf, old fashioned loaf, berlinger, bangers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelat, Lebanon bologna, potted meat or poultry food product, taco fillings, pie fillings.	55 g	n/a	__slice(s) (__g); __piece(s) (__g); __cup (__g); 2 oz (56g).
Linked meat or poultry sausage products, Vienna sausage, frankfurters, poultry franks, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, poultry Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, poultry smoked sausage, smoked pickled meat or poultry meat, pickled pigs feet.	55 g	n/a 75 g = uncooked meat sausage; 69 g = uncooked poultry sausage.	__slice(s) (__g); __piece(s) (__g); __oz (__g).
Entrees without sauce; *e.g.,* cuts of meat or poultry including marinated, tenderized, injected cuts of meat or poultry, patties, corn dogs, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, cured poultry ham products, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.	85 g	114 g	__piece(s) (__g); __slice(s) (__g); __oz (__g); __cup (__g).
Appetizers, hors d'oeuvres—Mini mixed dishes with meat or poultry; *e.g.,* mini bagel pizzas, mini egg rolls, dumplings, mini pizza rolls, mini quesadilla, mini quiche.	85 g (add 35 g for products with gravy or sauce toppings).	n/a	__piece(s) (__g); __piece(s) plus sauce (__g).
Appetizers, hors d'oeuvres—Dips with meat or poultry; *e.g.,* chicken dip, chicken and cheese dip, meat dip.	2 tbsp.	n/a	2 tbsp (_g).
Canned meats (*e.g.,* canned beef, canned pork) and Canned Poultry (*e.g.,* canned chicken, canned turkey).	85 g	n/a	__cup (__g); 3 oz (84g).
Entrees with sauce; *e.g.,* barbecued meat or poultry in sauce, meat or poultry and gravy.	140 g	n/a	__cup (__g); 2 oz (56g).
Mixed dishes NOT measurable with a cup; *e.g.,* burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches with meat or poultry, cracker and meat/poultry lunch type packages, gyro, Stromboli, burger on a bun, poultry burger on a bun, frank on a bun, poultry frank on a bun, calzone, taco, stuffed pockets, foldovers, stuffed vegetables with meat or poultry, shish kabobs, empanada, chicken cordon bleu.	140 g (add 55 g for products with gravy or sauce toppings).	n/a	__piece(s) (__g); __piece(s) plus sauce (__g); 5 oz (140g); __oz (__g).

TABLE 2—MEAT AND POULTRY PRODUCT REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1 2 3 4 5]—Continued

Product category	Reference amount Ready-to-serve	Reference amount Ready-to-cook	Label statement [6]
Mixed dishes measurable with a cup; *e.g.,* casserole, macaroni and cheese with meat or poultry, pot pie, spaghetti with sauce, poultry spaghetti with sauce, meat or poultry chili, meat or poultry chili with beans, hash, creamed chipped beef, creamed dried poultry, ravioli in sauce, stroganoff, Brunswick stew, goulash, poultry a la king, meat or poultry stew, ragout, meat or poultry lasagna, meat or poultry filled pasta.	1 cup	n/a	1 cup (__g).
Salads—pasta or potato, potato salad with bacon, potato salad with poultry, macaroni and meat or poultry salad.	140 g	n/a	__cup (__g).
Salads—all other meat salads, all other poultry salads; *e.g.,* chicken salad, ham salad, turkey salad.	100 g	n/a	__cup (__g).
Soups with meat or poultry—all varieties	245 g	n/a	__cup (__g).
Major main entrée type sauce; *e.g.,* spaghetti sauce with meat or poultry, spaghetti sauce with meatballs, spaghetti sauce with poultry meatballs.	125 g	n/a	__cup (__g); __meatballs plus __cup sauce (__g).
Minor main entrée sauce; *e.g.,* pizza sauce with meat or poultry, gravy.	1/4 c	n/a	1/4 c (__g).
Seasoning mixes dry, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with meat or poultry.			
As reconstituted:			
Amount to make one Reference Amount of the final dish; *e.g.,*.			
Gravy	¼ c	n/a	¼ c (__g);
Major main entrée type sauce	125 g	n/a	__cup (125 g);
Soup	245 g	n/a	__cup (245 g);
Entrée measurable with a cup	1 cup	n/a	1 cup (__g).
Candies with meat or poultry; *e.g.,* chocolate with bacon, chocolate dipped bacon, chocolate with salami.	30 g	n/a	__squares (__g); __pieces (__g); 1 oz (28g).

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture and updated by U.S. Department of Agriculture based on data from the National Health and Nutrition Examination Survey, 2003–2004, 2005–2006 and 2007–2008 conducted by the Centers for Diseases Control and Prevention, in the Department of Health and Human Services.

[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference.

[4] If packed or canned in liquid, the reference amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed (*e.g.,* canned chicken with broth).

[5] Pizza sauce is part of the pizza and is not considered to be a sauce topping.

[6] The label statements are meant to provide examples of serving size statements that may be used on the label, but that the specific wording may be changed as appropriate for individual products. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (*e.g.,* patty for patties, meatballs for meatballs, link for links, etc.). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (*e.g.,* dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 413.309(b) using the reference amount determined according to § 413.412(b).

(c) For products that have no Reference Amount listed in paragraph (b) of this section for the unprepared or the prepared form of the product and that consist of two or more foods packaged and presented to be consumed together (*e.g.,* lunch meat with cheese and crackers), the Reference Amount for the combined product shall be determined using the following rules:

(1) The reference amount for the combined product must be the reference amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient (*e.g.,* lunchmeat) plus proportioned amounts of all minor ingredients.

(2) If the Reference Amounts are in compatible units, the weights or volumes must be summed (*e.g.,* ingredients in equal volumes such as tablespoons). If the Reference Amounts are in incompatible units, all amounts must be converted to weights and summed (*e.g.,* grams of one ingredient plus gram weight of tablespoons of a second ingredient).

(d) If a product requires further preparation, *e.g.,* cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, but not the unprepared form, then the Reference Amount for the unprepared product must be the amount of the unprepared product required to make the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 413.313(d), such as a ''low calorie'' version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parentheses, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

(g) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, __________ submits this labeling application pursuant to 9 CFR 413.312 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (*e.g.,* ham as a luncheon meat, turkey as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (*e.g.,* infants through 12 months, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(1) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(2) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (*i.e.,* number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (*e.g.,* questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant ____________________

By ____________________

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the Reference Amount or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount or Product Category shall be approved for use on the labeling of meat food products or poultry food products.

(i) If the Reference Amount or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of an answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the Reference Amount or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the Reference Amount or Product Category.

§ 413.313 Nutrient content claims; general principles.

(a) This section applies to meat, meat food products, or poultry products that are intended for human consumption and that are offered for sale.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 413.309, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this part.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, *e.g.,* ''low sodium'' or ''contains 100 calories.''

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (*e.g.,* ''high in oat bran''); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (*e.g.,* ''healthy, contains 3 grams (g) of fat'').

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use by infants through 12 months and children less than 2 years of age unless the claim is specifically provided for in this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this part and their synonyms are permitted provided these variations are not misleading (*e.g.,* ''hi'' or ''lo'').

(c) Information that is required or permitted by § 413.309 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A ''substitute'' product is one that may be used interchangeably with another product that it resembles, *i.e.,* that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an ''imitation.''

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (*e.g.,* ''not recommended for frying'').

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 317.2(h) or § 381.121(c) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1⁄16-inch minimum height, except as permitted by § 413.400(d)(2).

(e)(1) Because the use of a ''free'' or ''low'' claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (*e.g.,* ''low sodium beef noodle soup'', ''low sodium chicken noodle soup'').

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (*e.g.,* ''lard, a sodium free food'', ''chicken breast meat, a low sodium food'').

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 413.313, 413.354, 413.356, 413.360, 413.361, 413.362, and 413.380, whose type size is not otherwise specified, is required to be in letters and/or numbers no less than 1⁄16 inch in height, except as permitted by § 413.400(d)(2).

(h) [Reserved]

(i) Except as provided in § 413.309 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in this part, for the nutrient that the label addresses. Such a claim might be, ''less than 10 g of fat per serving;''

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not ''low'' in or a ''good source'' of the nutrient, such as ''only 200 milligrams (mg) sodium per serving, not a low sodium product.'' The disclaimer must be in easily legible print or type and in a size no less than required by § 317.2(h) or § 381.121(c) for the net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1⁄16-inch minimum height, except as permitted by § 413.400(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (*e.g.,* ''100 calories'' or ''5 grams of fat''), in which case no disclaimer is required.

(4) ''Percent fat free'' claims are not authorized by this paragraph. Such claims shall comply with § 413.362(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference product. These statements shall be known as ''relative claims'' and include ''light,'' ''reduced,'' ''less'' (or ''fewer''), and ''more'' claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an appropriate reference product as specified in this paragraph (j).

(i)(A) For ''less'' (or ''fewer'') and ''more'' claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For ''light,'' ''reduced,'' and ''added'' claims, the reference product shall be a similar product, and

(ii)(A) For ''light'' claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; *e.g.,* a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than ''light,'' including ''less'' and ''more'' claims, the reference product may be the same as that provided for ''light'' in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (*i.e.,* that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by which the nutrient has been modified, (*e.g.,* ''50 percent less fat than 'reference product' '' or ''⅓ fewer calories than 'reference product' ''); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 317.2(h) or § 381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than 1⁄16-inch minimum height, except as permitted by § 413.400(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a ''low'' claim for that nutrient.

