Scientific name of crab	Common or usual name of crabmeat
Chionoecetes opilio, Chionoecetes tanneri, Chionoecetes bairdii, and Chionoecetes angulatus.	Snow crabmeat.
Erimacrus isenbeckii	Korean variety crabmeat or Kegani crabmeat.
Lithodes aequispinus	Golden King crabmeat.
Paralithodes brevipes	King crabmeat or Hanasaki crabmeat.
Paralithodes camtschaticus and Paralithodes platypus.	King crabmeat.

[42 FR 14322, Mar. 15, 1977, as amended at 60 FR 34460, July 3, 1995; 83 FR 19431, May 3, 2018]

§ 102.54 Seafood cocktails.

The common or usual name of a seafood cocktail in package form fabricated with one or more seafood ingredients shall be:

(a) When the cocktail contains only one seafood ingredient, the name of the seafood ingredient followed by the word ''cocktail'' (e.g., shrimp cocktail, crabmeat cocktail) and a statement of the percentage by weight of that seafood ingredient in the product in the manner set forth in §102.5(b).

(b) When the cocktail contains more than one seafood ingredient, the term ''seafood cocktail'' and a statement of the percentage by weight of each seafood ingredient in the product in the manner set forth in §102.5(b).

§ 102.55 Nonstandardized breaded composite shrimp units.

(a) The common on usual name of the food product that conforms to the definition and standard of identity described by §161.175(c)(6) of this chapter, except that the food is made from comminuted shrimp and is not in raw frozen form, shall be ''_____ made from minced shrimp,'' the blank to be filled in with the words ''breaded shrimp sticks'' or ''breaded shrimp cutlets'' depending upon the shape of the product, or if prepared in a shape other than that of sticks or cutlets ''breaded shrimp _____ made from minced shrimp,'' the blank to be filled by a word or phrase that accurately describes the shape and that is not misleading.

(b) The words ''made from minced shrimp'' shall immediately follow or appear on a line(s) immediately below the other words required by this section in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(1) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and no less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(2) Not less than one-half the height of the largest type used in the words ''breaded shrimp sticks'' or the other comparable words required by this section.

§ 102.57 Greenland turbot (*Reinhardtius hippoglossoides*).

''Greenland turbot'' is the common or usual name of the food fish *Reinhardtius hippoglossoides*, a species of *Pleuronectidae* right-eye flounders. The term ''halibut'' may be associated only with Atlantic halibut (*Hippoglossus hippoglossus*) or Pacific halibut (*Hippoglossus stenolepis*).

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

Subpart A—General Provisions

Subpart B—Fortification Policy

Subpart C—Specific Nutritional Quality Guidelines

AUTHORITY: 21 U.S.C. 321, 343, 371(a).

SOURCE: 42 FR 14327, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 104.5 General principles.

(a) A nutritional quality guideline prescribes the minimum level or range of nutrient composition (nutritional

quality) appropriate for a given class of food.

(b) Labeling for a product which complies with all of the requirements of the nutritional quality guideline established for its class of food may state ''This product provides nutrients in amounts appropriate for this class of food as determined by the U.S. Government,'' except that the words ''this product'' are optional. This statement, if used, shall be printed on the principal display panel, and may also be printed on the information panel, in letters not larger than twice the size of the minimum type required for the declaration of net quantity of contents by §101.7 of this chapter. Labeling of noncomplying products may not include any such statement or otherwise represent, suggest, or imply the product as being, in whole or in part, in compliance with a guideline.

(c) A product bearing the statement provided for in paragraph (b) of this section, in addition to meeting the requirements of the applicable nutritional quality guideline, shall comply with the following requirements:

(1) The label of the product shall bear the common or usual name of the food in accordance with the provisions of the guideline and §§101.3 and 102.5(a) of this chapter.

(2) The label of the product shall bear nutrition labeling in accordance with §§101.2 and 101.9 of this chapter and all other labeling required by applicable sections of part 101 of this chapter.

(d) No claim or statement may be made on the label or in labeling representing, suggesting, or implying any nutritional or other differences between a product to which nutrient addition has or has not been made in order to meet the guideline, except that a nutrient addition shall be declared in the ingredient statement.

(e) Compliance with a nutrient level specified in a nutritional quality guideline shall be determined by the procedures and requirements established in §101.9(g) of this chapter.

(f) A product within a class of food for which a nutritional quality guideline has been established and to which has been added a discrete nutrient either for which no minimum nutrient level or nutrient range or other allowance has been established as appropriate in the nutritional quality guideline, or at a level that exceeds any maximum established as appropriate in the guideline, shall be ineligible to bear the guideline statement provided for in paragraph (b) of this section, and such a product shall also be deemed to be misbranded under the act unless the label and all labeling bear the following prominent and conspicuous statement: ''The addition of _____ to (or ''The addition of _____ at the level contained in) this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food,'' the blank to be filled in with the common or usual name of the nutrient(s) involved.

