DEPARTMENT OF AGRICULTURE

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its nutrition labeling regulations to change the definition of “meal-type” products to allow for nutrient content claims on multiple-serve food containers, to adopt the definition of “main dish” used by the Food and Drug Administration (FDA), and to define how meal-type products and main dishes should be nutrition labeled. The change in the definition of meal-type products will allow nutrient content claims on qualifying products to be based on 100 grams of product rather than on the serving size, which is based on the Reference Amounts Customarily Consumed (RACCs) for the food components. These actions are in response to a petition filed by ConAgra, Inc. (the petitioner). The changes will help to ensure that FSIS’ nutrition labeling regulations are parallel, to the maximum extent possible, to the nutrition labeling regulations of FDA, which were promulgated under the Nutrition Labeling and Education Act (NLEA) of 1990.


FOR FURTHER INFORMATION CONTACT: Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff, Office of Policy, Program and Employee Development, FSIS, at (202) 205–0279 or by fax at (202) 205–3625.

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) authorize the Secretary of Agriculture to establish and maintain inspection programs designed to assure consumers that meat and poultry products distributed in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS regulates the labeling of meat and poultry products, and FDA has responsibility for all other food labeling.

In January of 1993, FSIS and FDA published their final rules on nutrition labeling. Both agencies amended their respective regulations to (1) Require either mandatory or voluntary nutrition labeling on most of the food products they regulate; (2) revise the list of required nutrients and food components; (3) specify a new format for declaring the nutrients and food components in nutrition labeling; (4) permit specific products to be exempt from nutrition labeling; (5) establish RACCs specific for food categories; and (6) prescribe a simplified form of nutrition labeling and the conditions under which such labeling may be used.

In order for persons to use the nutrition information to construct healthy diets that include products from across the food supply, the two agencies recognized that the regulations need to be as consistent as possible. There was overwhelming support for FSIS to proceed with the adoption of FDA-defined nutrient content claims, including adopting a constant value of 100 grams for comparison of nutrient content claims on meal-type products. As a result, both agencies issued regulations establishing, as nearly uniform as possible, definitions for nutrient content claims to allow consumers to make valid comparisons among food product categories.

In addition, the agencies participated in the Interagency Committee on Serving Sizes to jointly establish the RACCs for foods and the criteria for converting RACCs to serving sizes in common household measures. The final FSIS rule, among other things, established RACCs for 23 meat (9 CFR 317.312(b)) and 22 poultry product categories (9 CFR 381.412(b)). These RACCs were calculated to reflect the amount of food, including snacks, dinners, and condiments, that persons four years of age and older customarily consume. These calculations were based on consumption survey data and on data used by food manufacturers and grocers. RACCs are designed to be used by food companies as the basis for determining the serving sizes for nutrition labeling of their products.

Nutrient content claims for both FDA and FSIS are composed of two defined parts: The amount (weight) of the nutrient and the amount (generally a serving) of food in which the nutrient is found. If the food is considered to be an individual food, the amount of food (a serving) is represented as the RACC for the food category. If the food is a meal-type product, the amount of food is measured by weight, i.e., 100 grams. If a “low-fat” or “healthy” claim is used, the amount of fat is limited to a maximum of 3 grams per RACC for individual foods and 3 grams per 100 grams of product for meal-type products.

However, FSIS and FDA have established different criteria for what constitutes a meal. FSIS defined a “meal-type” product (9 CFR 317.313(l) and 381.413(l)) as a product for consumption by one person on one eating occasion that constitutes the major portion of a meal. For purposes of making a nutrition claim, a meal-type product must (1) make a significant contribution to the diet by weighing at least 6 ounces, but no more than 12 ounces per serving (container); (2) contain ingredients from two or more food groups, depending on the weight of the product; and (3) represent, or be in a form commonly understood to be, a meal (breakfast, dinner, etc). In addition, the serving size for meal-type products is defined as the entire content (edible portion only) of the package, i.e., single-serve container.

FDA defined a “meal-type” product (21 CFR 101.13(l)) for the purpose of making a claim as a product that makes a major contribution to the total diet by (1) weighing at least 10 ounces per labeled serving; (2) containing not less than three 40-gram portions of food or combinations of foods from two or more of the four food groups; and (3) representing, or being in a form commonly understood to be, a meal....
market for multi-serve meals that did not exist in 1993 when the nutrition labeling regulations were issued. Because of the increasing popularity of multi-serve meals and evidence that a significant number of consumers were purchasing such meals, FSIS said it was prepared to consider changing the regulatory definition of “meal-type” products and allowing nutrient content claims based on a 100 gram criterion as long as there are no established RACCs for the food product category in question. It also said that consistency in nutrient content claims and criteria for RACCs for all meat and poultry products must be maintained in accordance with the regulations. The Agency noted that if Federal regulations regarding the basis on which nutrient content claims are made are modified for consistency, FSIS and FDA need identical definitions for what constitutes a meal and a main-dish product. FSIS granted the petition in September 2001. The petition and supporting documentation are available in the FSIS Docket Room (see ADDRESSES) and on the FSIS Web site at http://www.fsis.usda.gov.