(k) The term ''modified'' may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (*e.g.,* ''modified fat 'product' ''). This statement of identity must be immediately followed by the comparative statement such as ''contains 35 percent less fat than 'reference product.' '' The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a ''meal-type'' product will be defined as a product that:

(1) Makes a major contribution to the diet by:

(i) Weighing at least 10 ounces per labeled serving; and

(ii) Containing not less than three 40 gram portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section:

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

(E) These foods will not be sauces (except for foods in the four food groups in paragraph (l)(1)(ii)(A) through (D) of this section, that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in the form commonly understood to be, a breakfast, lunch, dinner, meal, or entree. Such representations may be made by statements, photographs, or vignettes.

(m) For purposes of making a claim, a main-dish product will be defined as a food that:

(1) Makes a major contribution to the meal by:

(i) Weighing at least 6 ounces per labeled serving; and

(ii) Containing not less than 40 grams of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (m)(1)(ii)(E) of this section.

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

(E) These foods will not be sauces (except for foods in the four food groups in paragraph (m)(l)(ii)(A) through (D) of this section, that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(3) Is represented as, or is in a form commonly understood to be, a main dish (*e.g.,* not a beverage or dessert). Such representations may be made by statements, photographs, or vignettes.

(n) Nutrition labeling in accordance with § 413.309, shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with § 413.309(h).

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in § 413.312(b) through (e) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 413.312(f) (*e.g.,* ''very low sodium, 35 mg or less per 55 grams'').

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size that is no less than that required by § 317.2(h) or § 381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the criteria statement shall be no less than one-half the size of the claim but no smaller than 1⁄16-inch minimum height, except as permitted by § 413.400(d)(2).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) or 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants through 12 months and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in § 413.309 may be made on the label or in the labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral.

(4) The requirements of this section do not apply to infant formulas and medical foods, as described in 21 CFR 101.13(q)(4).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to § 413.369.

§§ 413.314–413.343 [Reserved]

§ 413.344 Identification of major cuts of meat products and poultry products.

(a) The major cuts of single-ingredient, raw meat products are: Beef chuck blade roast, beef loin top loin steak, beef rib roast large end, beef round eye round steak, beef round top round steak, beef round tip roast, beef chuck arm pot roast, beef loin sirloin steak, beef round bottom round steak, beef brisket (whole, flat half, or point half), beef rib steak small end, beef loin tenderloin steak, pork loin chop, pork loin country style ribs, pork loin top loin chop boneless, pork loin rib chop, pork spareribs, pork loin tenderloin, pork loin sirloin roast, pork shoulder blade steak, pork loin top roast boneless, ground pork, lamb shank, lamb shoulder arm chop, lamb shoulder blade chop, lamb rib roast, lamb loin chop, lamb leg (whole, sirloin half, or shank half), veal shoulder arm steak, veal shoulder blade steak, veal rib roast, veal loin chop, and veal cutlets.

(b) The major cuts of single-ingredient, raw poultry products are: Whole chicken (without neck and giblets), chicken breast, chicken wing, chicken drumstick, chicken thigh, whole turkey (without necks and giblets; separate nutrient panels for white and dark meat permitted as an option), turkey breast, turkey wing, turkey drumstick, and turkey thigh.

§ 413.345 Nutrition labeling of single-ingredient, raw meat or poultry products that are not ground or chopped products described in § 413.301.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw meat or poultry products identified in § 413.344, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under § 413.400. If nutrition information is presented on the label, it must be provided in accordance with § 413.309. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw products that are not ground or chopped products described in § 413.301 and are not major cuts of single-ingredient, raw products identified in § 413.344, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of § 413.309.

(3) A retailer may provide nutrition information at the point-of-purchase by various methods, such as by posting a sign or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of § 413.309 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of § 413.309 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 413.309(c)(8)) and footnote required by § 413.309(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

(b) [Reserved]

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in § 413.309(f).

(d) The nutrition label data for products covered in paragraphs (a)(1) and (a)(2) must be based on either the raw or cooked edible portions of meat cuts with external cover fat at trim levels reflecting current marketing practices or the raw or cooked edible portions of poultry cuts with skin. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the separable lean of meat cuts or the raw or cooked edible portions of the skinless poultry meat.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its released form, the USDA National Nutrient Database for Standard Reference, may be used for nutrition labeling of single-ingredient, raw products, including those that have been previously frozen. These data may be composite data that reflect different quality grades of beef or different classes of turkey or other variables affecting nutrient content. Alternatively, data that reflect specific grades or specific classes or other variables may be used, except that if data are used on labels attached to a product which is labeled as to grade of meat or class of poultry or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible meat tissues or the edible poultry tissues present in the package.

(f) If the nutrition information is provided in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 413.309(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw products, including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this part for the mandatory nutrition labeling program.

§§ 413.346–413.353 [Reserved]

§ 413.354 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV) established for that nutrient (excluding total carbohydrate) in § 413.309(c), may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) "*High*" *claims.* (1) The terms "high," "rich in," or "excellent source of" may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l), and main-dish products as defined in § 413.313(m) provided that the product contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l), and main-dish product as defined in § 413.313(m) provided that:

(i) The product contains a food that meets the definition of "high" in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (*e.g.,* ''the serving of broccoli in this meal is high in vitamin C'').

(c) ''*Good Source*'' *claims.* (1) The terms ''good source,'' ''contains,'' or ''provides'' may be used on the label or in labeling of products, except meal-type products as described in § 413.313(l), and main-dish products as defined in § 413.313(m) provided that the product contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l), and main-dish product as defined in § 413.313(m) provided that:

(i) The product contains a food that meets the definition of ''good source'' in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (*e.g.,* ''the serving of sweet potatoes in this meal is a good source of fiber'').

(d) *Fiber claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, *i.e.,* that the product is high in fiber, a good source of fiber, or that the product contains ''more'' fiber, and the product is not ''low'' in total fat as defined in § 413.362(b)(2) or, in the case of a meal-type product or a main-dish product, is not ''low'' in total fat as defined in § 413.362(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (*e.g.,* ''contains 12 grams (g) of fat per serving''); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) ''*More*'' *claims.* (1) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in § 413.313(l), and main-dish products as defined in § 413.313(m) provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (*e.g.,* ''contains 10 percent more of the Daily Value for fiber than 'reference product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''fiber content of 'reference product' is 1 g per serving; 'this product' contains 4 g per serving'').

(2) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in § 413.313(l), and main-dish products as defined in § 413.313(m) provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (*e.g.,* ''contains 10 percent more of the Daily Value for fiber per 3 ounces (oz) than does 'reference product' ''), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product or a main-dish product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''fiber content of 'reference product' is 2 g per 3 oz; 'this product' contains 5 g per 3 oz'').

§ 413.355 [Reserved]

§ 413.356 Nutrient content claims for ''light'' or ''lite.''

(a) *General requirements.* A claim using the terms ''light'' or ''lite'' to describe a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) ''*Light*'' *claims.* The terms ''light'' or ''lite'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), without further qualification, provided that:

(1) If the product derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference product as described in § 413.313(j)(1); or

(2) If the product derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33 ⅓ percent) per reference amount customarily consumed compared to an appropriate reference product as described in § 413.313(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the appropriate reference product as described in § 413.313(j)(1); and

(3) As required in § 413.313(j)(2) for relative claims:

(i) The identity of the reference product and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim (*e.g.,* ''⅓ fewer calories and 50 percent less fat than the market leader''); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''lite 'this product'—200 calories, 4 grams (g) fat; regular 'reference product'—300 calories, 8 g fat per serving''); and

(iii) If the labeled product contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A ''light'' claim may not be made on a product for which the reference product meets the definition of ''low fat'' and ''low calorie.''

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms ''light'' or ''lite'' without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (*e.g.,* ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''lite 'this product'—500 milligrams (mg) sodium per serving; regular 'reference product'—1,000 mg sodium per serving'').

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms ''light in sodium'' or ''lite in sodium'' if it is reduced by 50 percent or more in sodium content compared to the reference product, provided that ''light'' or ''lite'' is presented in immediate proximity with ''in sodium'' and the entire term is presented in uniform type size, style, color, and prominence; and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (*e.g.,* ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* or ''lite 'this product'—170 mg sodium per serving; regular 'reference product'—350 mg per serving'').

(3) Except for meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), a ''light in sodium'' claim may not be made on a product for which the reference product meets the definition of ''low in sodium.''

(d)(1) The terms ''light'' or ''lite'' may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product meets the definition of:

(A) ''Low in calories'' as defined in § 413.360(b)(3); or

(B) ''Low in fat'' as defined in § 413.362(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether ''light'' is used to mean ''low fat,'' ''low calories,'' or both (*e.g.,* ''Light Delight, a low fat meal''); and

(B) The accompanying statement is no less than one-half the type size of the ''light'' or ''lite'' claim.

(2)(i) The terms ''light in sodium'' or ''lite in sodium'' may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that the product meets the definition of ''low in sodium'' as defined in § 413.361(b)(5)(i); and

(ii) ''Light'' or ''lite'' and ''in sodium'' are presented in uniform type size, style, color, and prominence.

(3) The term ''light'' or ''lite'' may be used in the brand name of a product to describe the sodium content, provided that:

(i) The product is reduced by 50 percent or more in sodium content compared to the reference product;

(ii) A statement specifically stating that the product is ''light in sodium'' or ''lite in sodium'' appears:

(A) Contiguous to the brand name; and

(B) In uniform type size, style, color, and prominence as the product name; and

(iii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim; and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information.

(e) Except as provided in paragraphs (b) through (d) of this section, the terms ''light'' or ''lite'' may not be used to refer to a product that is not reduced in fat by 50 percent, or, if applicable, in calories by ⅓ or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the product such as texture or color and the information (*e.g.,* ''light in color'' or ''light in texture'') so stated, clearly conveys the nature of the product; and

(2) The attribute (*e.g.,* ''color'' or ''texture'') is in the same style, color, and at least one-half the type size as the word ''light'' and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word ''light'' has been associated, through common use, with a particular product to reflect a physical or organoleptic attribute to the point where it has become part of the statement of identity, such use of the term ''light'' shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term ''lightly salted'' may be used on a product to which has been added 50 percent less sodium than is normally added to the reference product as described in § 413.313(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not ''low in sodium'' as defined in § 413.361(b)(4), the statement ''not a low sodium food,'' shall appear adjacent to the nutrition information and the information required to accompany a relative claim shall appear on the label or labeling as specified in § 413.313(j)(2).

§§ 413.357–413.359 [Reserved]

§ 413.360 Nutrient content claims for calorie content.

(a) *General requirements.* A claim about the calorie or sugar content of a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) *Calorie content claims.* (1) The terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietarily insignificant source of calories'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low calorie,'' ''few calories,'' ''contains a small amount of calories,'' ''low source of calories,'' or ''low in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and does not provide more than 40 calories per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 120 calories or less per 100 g of product; and (ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches.

(4) The terms ''reduced calorie,'' ''reduced in calories,'' ''calorie reduced,'' ''fewer calories,'' ''lower calorie,'' or ''lower in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* lower calorie 'product'— ''33⅓ percent fewer calories than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''calorie content has been reduced from 150 to 100 calories per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent fewer calories per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* ''calorie reduced 'product', 25% less calories per ounce (oz) (or 3 oz) than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''calorie content has been reduced from 110 calories per 3 oz to 80 calories per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(c) *Sugar content claims.* (1) Terms such as ''sugar free,'' ''free of sugar,'' ''no sugar,'' ''zero sugar,'' ''without sugar,'' ''sugarless,'' ''trivial source of sugar,'' ''negligible source of sugar,'' or ''dietarily insignificant source of sugar'' may reasonably be expected to be regarded by consumers as terms that represent that the product contains no sugars or sweeteners, *e.g.,* ''sugar free,'' or ''no sugar,'' as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a product may not be labeled with such terms unless:

(i) The product contains less than 0.5 g of sugars, as defined in § 413.309(c)(6)(ii), per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of sugars per labeled serving size;

(ii) The product contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of sugar,'' ''adds a negligible amount of sugar,'' or ''adds a dietarily insignificant amount of sugar;'' and

(iii)(A) It is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement ''not a reduced calorie product,'' ''not a low calorie product,'' or ''not for weight control.''

(2) The terms ''no added sugar,'' ''without added sugar,'' or ''no sugar added'' may be used only if:

(i) No amount of sugars, as defined in § 413.309(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging;

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice;

(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a product, and a functionally insignificant increase in sugars results;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the product is not ''low calorie'' or ''calorie reduced'' (unless the product meets the requirements for a ''low'' or ''reduced calorie'' product) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a product, including products intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, *e.g.,* juices.

(4) The terms ''reduced sugar,'' ''reduced in sugar,'' ''sugar reduced,'' ''less sugar,'' ''lower sugar,'' or ''lower in sugar'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less sugars per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* ''this product contains 25 percent less sugar than our regular product''); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''sugar content has been lowered from 8 g to 6 g per serving'').

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less sugars per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* ''reduced sugar 'product'—25% less sugar than our regular 'product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz'').

§ 413.361 Nutrient content claims for the sodium content.

(a) *General requirements.* A claim about the level of sodium in a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) *Sodium content claims.* (1) The terms ''sodium free,'' ''free of sodium,'' ''no sodium,'' ''zero sodium,'' ''without sodium,'' ''trivial source of sodium,'' ''negligible source of sodium,'' or ''dietarily insignificant source of sodium'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 5 mg of sodium per labeled serving size;

(ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of sodium,'' ''adds a negligible amount of sodium'' or ''adds a dietarily insignificant amount of sodium''; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''very low sodium'' or ''very low in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''low sodium,'' ''low in sodium,'' ''little sodium,'' ''contains a small amount of sodium,'' or ''low source of sodium'' may be used on the label and in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(6) The terms ''reduced sodium,'' ''reduced in sodium,'' ''sodium reduced,'' ''less sodium,'' ''lower

sodium,'' or ''lower in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* ''reduced sodium 'product', 50 percent less sodium than regular 'product' ''); and

(B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''sodium content has been lowered from 300 to 150 mg per serving'').