[42 FR 14327, Mar. 15, 1977, as amended at 63 FR 14818, Mar. 27, 1998; 81 FR 59131, Aug. 29, 2016]

Subpart B—Fortification Policy

§ 104.20 Statement of purpose.

(a) The fundamental objective of this subpart is to establish a uniform set of principles that will serve as a model for the rational addition of nutrients to foods. The achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective. The addition of nutrients to specific foods can be an effective way of maintaining and improving the overall nutritional quality of the food supply. However, random fortification of foods could result in over- or underfortification in consumer diets and create nutrient imbalances in the food supply. It could also result in deceptive or misleading claims for certain foods. The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. To preserve a balance of nutrients in the diet, manufacturers who elect to fortify foods are urged to utilize these principles when adding nutrients to food. It is reasonable to anticipate that the Reference Daily Intakes (RDI's) as delineated in §101.9 of this chapter and

in paragraph (d) of this section will be amended from time to time to list additional nutrients and/or to change the levels of specific RDI's as improved knowledge about human nutrient requirements and allowances develops. The policy set forth in this section is based on U.S. dietary practices and nutritional needs and may not be applicable in other countries.

(b) A nutrient(s) listed in paragraph (d)(3) of this section may appropriately be added to a food to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency disease if:

(1) Sufficient information is available to identify the nutritional problem and the affected population groups, and the food is suitable to act as a vehicle for the added nutrients. Manufacturers contemplating using this principle are urged to contact the Food and Drug Administration before implementing a fortification plan based on this principle.

(2) The food is not the subject of any other Federal regulation for a food or class of food that requires, permits, or prohibits nutrient additions. (Other Federal regulations include, but are not limited to, standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, nutritional quality guidelines established in subpart C of this part, and common or usual name regulations established in part 102 of this chapter.)

(c) A nutrient(s) listed in paragraph (d)(3) of this section may appropriately be added to a food to restore such nutrient(s) to a level(s) representative of the food prior to storage, handling, and processing, when:

(1) The nutrient is shown by adequate scientific documentation to have been lost in storage, handling, or processing in a measurable amount equal to at least 2 percent of the Daily Reference Value (DRV) of protein and of potassium and 2 percent of the Reference Daily Intake (RDI) in a normal serving of the food.

(2) Good manufacturing practices and normal storage and handling procedures cannot prevent the loss of such nutrient(s),

(3) All nutrients, including protein, iodine and vitamin D, that are lost in a measurable amount are restored and all ingredients of the food product that contribute nutrients are considered in determining restoration levels; and

(4) The food is not the subject of any other Federal regulation that requires or prohibits nutrient addition(s), or the food has not been fortified in accordance with any other Federal regulation that permits voluntary nutrient additions.

(d) A nutrient(s) listed in paragraph (d)(3) of this section may be added to a food in proportion to the total caloric content of the food, to balance the vitamin, mineral, and protein content if:

(1) A normal serving of the food contains at least 40 kilocalories (that is, 2 percent of a daily intake of 2,000 kilocalories);

(2) The food is not the subject of any other Federal regulation for a food or class of food that requires, permits, or prohibits nutrient additions; and

(3) The food contains all of the following nutrients per 100 calories based on 2,000 calorie total intake as a daily standard:

Nutrient	Unit of measurement	DRV or RDI [1]	Amount per 100 calories
Protein	grams (g)	50	2.5
Vitamin A	International Unit (IU)	5,000	250
Vitamin C	milligrams (mg)	60	3
Calcium	g	1	0.05
Iron	mg	18	0.9
Vitamin D	IU	400	20
Vitamin E	do	30	1.5
Thiamin	mg	1.5	0.08
Riboflavin	do	1.7	0.09
Niacin	do	20	1
Vitamin B_6	do	2.0	0.1
Folate	micrograms (μg)	400	20
Vitamin B_{12}	do	6.0	0.3
Biotin	mg	0.3	0.015
Pantothenic acid	do	10	0.5
Phosphorus	g	1.0	0.05
Magnesium	mg	400	20
Zinc	do	15	0.8
Iodine	μg	150	7.5
Copper	mg	2.0	0.1
Potassium	do	3,500	175

[1] RDI's for adults and children 4 or more years of age.

(e) A nutrient(s) may appropriately be added to a food that replaces traditional food in the diet to avoid nutritional inferiority in accordance with §101.3(e)(2) of this chapter.

(f) Nutrient(s) may be added to foods as permitted or required by applicable

regulations established elsewhere in this chapter.

(g) A nutrient added to a food is appropriate only when the nutrient:

(1) Is stable in the food under customary conditions of storage, distribution, and use;

(2) Is physiologically available from the food;

(3) Is present at a level at which there is a reasonable assurance that consumption of the food containing the added nutrient will not result in an excessive intake of the nutrient, considering cumulative amounts from other sources in the diet; and

(4) Is suitable for its intended purpose and is in compliance with applicable provisions of the act and regulations governing the safety of substances in food.

