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§ 210.31 OMB control numbers.

The following control numbers have been assigned to the information collection requirements in 7 CFR part 210 by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96-511.

7 CFR section where requirements are described	Current OMB control No.
210.3(b)	0584-0327
210.5(d)	0584-0006
210.5(d)(1)	0584-0002
210.5(d)(2)	0584-0341
210.5(d)(3)	0584-0341
210.6(b)	0584-0006
210.8	0584-0006
	0584-0284
210.9	0584-0006
	0584-0026
	0584-0329
210.10(b)	0584-0006
210.10(i)(1)	0584-0006
210.14(c)	0584-0006
210.16	0584-0006
210.17	0584-0006
210.17(g)	0584-0075
210.18	0584-0006
210.19	0584-0006
210.22	0584-0006
210.23(c)	0584-0006
210.24	0584-0006
210.27	0584-0006

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APPENDIX A TO PART 210—ALTERNATE FOODS FOR MEALS

I. ENRICHED MACARONI PRODUCTS WITH FORTIFIED PROTEIN

1. Schools may utilize the enriched macaroni products with fortified protein defined in paragraph 3 as a food item in meeting the meal requirements of this part under the following terms and conditions:

(a) One ounce (28.35 grams) of a dry enriched macaroni product with fortified protein may be used to meet not more than one-half of the meat or meat alternate requirements specified in §210.10, when served in combination with 1 or more ounces (28.35

grams) of cooked meat, poultry, fish, or cheese. The size of servings of the cooked combination may be adjusted for various age groups.

(b) Only enriched macaroni products with fortified protein that bear a label containing substantially the following legend shall be so utilized: "One ounce (28.35 grams) dry weight of this product meets one-half of the meat or meat alternate requirements of lunch or supper of the USDA child nutrition programs when served in combination with 1 or more ounces (28.35 grams) of cooked meat, poultry, fish, or cheese. In those States where State or local law prohibits the wording specified, a legend acceptable to both the State or local authorities and FNS shall be substituted."

(c) Enriched macaroni product may not be used for infants under 1 year of age.

2. Only enriched macaroni products with fortified protein that have been accepted by FNS for use in the USDA Child Nutrition Programs may be labeled as provided in paragraph 1(b) of this appendix. Manufacturers seeking acceptance of their product shall furnish FNS a chemical analysis, the Protein Digestibility-Corrected Amino Acid Score (PDCAAS), and such other pertinent data as may be requested by FNS, except that prior to November 7, 1994, manufacturers may submit protein efficiency ratio analysis in lieu of the PDCAAS. This information is to be forwarded to: Director, Nutrition and Technical Services Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, room 607, Alexandria, VA 22302. All laboratory analyses are to be performed by independent or other laboratories acceptable to FNS. (FNS prefers an independent laboratory.) All laboratories shall retain the "raw" laboratory data for a period of 1 year. Such information shall be made available to FNS upon request. Manufacturers must notify FNS if there is a change in the protein portion of their product after the original testing. Manufacturers who report such a change in protein in a previously approved product must submit protein data in accordance with the method specified in this paragraph.

3. The product should not be designed in such a manner that would require it to be classified as a Dietary Supplement as described by the Food and Drug Administration (FDA) in 21 CFR part 105. To be accepted by FNS, enriched macaroni products with fortified protein must conform to the following requirements:

(a)(1) Each of these foods is produced by drying formed units of dough made with one or more of the milled wheat ingredients designated in 21 CFR 139.110(a) and 139.138(a), and other ingredients to enable the finished food to meet the protein requirements set out in paragraph 3.(a)(2)(i) under Enriched Macaroni Products with Fortified Protein in

this appendix. Edible protein sources, including food grade flours or meals made from nonwheat cereals or from oilseeds, may be used. Vitamin and mineral enrichment nutrients are added to bring the food into conformity with the requirements of paragraph (b) under Enriched Macaroni Products with Fortified Protein in this appendix. Safe and suitable ingredients, as provided for in paragraph (c) under Enriched Macaroni Products with Fortified Protein in this appendix, may be added. The proportion of the milled wheat ingredient is larger than the proportion of any other ingredient used.

(2) Each such finished food, when tested by the methods described in the pertinent sections of "Official Methods of Analysis of the AOAC International," (formerly the Association of Official Analytical Chemists), 15th Ed. (1990) meets the following specifications. This publication is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC International, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301. This publication may be examined at the Food and Nutrition Service, Nutrition and Technical Services Division, 3101 Park Center Drive, room 607, Alexandria, Virginia 22302 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(i) The protein content (N×6.25) is not less than 20 percent by weight (on a 13 percent moisture basis) as determined by the appropriate method of analysis in the AOAC manual cited in (a)(2) under Enriched Macaroni Products with Fortified Protein in this appendix. The protein quality is not less than 95 percent that of casein as determined on a dry basis by the PDCAAS method as described below:

(A) The PDCAAS shall be determined by the methods given in sections 5.4.1, 7.2.1. and 8.0 as described in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, as published by the Food and Agriculture Organization (FAO) of the United Nations/World Health Organization (WHO). This report is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this report may be obtained from the Nutrition and Technical Services Division, Food and Nutrition Service, 3101 Park Center Drive, room 607, Alexandria, Virginia 22302. This report may also be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(B) The standard used for assessing protein quality in the PDCAAS method is the amino acid scoring pattern established by FAO/WHO and United Nations University (UNU) in 1985 for preschool children 2 to 5 years of age which has been adopted by the National Academy of Sciences, Recommended Dietary Allowances (RDA), 1989.

(C) To calculate the PDCAAS for an individual food, the test food must be analyzed for proximate analysis and amino acid composition according to AOAC methods.

(D) The PDCAAS may be calculated using FDA's limited data base of published true digestibility values (determined using humans and rats). The true digestibility values contained in the WHO/FAO report referenced in paragraph 3.(a)(2)(i)(A) under Enriched Macaroni Products with Fortified Protein in this appendix may also be used. If the digestibility of the protein is not available from these sources it must be determined by a laboratory according to methods in the FAO/WHO report (sections 7.2.1 and 8.0).

(E) The most limiting essential amino acid (that is, the amino acid that is present at the lowest level in the test food compared to the standard) is identified in the test food by comparing the levels of individual amino acids in the test food with the 1985 FAO/WHO/UNU pattern of essential amino acids established as a standard for children 2 to 5 years of age.

(F) The value of the most limiting amino acid (the ratio of the amino acid in the test food over the amino acid value from the pattern) is multiplied by the percent digestibility of the protein. The resulting number is the PDCAAS.

(G) The PDCAAS of food mixtures must be calculated from data for the amino acid composition and digestibility of the individual components by means of a weighted average procedure. An example for calculating a PDCAAS for a food mixture of varying protein sources is shown in section 8.0 of the FAO/WHO report cited in paragraph 3.(a)(2)(i)(A) under Enriched Macaroni Products with Fortified Protein in this appendix.

(H) For the purpose of this regulation, each 100 grams of the product (on a 13 percent moisture basis) must contain protein in amounts which is equivalent to that provided by 20 grams of protein with a quality of not less than 95 percent casein. The equivalent grams of protein required per 100 grams of product (on a 13 percent moisture basis) would be determined by the following equation:

$$X = \frac{a \times b}{c}$$

X=grams of protein required per 100 grams of product

a=20 grams (amount of protein if casein)

b=.95 [95% × 1 (PDCAAS of casein)]

c=PDCAAS for protein used in formulation

(ii) The total solids content is not less than 87 percent by weight as determined by the methods described in the "Official Methods of Analysis of the AOAC International" cited in paragraph (a)(2) under Enriched Macaroni Products with Fortified Protein in this appendix.

(b)(1) Each pound of food covered by this section shall contain 5 milligrams of thiamine, 2.2 milligrams of riboflavin, 34 milligrams of niacin or niacinamide, and 16.5 milligrams of iron.

(2) Each pound of such food may also contain 625 milligrams of calcium.