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low sodium.''

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* ''reduced sodium 'product'—30% less sodium per 3 oz than our 'regular product' ''); and

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz'').

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product meets the definition for ''low sodium.''

(c) The term ''salt'' is not synonymous with ''sodium.'' Salt refers to sodium chloride. However, references to salt content such as ''unsalted,'' ''no salt,'' ''no salt added'' are potentially misleading.

(1) The term ''salt free'' may be used on the label or in labeling of products only if the product is ''sodium free'' as defined in paragraph (b)(1) of this section.

(2) The terms ''unsalted,'' ''without added salt,'' and ''no salt added'' may be used on the label or in labeling of products only if:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, the statement, ''not a sodium free product'' or ''not for control of sodium in the diet'' appears adjacent to the nutrition information of the product bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a product intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the product and is not false or otherwise misleading.

§ 413.362 Nutrient content claims for fat, fatty acids, and cholesterol content.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) *Fat content claims.* (1) The terms ''fat free,'' ''free of fat,'' ''no fat,'' ''zero fat,'' ''without fat,'' ''nonfat,'' ''trivial source of fat,'' ''negligible source of fat,'' or ''dietarily insignificant source of fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of fat per labeled serving size;

(ii) The product contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of fat,'' ''adds a negligible amount of fat,'' or ''adds a dietarily insignificant amount of fat''; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low fat,'' ''low in fat,'' ''contains a small amount of fat,'' ''low source of fat,'' or ''little fat'' may be used on the label and in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons (tbsp) and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced fat,'' ''reduced in fat,'' ''fat reduced,'' ''less fat,'' ''lower fat,'' or ''lower in fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* ''reduced fat—50 percent less fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''fat content has been reduced from 8 g to 4 g per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* ''reduced fat 'product', 33 percent less fat per 3 oz than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (*e.g.,* ''fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(6) The term ''____ percent fat free'' may be used on the label or in labeling of products, provided that:

(i) The product meets the criteria for ''low fat'' in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent declared and the words ''fat free'' are in uniform type size; and

(iii) A ''100 percent fat free'' claim may be made only on products that meet the criteria for ''fat free'' in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(iv) A synonym for ''____ percent fat free'' is ''____ percent lean.''

(c) *Fatty acid content claims.* (1) The terms ''saturated fat free,'' ''free of saturated fat,'' ''no saturated fat,'' ''zero saturated fat,'' ''without saturated fat,'' ''trivial source of saturated fat,'' ''negligible source of saturated fat,'' or ''dietarily insignificant source of saturated fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of saturated fat,'' ''adds a negligible amount of saturated fat,'' or ''adds a dietarily insignificant amount of saturated fat;'' and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low in saturated fat,'' ''low saturated fat,'' ''contains a small amount of saturated fat,'' ''low source of saturated fat,'' or ''a little saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains 1 g or less of saturated fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat; and

(ii) If the product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 1 g or less of saturated fat per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced saturated fat,'' ''reduced in saturated fat,'' ''saturated fat reduced,'' ''less saturated fat,'' ''lower saturated fat,'' or ''lower in saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* ''reduced saturated fat 'product', contains 50 percent less saturated fat than the national average for 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''saturated fat reduced from 3 g to 1.5 g per serving'').

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(5) The terms defined in paragraph (c)(4) of this section may be used on the

label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (*e.g.,* ''reduced saturated fat 'product',' ''50 percent less saturated fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''saturated fat content has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz'').

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(d) *Cholesterol content claims.* (1) The terms ''cholesterol free,'' ''free of cholesterol,'' ''zero cholesterol,'' ''without cholesterol,'' ''no cholesterol,'' ''trivial source of cholesterol,'' ''negligible source of cholesterol,'' or ''dietarily insignificant source of cholesterol'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of cholesterol,'' ''adds a negligible amount of cholesterol,'' or ''adds a dietarily insignificant amount of cholesterol'';

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), 2 g or less of saturated fat per labeled serving size; and

(iv) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 413.313(j)(1) and for which it substitutes as described in § 413.313(d) that has a significant (*e.g.,* 5 percent or more of a national or regional market) market share. As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (*e.g.,* ''cholesterol free 'product', contains 100 percent less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''contains no cholesterol compared with 30 mg in one serving of 'reference product' '').

(2) The terms ''low in cholesterol,'' ''low cholesterol,'' ''contains a small amount of cholesterol,'' ''low source of cholesterol,'' or ''little cholesterol'' may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 413.313(j)(1) and for which it substitutes as described in § 413.313(d) that has a significant (*e.g.,* 5 percent or more of a national or regional market) market share. As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (*e.g.,* ''low cholesterol 'product', contains 85 percent less cholesterol than our regular 'product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''cholesterol lowered from 30 mg to 5 mg per serving'').