Response to Comments

The proposed rule was published in the Federal Register on April 16, 2003 (68 FR 18560–65). The public comment period of the proposed rule closed on June 16, 2003. Four comments were received. All of the respondents supported the proposal because it increased the regulatory consistency between FSIS and FDA on nutrient content claims, and it would benefit consumers by permitting them to choose from more healthy food options.

Several respondents commented that, with this change, FSIS has positioned meat and poultry meals as being as nutritious as similar products regulated by FDA. The commenters further stated that the FSIS regulations will no longer promote the idea of good versus bad foods, and that the change will eliminate nutrient content claims based on the packaging format instead of the product formulation.

While it is true that some consumers tend to infer that multi-serve and other products are nutritionally inferior if they lack the claims that other products have, FSIS has never promoted a good food/bad food policy.

The commenters asserted that the change will be an incentive for manufacturers to provide more low-fat or healthy meal options. FSIS agrees. In addition, the consistency in the nutrient claim criteria will benefit consumers by providing them with additional tools and guidance for adhering to a low-fat diet at a more favorable cost.

We are adopting the proposed rule as final but are making some minor editorial changes to conform the existing regulations with this final rule. In addition, although discussed in the preamble of the proposed rule, the definition of “main-dish” was inadvertently omitted in the regulatory changes of the proposed rule to Part 317 of the meat regulations (but was included in Part 381 of the proposed rule’s regulatory changes to the poultry regulations). In the final rule, paragraph (m) of section 317.363 of the meat regulations contains the definition of main-dish.

Costs and Benefits Associated With the Rule

No significant cost impact is seen as a result of this final rule. All costs would be borne by industry, which petitioned for the change. The only labels that would be affected would be those of multi-serve, meal-type products above 6 ounces that would be able to bear nutrient content claims. The Agency believes that no more than 300 products currently on the market will be affected by the change. Therefore, the expected additional labeling costs would be nominal for the industry.

A more consistent format across similar food products will be of benefit to consumers, who will be able to make more informed choices in their food purchases. Consumers report that they are experiencing some confusion about how some food products are labeled, and why some packages bear claims specifying the nutrient content of the product and others do not.

The Final Rule

The final rule will provide consumers of meat and poultry products with consistency in nutrition labeling with FDA’s requirements by amending §317.309 and the parallel poultry regulations at §381.409 to provide for the nutrition labeling of multi-serve meal-type products and of main-dish products. The final rule also will amend §317.313(l) and §317.313(m) and the parallel poultry regulations at §381.413(l) and §381.413(m) by revising the definitions of a “meal-type” product and adding a “main-dish” product for the purpose of making a claim on the packaging of the food products. In addition, this rule will amend the individual nutrient content claim regulations for both meat and poultry products at 9 CFR §317.319(l) and (m) and 9 CFR §§381.413(l) and (m).
FSIS’ paramount objectives in considering this modification of its nutrition labeling regulations were that the changes not undermine the basic principles or intent of the misbranding provisions of the Federal Meat Inspection Act and the Poultry Products Inspection Act, and that such modifications would result in labels that would not mislead consumers or create unfair marketing advantages for any segment of the food industry. The Agency also was concerned about extending the use of the 100-gram criterion for nutrient content claims to include products not in single-serve containers. Although useful, the 100-gram criterion does not provide nutrient information to consumers that is as definitive as the amount of nutrient per RACC.

However, in the interests of maintaining consistency between FSIS and FDA and of providing incentives to industry to develop more less-caloric yet economical meals and main dish products in multi-serve containers that would qualify for nutrient content claims, FSIS is making changes in its nutrition labeling regulations. The Agency believes that consumers will benefit from the information on the containers of products that were formulated to qualify to bear such claims.

Executive Order 12866 and the Regulatory Flexibility Act

This final rule has been determined to be not economically significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. FSIS is responding to an industry petition for a labeling change affecting approximately 300 food products.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. When this rule becomes final: (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) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Effect on Small Entities

The Administrator, FSIS, has made a determination that this final rule will not have a significant economic impact on a substantial number of small entities. This rule will change the definition of “meal-type” products to allow for nutrient content claims based on 100 grams of product on multi-serve food containers and adopt FDA’s definition of “main-dish” products; however, it will not require anyone to change their labeling.