(3) Only harmless and assimilable forms of iron and calcium may be added. The enrichment nutrients may be added in a harmless carrier used only in a quantity necessary to effect a uniform distribution of the nutrients in the finished food. Reasonable overages, within the limits of good manufacturing practice, may be used to assure that the prescribed levels of the vitamins and mineral(s) in paragraphs (b)(1) and (2) under Enriched Macaroni Products with Fortified Protein in this appendix are maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) Ingredients that serve a useful purpose such as to fortify the protein or facilitate production of the food are the safe and suitable ingredients referred to in paragraph (a) under Enriched Macaroni Products with Fortified Protein in this appendix. This does not include color additives, artificial flavorings, artificial sweeteners, chemical preservatives, or starches. Ingredients deemed suitable for use by this paragraph are added in amounts that are not in excess of those reasonably required to achieve their intended purposes. Ingredients are deemed to be safe if they are not food additives within the meaning of section 201(s) of the Federal Food, Drug and Cosmetic Act, or in case they are food additives if they are used in conformity with regulations established pursuant to section 409 of the act.

(d)(1) The name of any food covered by this section is "Enriched Wheat Macaroni Product with Fortified Protein", the blank being filled in with appropriate word(s) such as "Soy" to show the source of any flours or meals used that were made from non-wheat cereals or from oilseeds. In lieu of the words "Macaroni Product" the words "Macaroni", "Spaghetti", or "Vermicelli" as appropriate, may be used if the units conform in shape and size to the requirements of 21 CFR 139.110 (b), (c), or (d).

(2) When any ingredient not designated in the part of the name prescribed in paragraph (d)(1) under Enriched Macaroni Products with Fortified Protein in this appendix, is added in such proportion as to contribute 10 percent or more of the quantity of protein contained in the finished food, the name

shall include the statement "Made with _____", the blank being filled in with the name of each such ingredient, e.g. "Made with nonfat milk".

(3) When, in conformity with paragraph (d)(1) or (d)(2) under Enriched Macaroni Products with Fortified Protein in this appendix, two or more ingredients are listed in the name, their designations shall be arranged in descending order of predominance by weight.

(4) If a food is made to comply with a section of 21 CFR part 139, but also meets the compositional requirements of the Enriched Macaroni with Fortified Protein Appendix, it may alternatively bear the name set out in the other section.

(e) Each ingredient used shall declare its common name as required by the applicable section of 21 CFR part 101. In addition, the ingredients statement shall appear in letters not less than one half the size of that required by 21 CFR 101.105 for the declaration of net quantity of contents, and in no case less than one-sixteenth of an inch in height.

II. ALTERNATE PROTEIN PRODUCTS

A. What Are the Criteria for Alternate Protein Products Used in the National School Lunch Program?

1. An alternate protein product used in meals planned under the food-based menu planning approaches in §210.10(k), must meet all of the criteria in this section.

2. An alternate protein product whether used alone or in combination with meat or other meat alternates must meet the following criteria:

a. The alternate protein product must be processed so that some portion of the non-protein constituents of the food is removed. These alternate protein products must be safe and suitable edible products produced from plant or animal sources.

b. The biological quality of the protein in the alternate protein product must be at least 80 percent that of casein, determined by performing a Protein Digestibility Corrected Amino Acid Score (PDCAAS).

c. The alternate protein product must contain at least 18 percent protein by weight when fully hydrated or formulated. ("When hydrated or formulated" refers to a dry alternate protein product and the amount of water, fat, oil, colors, flavors or any other substances which have been added).

d. Manufacturers supplying an alternate protein product to participating schools or institutions must provide documentation that the product meets the criteria in paragraphs A2. a through c of this appendix.

e. Manufacturers should provide information on the percent protein contained in the dry alternate protein product and on an as prepared basis.

f. For an alternate protein product mix, manufacturers should provide information on:

- (1) the amount by weight of dry alternate protein product in the package;
- (2) hydration instructions; and
- (3) instructions on how to combine the mix with meat or other meat alternates.

B. How Are Alternate Protein Products Used in the National School Lunch Program?

1. Schools, institutions, and service institutions may use alternate protein products to fulfill all or part of the meat/meat alternate component discussed in §210.10.

2. The following terms and conditions apply:

a. The alternate protein product may be used alone or in combination with other food ingredients. Examples of combination items are beef patties, beef crumbles, pizza topping, meat loaf, meat sauce, taco filling, burritos, and tuna salad.

b. Alternate protein products may be used in the dry form (nonhydrated), partially hydrated or fully hydrated form. The moisture content of the fully hydrated alternate protein product (if prepared from a dry concentrated form) must be such that the mixture will have a minimum of 18 percent protein by weight or equivalent amount for the dry or partially hydrated form (based on the level that would be provided if the product were fully hydrated).

C. How Are Commercially Prepared Products Used in the National School Lunch Program?

Schools, institutions, and service institutions may use a commercially prepared meat or meat alternate product combined with alternate protein products or use a commercially prepared product that contains only alternate protein products.

[51 FR 34874, Sept. 30, 1986; 51 FR 41295, Nov. 14, 1986, as amended at 53 FR 29164, Aug. 2, 1988; 59 FR 51086, Oct. 7, 1994; 60 FR 31216; June 13, 1995; 61 FR 37671, July 19, 1996; 65 FR 12434, Mar. 9, 2000; 65 FR 26912, May 9, 2000; 69 FR 18803, Apr. 9, 2004]

APPENDIX B TO PART 210—CATEGORIES OF FOODS OF MINIMAL NUTRITIONAL VALUE

(a) *Foods of minimal nutritional value*—Foods of minimal nutritional value are:

(1) *Soda Water*—A class of beverages made by absorbing carbon dioxide in potable water. The amount of carbon dioxide used is not less than that which will be absorbed by the beverage at a pressure of one atmosphere and at a temperature of 60 °F. It either contains no alcohol or only such alcohol, not in excess of 0.5 percent by weight of the finished beverage, as is contributed by the flavoring ingredient used. No product shall be

excluded from this definition because it contains artificial sweeteners or discrete nutrients added to the food such as vitamins, minerals and protein.

(2) *Water Ices*—As defined by 21 CFR 135.160 Food and Drug Administration Regulations except that water ices which contain fruit or fruit juices are not included in this definition.

(3) *Chewing Gum*—Flavored products from natural or synthetic gums and other ingredients which form an insoluble mass for chewing.

(4) *Certain Candies*—Processed foods made predominantly from sweeteners or artificial sweeteners with a variety of minor ingredients which characterize the following types:

(i) *Hard Candy*—A product made predominantly from sugar (sucrose) and corn syrup which may be flavored and colored, is characterized by a hard, brittle texture, and includes such items as sour balls, fruit balls, candy sticks, lollipops, starlight mints, after dinner mints, sugar wafers, rock candy, cinnamon candies, breath mints, jaw breakers and cough drops.

(ii) *Jellies and Gums*—A mixture of carbohydrates which are combined to form a stable gelatinous system of jelly-like character, and are generally flavored and colored, and include gum drops, jelly beans, jellied and fruit-flavored slices.

(iii) *Marshmallow Candies*—An aerated confection composed as sugar, corn syrup, invert sugar, 20 percent water and gelatin or egg white to which flavors and colors may be added.

(iv) *Fondant*—A product consisting of microscopic-sized sugar crystals which are separated by thin film of sugar and/or invert sugar in solution such as candy corn, soft mints.

(v) *Licorice*—A product made predominantly from sugar and corn syrup which is flavored with an extract made from the licorice root.

(vi) *Spun Candy*—A product that is made from sugar that has been boiled at high temperature and spun at a high speed in a special machine.

(vii) *Candy Coated Popcorn*—Popcorn which is coated with a mixture made predominantly from sugar and corn syrup.

(b) *Petitioning Procedures*—Reconsideration of the list of foods of minimal nutritional value identified in paragraph (a) of this section may be pursued as follows:

(1) Any person may submit a petition to FNS requesting that an individual food be exempted from a category of foods of minimal nutritional value listed in paragraph (a). In the case of artificially sweetened foods, the petition must include a statement of the percent of Reference Daily Intake (RDI) for the eight nutrients listed in §210.11(a)(2) “Foods of minimal nutritional value,” that