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced cholesterol,'' ''reduced in cholesterol,'' ''cholesterol reduced,'' ''less cholesterol,'' ''lower cholesterol,'' or ''lower in cholesterol'' may be used on the label or in labeling of products or products that substitute for those products as specified in

§ 413.313(d), excluding meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 413.313(j)(1) and for which it substitutes as described in § 413.313(d) that has a significant (*e.g.,* 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per reference amount customarily consumed; and

(iii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (*e.g.,* ''25 percent less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''cholesterol lowered from 55 mg to 30 mg per serving'').

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 413.313(j)(1) and for which it substitutes as described in § 413.313(d) that has a significant (*e.g.,* 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (*e.g.,* ''25% less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (*e.g.,* ''cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz'').

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(e) *''Lean'' and ''Extra Lean'' claims.* (1) The term ''lean'' may be used on the label or in labeling of a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m).

(2) The term ''extra lean'' may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m).

(f) A statement of the lean percentage may be used on the label or in labeling of ground or chopped products described in § 413.301 when the product does not meet the criteria for ''low fat,'' defined in § 413.362(b)(2), provided that a statement of the fat percentage is contiguous to and in lettering of the same color, size, type, and on the same color background, as the statement of the lean percentage.

§ 413.363 Nutrient content claims for ''healthy.''

(a) The term ''healthy,'' or any other derivative of the term ''health,'' may be used on the labeling of any meat, meat food product, or poultry product, provided that the product is labeled in accordance with § 413.309 and § 413.313.

(b)(1) The product shall meet the requirements for ''low fat'' and ''low saturated fat,'' as defined in § 413.362, except that single-ingredient, raw products may meet the total fat and saturated fat criteria for ''extra lean'' in § 413.362.

(2) The product shall not contain more than 60 milligrams (mg) of cholesterol per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 grams (g) or less or 2 tablespoons (tbsp) or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in § 413.313(m), and a meal-type product, as defined in § 413.313(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for ''extra lean'' in § 413.362.

(3) The product shall not contain more than 480 mg of sodium per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in § 413.313(m), and a meal-type product, as defined in § 413.313(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 600 mg of sodium per labeled serving size; [1] and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in § 413.309 for vitamin A, vitamin C, calcium, iron, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A main-dish product, as defined in § 413.313(m), and including main-dish products that weigh less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

[1] This regulation previously provided that, after January 1, 2006, individual meat and poultry products bearing the claim ''healthy'' (or any derivative of the term ''health'') must contain no more than 360 mg of sodium and that meal-type products bearing the claim ''healthy'' (or any other derivative of the term ''health'') must contain no more than 600 mg of sodium. Implementation of these sodium level requirements for products bearing the claim ''healthy'' (or any derivative of the term ''health'') has been deferred indefinitely due to technological barriers and consumer preferences.

(ii) A meal-type product, as defined in § 413.313(l), shall meet the level for three of the nutrients per labeled serving size.

§§ 413.364–413.368 [Reserved]

§ 413.369 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this part.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (*i.e.,* one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, Washington, DC 20250.

____

(Date)

The undersigned, ______, submits this labeling application pursuant to 9 CFR 413.369 with respect to (statement of the claim and its proposed use). Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with § 413.309(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant ____________________________

By ____________________________

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it

has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of meat and meat food products and poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the claim.

(l)(1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, Washington, DC 20250:

____
(Date)

The undersigned, ______ submits this labeling application pursuant to 9 CFR 413.369 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under part 413).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant ______________________________

By ______________________________

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way

of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the **Federal Register** a notice informing the public that the synonymous term has been approved for use.

(m)(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, Washington, DC 20250:

____

(Date)

The undersigned, ______ submits this labeling application pursuant to 9 CFR 413.369 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant ____________________________

By ____________________________

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the **Federal Register** seeking comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of meat food products or for poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a notice informing the public that the implied nutrient content claim has been approved for use.

§§ 413.370–413.379 [Reserved]

§ 413.380 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 413.309 of this part, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (*i.e.,* one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If nutritive sweeteners as well as nonnutritive sweeteners are added, the statement shall indicate the presence of both types of sweetener; *e.g.,* ''Sweetened with nutritive sweeteners and nonnutritive sweeteners.''

(c) ''*Low calorie*'' *foods.* A product purporting to be ''low calorie'' must comply with the criteria set forth for such foods in § 413.360.

(d) ''*Reduced calorie*'' *foods and other comparative claims.* A product purporting to be ''reduced calorie'' or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 413.360(b) (4) and (5).

(e) ''*Label terms suggesting usefulness as low calorie or reduced calorie foods*''.

