

§ 137.350

21 CFR Ch. I (4-1-03 Edition)

germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.92 percent. Its moisture content is not more than 15 percent.

(b) For the purpose of this section, ash and moisture are determined by the methods therefor referred to in § 137.105(c).

§ 137.350 Enriched rice.

(a) The foods for which definitions and standards of identity are prescribed by this section are forms of milled rice (except rice coated with talc and glucose and known as coated rice), to which nutrients have been added so that each pound of the rice contains:

(1) Not less than 2.0 milligrams (mg) and not more than 4.0 mg of thiamin, not less than 1.2 mg and not more than 2.4 mg of riboflavin, not less than 16 mg and not more than 32 mg of niacin or niacinamide, not less than 0.7 mg and not more than 1.4 mg of folic acid, and not less than 13 mg and not more than 26 mg of iron (Fe).

(2) Each pound may contain not less than 250 U.S.P. units and not more than 1,000 U.S.P. units of vitamin D.

(3) Each pound may contain not less than 500 milligrams and not more than 1,000 milligrams of calcium (Ca). Calcium carbonate derived from the use of this substance in milling rice, when present in quantities that furnish less than 500 milligrams of calcium (Ca) per pound, is considered a normal ingredient of the milled rice used and not an optional ingredient of the enriched rice unless such enriched rice is labeled to show it contains the optional ingredient calcium. Iron and calcium may be added only in forms that are harmless and assimilable. The vitamins referred to in paragraphs (a) (1) and (2) of this section may be combined with harmless substances to render them insoluble in water, if the water-insoluble products are assimilable.

(4) In the case of enriched parboiled rice, butylated hydroxytoluene may be added as an optional ingredient in an amount not to exceed 0.0033 percent by weight of the finished food.

(b) The substances referred to in paragraphs (a) (1), (2), and (3) of this section may be added in a harmless

carrier. Such carrier is used only in the quantity necessary to effect an intimate and uniform mixture of such substances with the rice.

(c) Unless the label of the food bears the statement "To retain vitamins do not rinse before or drain after cooking" immediately preceding or following the name of the food and in letters not less than one-fourth the point size of type used for printing the name of the food (but in no case less than 8-point type) and the label bears no cooking directions calling for washing or draining or unless the food is precooked and it is packaged in consumer packages which are conspicuously and prominently labeled with directions for preparation which, if followed, will avoid washing away or draining off enriching ingredients, the substances named in paragraphs (a) (1), (2), and (3) of this section shall be present in such quantity or in such form that when the enriched rice is washed as prescribed in paragraph (e) of this section, the washed rice contains not less than 85 percent of the minimum quantities of the substances named in paragraph (a)(1) of this section, as required for enriched rice; and in case any optional ingredients named in paragraphs (a) (2) and (3) of this section are used, the washed rice also contains not less than 85 percent of the minimum quantity specified for the substance or substances used.

(d) The name specified for each food for which a definition and standard of identity is prescribed by this section is the common name of the kind of milled rice to which the enriching substances are added, preceded by the word "enriched" as, for example, "Enriched rice" or "Enriched parboiled rice".

(e) The method referred to in paragraph (c) of this section is as follows: Mix the contents of one or more containers and transfer ½ pound thereof to a 4-liter flask containing 2 liters of distilled water at room temperature (but not below 20 °C). Stopper the flask and swirl it moderately for ½ minute so that the rice is in motion and in uniform suspension. Allow the rice to settle for ½ minute, then pour off 1,600 milliliters of the water, together with any floating and suspended matter, and discard. To the contents of the flask, add 1,600 milliliters of distilled water

and 20 milliliters of 10 *N* hydrochloric acid. Agitate vigorously and wash down the sides of the flask with 150 milliliters of 0.1 *N* hydrochloric acid. In order to avoid excess foaming during the extraction, heat the mixture slowly to about 100 °C, agitate if necessary, and maintain at this temperature until air is expelled. Again wash down the sides of the flask with 150 milliliters of 0.1 *N* hydrochloric acid. Heat the mixture in an autoclave at 120 °C to 123 °C for 30 minutes, remove and cool to room temperature. Dilute the mixture with distilled water so that the total volume is 2,500 milliliters. Swirl the flask, and while the solids are in uniform suspension pour off about 250 milliliters of the mixture for later determination of iron (and calcium, if this is to be determined). With filter paper that has been shown not to adsorb thiamine, riboflavin, or niacin, filter enough of the remaining mixture for determination of thiamine, riboflavin, and niacin. (In the case of a mixture difficult to filter, centrifuging or filtering through fritted glass, or both, using a suitable analytical filter-aid, may be substituted for, or may precede, filtering through paper.) Dilute an aliquot of filtrate with 0.1 *N* hydrochloric acid, so that each milliliter contains about 0.2 microgram of thiamine, and determine thiamine by the "Rapid Fluorometric Method—Official Final Action," in section 43.034 of "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. With a suitable aliquot determine riboflavin by the method prescribed in section 43.041(a) by the "Fluorometric Method—Official Final Action," AOAC, 13th Ed. (1980), beginning with the third sentence of the second paragraph, "Adjust, with vigorous agitation * * *." Determine niacin in a 200-milliliter aliquot of the filtrate by the "Colorimetric Method—Official Final Action," in section 43.045, AOAC, 13th

Ed. (1980), beginning with the sixth sentence of the first paragraph, "Adjust to pH 4.5 with * * *." Evaporate to dryness a 100-milliliter aliquot of the non-filtered material withdrawn while agitating, and determine iron using the method "Iron—Official Final Action," in sections 14.011, 14.012, and 14.013, AOAC, 13th Ed. (1980), and, if required, determine calcium as directed in section 14.014 under the heading "Calcium—Official Final Action," AOAC, 13th Ed. (1980).

(f) When the optional ingredient specified in paragraph (a)(4) of this section is added, the statement "Butylated hydroxytoluene added as a preservative" shall be placed on the label prominently and with such conspicuousness (as compared with other words, statements, designs, or devices in the label) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

NOTE: The Order of the Commissioner of Food and Drugs appearing at 23 FR 1170, Feb. 25, 1958, amending paragraphs (a)(1) and (c) provides in part as follows: The regulations in § 137.350 (formerly § 15.525) are stayed insofar as they require each pound of the food to contain not less than 1.2 milligrams and not more than 2.4 milligrams of riboflavin. This stay shall continue until final action is taken disposing of the objections, after public hearing thereon.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11828, Mar. 19, 1982; 49 FR 10098, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2878, Jan. 6, 1993; 61 FR 8796, Mar 5, 1996]

PART 139—MACARONI AND NOODLE PRODUCTS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Macaroni and Noodle Products

- Sec.
 139.110 Macaroni products.
 139.115 Enriched macaroni products.
 139.117 Enriched macaroni products with fortified protein.
 139.120 Milk macaroni products.