Paperwork Requirements

This rule has been reviewed under the Paperwork Reduction Act and imposes no new paperwork or recordkeeping requirements.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this final rule, FSIS will announce it on-line through the FSIS Web page located at http://www.fsis.usda.gov.

The Regulations.gov website is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government’s regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at http://www.regulations.gov.

FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, recalls, and other types of information that could affect or be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS web page. Through Listserv and the web page, FSIS is able to provide information to a much broader, more diverse audience.

List of Subjects

9 CFR Part 317
Food labeling, Food packaging, Meat inspection, Nutrition.

9 CFR Part 381
Food labeling, Food packaging, Nutrition, Poultry and poultry products

The Final Rule

For the reasons discussed in the preamble, FSIS is amending 9 CFR, Parts 317 and 381, as follows:

PART 317—LABELING, MARKING DEVICES AND CONTAINERS

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


2. Section 317.309 is amended as follows:

(a) By removing the phrase “and meal type products” in paragraph (b)(7)(iv).

(b) By revising paragraph (b)(12) to read as follows:

§ 317.309 Nutrition label content.

(b) * * *

(12) The serving size for meal-type products and main-dish products as defined in § 317.313(l) and § 317.313(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 § 317.312(b) if the product is listed in § 317.312(b). Serving size for meal-type products and main-dish products in multi-serve containers that are not listed in § 317.312(b) will be based on the reference amount according to § 317.312(c), (d), and (e).

§ 317.310 Nutrition label content; general principles.

(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),
§ 317.354 [Amended]

4. Section 317.354 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in § 317.313(m)” after the phrase “meal-type products as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (b)(1), (e)(1) and (e)(2),
   b. By adding the phrase “and main-dish products as defined in § 317.313(m)” after the phrase “meal-type products as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (b)(2) and (c)(2).
   d. By adding the phrase “and main-dish product as defined in § 317.313(m)” after the phrase “meal-type product as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (d)(1) and (e)(2)(ii)(B).

§ 317.356 [Amended]

5. Section 317.356 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in § 317.313(m)” after the phrase “meal-type products as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (b)(3), (b)(5), (c)(3), (c)(5), (d)(1)(i), (d)(1)(ii)(i), (d)(3), and (d)(5).
   c. By adding the phrase “or a main-dish product” after the phrase “a meal-type product”, in paragraphs (b)(1)(i) and (c)(1)(i).

§ 317.360 [Amended]

6. Section 317.360 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in § 317.313(m)” after the phrase “meal-type products as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (b)(1) introductory text and paragraph (d)(2)(i).

§ 317.361 [Amended]

7. Section 317.361 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in § 317.313(m)” after the phrase “meal-type products as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (b)(2), (b)(4), and (c)(4).
   b. By adding the phrase “and main-dish product as defined in § 317.313(m)” after the phrase “meal-type product as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (b)(3), (b)(5), and (c)(5).
   c. By adding the phrase “or a main-dish product” after the phrase “a meal-type product” in paragraph (c)(1)(i).

§ 317.362 [Amended]

8. Section 317.362 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in § 317.313(m)” after the phrase “meal-type products as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (b)(2) and (c)(2).
   b. By adding the phrase “and main-dish product as defined in § 317.313(m)” after the phrase “meal-type product as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (d)(1) and (e)(2)(ii)(B).
   c. By adding the phrase “and main-dish products as defined in § 317.313(m)” after the phrase “meal-type products as defined in § 317.313(l)”, whenever it occurs in the introductory text of paragraphs (b)(3), (b)(5), (c)(3), (c)(5), (d)(1)(i), (d)(1)(ii)(i), (d)(3), and (d)(5).
   d. By adding the phrase “or a main-dish product” after the phrase “a meal-type product”, in paragraphs (b)(1)(i) and (c)(1)(i).

§ 317.363 [Amended]

9. Section 317.363 is amended as follows:
   a. By adding the phrase “main-dish product, as defined in § 317.313(m), and before the phrase “meal-type product, as defined in § 317.313(l)” in the introductory text of paragraphs (b)(2)(i) and (b)(3)(i).
   b. By removing the phrase “meal-type product, as defined in § 317.313(l),” and adding the phrase “main-dish product, as defined in § 317.313(m),” in its place in paragraph (b)(4)(i) and by removing the phrase “meal-type products that weigh at least 6 oz. but” and adding the phrase “main-dish products that weigh 10 oz. or more per serving (container),” in paragraph (b)(4)(ii).
   c. By removing the phrase “and including meal-type products that weigh 10 oz. or more per serving (container),” in paragraph (b)(4)(ii).

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

10. The authority citation for Part 381 continues to read as follows:


11. Section 381.409 is amended as follows:
   a. By removing the phrase “and meal-type products” in paragraph (b)(7)(iv).
   b. By revising paragraph (b)(12) to read as follows:

§ 381.409 Nutrition label content.

(12) The serving size for meal-type products and main-dish products as defined in § 381.413(l) and § 381.413(m) in single-serve 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 § 381.412(b) if the product is listed in § 381.412(b). Serving size for meal-type products and main-dish products in multi-serve containers that are not listed in § 381.412(b) will be based on the reference amount according to § 381.412(c), (d), and (e).
§ 381.413 Nutrient content claims; general principles.
* * * * *
(1) 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, braidings, or garnishes; and
   (2) Is represented as, or is in the form commonly understood to be, a breakfast, lunch, dinner, meal, or entrée. Such representations may be made by statements, photographs, or vignettes.

§ 381.454 [Amended]
13. Section 381.454 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in” after the phrase “meal-type products as defined in” § 381.413(m)” after the phrase “meal-type products as defined in” § 381.413(l)” wherever it occurs in the introductory text of paragraphs (b)(1), (e)(1), and (e)(2).
   b. By adding the phrase “and main-dish products as defined in” § 381.413(m)” after the phrase “meal-type products as defined in” § 381.413(l)” whenever it occurs in the introductory text of paragraphs (b)(1), (e)(1), and (e)(2).
   c. By adding the phrase “or a main-dish product” after the phrase “a meal-type product” in paragraph (b)(1)(i).

§ 381.462 [Amended]
17. Section 381.462 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in” § 381.413(m)” after the phrase “meal-type products as defined in” § 381.413(l)” whenever it occurs in the introductory text of paragraphs (b)(2) and (c)(2).
   b. By adding the phrase “or a main-dish product” after the phrase “a meal-type product” in paragraphs (d)(1) and (e)(2)(ii)(B).

§ 381.456 [Amended]
14. Section 381.456 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in” § 381.413(m)” after the phrase “meal-type products as defined in” § 381.413(l)” whenever it occurs in the introductory text of paragraphs (b)(1), (e)(1), and (e)(2).
   b. By adding the phrase “and main-dish products as defined in” § 381.413(m)” after the phrase “meal-type products as defined in” § 381.413(l)” whenever it occurs in the introductory text of paragraphs (b)(2) and (c)(2).
   c. By adding the phrase “or a main-dish product” after the phrase “a meal-type product”, in paragraphs (b)(1)(i) and (c)(1)(i).

§ 381.460 [Amended]
15. Section 381.460 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in” § 381.413(m)” after the phrase “meal-type products as defined in” § 381.413(l)” whenever it occurs in the introductory text of paragraphs (b)(2) and (c)(4).
   b. By adding the phrase “and main-dish product as defined in” § 381.413(m)” after the phrase “meal-type product as defined in” § 381.413(l)” whenever it occurs in the introductory text of paragraphs (b)(3) and (c)(5).
   c. By adding the phrase “or a main-dish product” after the phrase “a meal-type product” in paragraph (c)(1)(i).

§ 381.461 [Amended]
16. Section 381.461 is amended as follows:
   a. By adding the phrase “and main-dish products as defined in” § 381.413(m)” after the phrase “meal-type products as defined in” § 381.413(l)” whenever it occurs in the introductory text of paragraphs (b)(2), (b)(4), and (b)(6).
   b. By adding the phrase “and main-dish product as defined in” § 381.413(m)” after the phrase “meal-type product as defined in” § 381.413(l)” whenever it occurs in the introductory text of paragraphs (b)(3), (b)(5), and (b)(7).
   c. By adding the phrase “or a main-dish product” after the phrase “a meal-type product” in paragraph (b)(1)(i).

§ 381.463 [Amended]
18. Section 381.463 is amended as follows:
   a. By adding the phrase “main-dish product, as defined in § 381.413(m),” and before the phrase “meal-type product, as defined in § 381.413(l)” in the introductory text of paragraph (b)(2)(i) and (b)(3)(i).
   b. By removing the phrase “meal-type product, as defined in § 381.413(l)” and adding the phrase “main-dish product, as defined in § 381.413(m),” in its place in paragraph (b)(4)(i) and by removing the phrase “meal-type products that weigh at least 6 oz. but” and adding the phrase “meal-type products that weigh 10 oz. or more per serving container.” in paragraph (b)(4)(ii).
   c. By removing the phrase “and including meal-type products that weigh 10 oz. or more per serving container.” in paragraph (b)(4)(ii).

Done at Washington, DC, on: September 27, 2004.
Barbara J. Masters,
Acting Administrator.
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