(1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as ''diet,'' ''dietetic,'' ''artificially sweetened,'' or ''sweetened with nonnutritive sweetener'' only if the claim is not false or misleading, and the product is labeled ''low calorie'' or ''reduced calorie'' or bears another comparative calorie claim in compliance with the applicable provisions in this part.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term ''diet'' that clearly shows that the product is offered solely for a dietary use other than regulating body weight, *e.g.,* ''for low sodium diets.''

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) ''*Sugar free*'' *and* ''*no added sugar*''*.* Criteria for the use of the terms ''sugar free'' and ''no added sugar'' are provided for in § 413.360(c).

§§ 413.381–413.399 [Reserved]

§ 413.400 Exemptions from nutrition labeling.

(a) The following products are exempt from nutrition labeling:

(1) Food products produced by small businesses, other than the major cuts of single-ingredient, raw products identified in § 413.344 produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information, and ground or chopped products described in § 413.301 produced by small businesses that bear a statement of the lean percentage and fat percentage on the label or in labeling in accordance with § 413.362(f), provided that labels or labeling for these products bear no other nutrition claims or nutrition information,

(i) A food product, for the purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility, including a single retail store, or multi-plant company/firm, including a multi-retail store operation, that employs 500 or fewer people and produces no more than 100,000 pounds of the product qualifying the firm for exemption from this part.

(iii) For purposes of this paragraph, calculation of the amount of pounds shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years or where products have been produced for less than 2 years, reasonable estimates must indicate that the annual pounds produced will not exceed the amounts specified.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claim or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment, provided, however, that this exemption does not apply to ready-to-eat ground or chopped products described in § 413.301 that are packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under (a)(1) of this section;

(ii) Multi-ingredient products (*e.g.,* sausage) processed at a retail store or similar retail-type establishment, provided, however, that this exemption does not apply to multi-ingredient ground or chopped products described in § 413.301 that are processed at a retail establishment, unless the establishment qualifies for an exemption under (a)(1) of this section; and

(iii) Products that are ground or chopped at an individual customer's request.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c)(1) Foods represented or purported to be specifically for infants through 12 months of age and children 1 through 3 years of age shall bear nutrition labeling. The nutrients declared for infants through 12 months of age and children 1 through 3 years of age shall include calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, and the following vitamins and minerals: Vitamin D, calcium, iron, and potassium.

(2) Foods represented or purported to be specifically for infants through 12 months of age shall bear nutrition labeling, except that:

(i) Such labeling shall not declare a percent of Daily Value for saturated fat, *trans* fat, cholesterol, sodium, dietary fiber, total sugars, or added sugars and shall not include a footnote.

(ii) The following sample label illustrates the provisions of paragraph (c)(2) of this section.

Nutrition Facts	
4 servings per container	
Serving size	**1 pack (70g)**
Amount per serving	
Calories	**25**
	% Daily Value
Total Fat 0g	**0%**
Saturated Fat 0g	
Trans Fat 0g	
Cholesterol 0mg	
Sodium 74mg	
Total Carbohydrate 5g	**5%**
Dietary Fiber 1g	
Total Sugars 3g	
Includes 0g Added Sugars	
Protein 0g	**0%**
Vitamin D 0mcg	0%
Calcium 5mg	2%
Iron 1mg	10%
Potassium 230mg	35%

(3) Foods represented or purported to be specifically for children 1 through 3 years of age shall include a footnote that states: '' * The %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.''

(i) The following sample label illustrates the provisions of paragraph (c)(3) of this section.

Nutrition Facts	
1 serving per container	
Serving size	**1 container (85g)**
Amount per serving	
Calories	**70**
	% Daily Value*
Total Fat 1.5g	**4%**
Saturated Fat 0.5g	**5%**
Trans Fat 0g	
Cholesterol 10mg	**3%**
Sodium 240mg	**16%**
Total Carbohydrate 11g	**7%**
Dietary Fiber 1g	**7%**
Total Sugars 1g	
Includes 1g Added Sugars	**4%**
Protein 3g	**23%**
Vitamin D 0mcg	0%
Calcium 35mg	6%
Iron 0.6mg	8%
Potassium 30mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.

(ii) [Reserved]

(d)(1) Products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided that the labeling for these products bear no nutrition claims or other nutrition information, except that this exemption does not apply to the major cuts of single-ingredient, raw products identified in § 413.344. The manufacturer, packer, or distributor shall provide, on the label of packages that qualify for and use this exemption, an address or telephone number that a consumer can use to obtain the required nutrition information (*e.g.,* ''For nutrition information call 1–800–123–4567'').

(2) When products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be provided in accordance with 9 CFR 413.309(d) for the linear nutrition display as shown in 9 CFR 413.309(g)(1)(i)(B).

Done at Washington, DC, on: November 28, 2016.

Alfred V. Almanza,

Acting Administrator.

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