Food and Drug Administration, HHS

§ 137.350

(2) Vitamin D may be added in such quantity that each pound of the finished enriched farina contains not less than 250 U.S.P. units of the optional ingredient vitamin D.

(3) Calcium may be added in such quantity that each pound of the finished enriched farina contains not less than 500 milligrams of the optional ingredient calcium (Ca).

(4) It may contain not more than 8 percent by weight of the optional ingredient wheat germ or partly defatted wheat germ.

(5)(i) It may contain not less than 0.5 percent and not more than 1 percent by weight of the optional ingredient disodium phosphate; or

(ii) It may be treated with one of the proteinase enzymes papain or pepsin to reduce substantially the time required for cooking. In such treatment papain or pepsin, in an amount not to exceed 0.1 percent by weight, is added to the farina, which is moistened, warmed, and subsequently heated sufficiently to inactivate the enzyme and to dry the product to comply with the limit for moisture prescribed by § 137.300(a).

(6) In determining whether the ash content complies with the requirements of this section allowance is made for ash resulting from any added iron or salts of iron or calcium, or from any added disodium phosphate, or from any added wheat germ or partly defatted wheat germ.

Iron and calcium may be added only in forms which are harmless and assimilable. Dried irradiated yeast may be used as a source of vitamin D. The substances referred to in paragraphs (a) (1) and (2) of this section may be added in a harmless carrier which does not impair the enriched farina; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the farina.

(b)(1) 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.

(b)(2) Label declaration. When the optional ingredient disodium phosphate is used, the label shall bear the statement “Disodium phosphate added for quick cooking”. When the proteinase enzyme treatment is used, the label shall bear the statement “Enzyme treated for quicker cooking”.

§ 137.320 Semolina.

(a) Semolina is the food prepared by grinding and bolting cleaned durum wheat to such fineness that, when tested by the method prescribed in § 137.300(b)(2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and 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 ¼ 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. 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 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 pre-
cede, filtering through paper.) Dilute an aliquot of filtrate with 0.1 N hydro-
chloric acid, so that each milliliter contains about 0.2 microgram of thi-
amine, and determine thiamine by the “Rapid Fluorometric Method—Official Final Action,” in section 43.034 of “Of-
ficial Methods of Analysis of the Asso-
ciation of Official Analytical Chem-
ists” (AOAC, 13th Ed. (1980), which is incorporated by reference. Copies may 
be obtained from the AOAC INTER-
ATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or 
may be examined at the National Ar-
chives and Records Administration 
(NARA). For information on the avail-
bility 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. With a suitable ali-
quot determine riboflavin by the meth-
od prescribed in section 43.041(a) by the 
“Fluorometric Method—Official Final Action,” AOAC, 13th Ed. (1980), begin-
ning with the third sentence of the sec-
ond 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, “Ad-
just to pH 4.5 with * * *.” Evaporate to 
dryness a 100-milliliter aliquot of the nonfiltered 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 sec-
tion 14.014 under the heading “Cal-

(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 con-
spicuousness (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 in-
gredients used in the food shall be de-
claried 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. 
20, 1958, amending paragraphs (a)(1) and (c) 
provides in part as follows: The regulations 
in §137.350 (formerly §15.325) are stayed inso-
far 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 pub-
lic 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 26894, June 12, 1989; 58 FR 2978, 
Jan. 6, 1993; 61 FR 8796, Mar. 5, 1996]