(h) Any claims or statements in the labeling of food about the addition of a vitamin, mineral, or protein to a food shall be made only if the claim or statement is not false or misleading and otherwise complies with the act and any applicable regulations. The following label claims are acceptable:

(1) The labeling claim ''fully restored with vitamins and minerals'' or ''fully restored with vitamins and minerals to the level of unprocessed _____'' (the blank to be filled in with the common or usual name of the food) may be used to describe foods fortified in accordance with the principles established in paragraph (c) of the section.

(2) The labeling claim, ''vitamins and minerals (and ''protein'' when appropriate) added are in proportion to caloric content'' may be used to describe food fortified in accordance with the principles established in paragraph (d) of this section.

(3) When labeling claims are permitted, the term ''enriched,'' ''fortified,'' ''added,'' or similar terms may be used interchangeably to indicate the addition of one or more vitamins or minerals or protein to a food, unless an applicable Federal regulation requires the use of specific words or statements.

(i) It is inappropriate to make any claim or statement on a label or in labeling, other than in a listing of the nutrient ingredients as part of the ingredient statement, that any vitamin, mineral, or protein has been added to a food to which nutrients have been added pursuant to paragraph (e) of this section.

[45 FR 6323, Jan. 25, 1980, as amended at 58 FR 2228, Jan. 6, 1993]

Subpart C—Specific Nutritional Quality Guidelines

§ 104.47 Frozen "heat and serve" dinner.

(a) A product, for which a common or usual name is established in § 102.26 of this chapter, in order to be eligible to bear the guideline statement set forth at § 104.5(b), shall contain at least the following three components:

(1) One or more sources of protein derived from meat, poultry, fish, cheese, or eggs.

(2) One or more vegetables or vegetable mixtures other than potatoes, rice, or cereal-based product.

(3) Potatoes, rice, or cereal-based product (other than bread or rolls) or another vegetable or vegetable mixture.

(b) The three or more components named in paragraph (a) of this section, including their sauces, gravies, breading, etc.:

(1) Shall contribute not less than the minimum levels of nutrients prescribed in paragraph (d) of this section.

(2) Shall be selected so that one or more of the listed protein sources of paragraph (a)(1) of this section, excluding their sauces, gravies, breading, etc., shall provide not less than 70 percent of the total protein supplied by the components named in paragraph (a) of this section.

(c) If it is necessary to add any nutrient(s) in order to meet the minimum nutrient levels prescribed in paragraph (d) of this section, the addition of each such nutrient may not result in a total nutrient level exceeding 150 percent of the minimum level prescribed. Nutrients used for such addition shall be biologically available in the final product.

(d) Minimum levels of nutrients for a frozen ''heat and serve'' dinner are as follows:

Nutrient	Minimum levels for frozen "heat and serve" dinner—	
	For each 100 Calories (kcal) of the total components specified in par. (a)	For the total components specified in par. (a)
Protein, grams	4.60	16.0
Vitamin A, IU	150.00	520.0
Thiamine, mg	.05	.2
Riboflavin, mg	.06	.2
Niacin, mg	.99	3.4
Pantothenic acid, mg	.32	1.1
Vitamin, B_6, mg	.15	.5
Vitamin, B_1	.33	1.1
Iron, mg	.62	2.2

(1) A frozen ''heat and serve'' dinner prepared from conventional food ingredients listed in paragraph (a) of this section will also contain folic acid, magnesium, iodine, calcium, and zinc. Minimum levels for these nutrients cannot be established at the present time but may be specified as additional data are obtained.

(2) The minimum levels for pantothenic acid, vitamin B–6, and vitamin B–12 are tentative. Final levels will be established when sufficient data are available. Until final levels are established, a product containing less than the tentative levels will not be deemed to be misbranded when labeled in accordance with §104.5(b).

(3) When technologically practicable, iodized salt shall be used or iodine shall be present at a level equivalent to that which would be present if iodized salt were used in the manufacture of the product.

(4) When technologically practicable, product components and ingredients shall be selected to obtain the desirable calcium to phosphorous ratio of 1:1. Technological addition of phosphates shall be minimized and shall not exceed the amount necessary for the intended effect.

(e) If the product includes servings of food which are not prescribed by paragraph (a) of this section (e.g., soup, bread or rolls, beverage, or dessert), their contribution shall not be considered in determining compliance with the nutrient levels established in paragraph (d) of this section but shall be included in any nutrition labeling.

(f) For the purposes of labeling, an ''average serving'' shall be one entire frozen ''heat and serve'' dinner.

[42 FR 14327, Mar. 5, 1977]

PART 105—FOODS FOR SPECIAL DIETARY USE

Subpart A—General Provisions

Sec.
105.3 Definitions and interpretations.

Subpart B—Label Statements

105.62 Hypoallergenic foods.
105.65 Infant foods.
105.66 Label statements relating to usefulness in reducing or maintaining body weight.

Subpart C [Reserved]

Subpart D—Standards of Identity [Reserved]

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 350, 371, 379e.

SOURCE: 42 FR 14328, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 105.3 Definitions and interpretations.

The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (hereafter ''the act'') shall be applicable with the following additions:

(a)(1) The term *special dietary uses*, as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless