as a statistically significant difference with at least a probability (P) value of less than 0.05.

(4) The amount of the additive added for nutritive purposes plus the amount naturally present in free and combined (as protein) form does not exceed the following levels of amino acids expressed as percent by weight of the total protein of the finished food:

	Percent by weight of total protein (expressed as free amino acid)
L-Alanine	6.1
L-Arginine	6.6
L-Aspartic acid (including L-asparagine)	7.0
L-Cystine (including L-cysteine)	2.3
L-Glutamic acid (including L-glutamine)	12.4
Aminoacetic acid (glycine)	3.5
L-Histidine	2.4
L-Isoleucine	6.6
L-Leucine	8.8
L-Lysine	6.4
L- and DL-Methionine	3.1
L-Phenylalanine	5.8
L-Proline	4.2
L-Serine	8.4
L-Threonine	5.0
L-Tryptophan	1.6
L-Tyrosine	4.3
L-Valine	7.4

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in sections 43.212–43.216, ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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*. Each manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation and shall make such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health and Human Services and shall permit such officer or employee to conduct such inventories of raw and finished materials on hand as he deems necessary and otherwise to check the correctness of such records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the amino acid(s) contained therein including the specific optical and chemical form.

(2) The amounts of each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) The food additive amino acids added as nutrients to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and comply with the requirements of part 105 of this chapter are exempt from the limitations in paragraphs (c) and (d) of this section and may be used in such foods at levels not to exceed good manufacturing practices.

[42 FR 14491, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 47 FR 11836, Mar. 19, 1982; 49 FR 10104, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 59 FR 14550, Mar. 29, 1994; 61 FR 14480, Apr. 2, 1996]

§ 172.325 Bakers yeast protein.

Bakers yeast protein may be safely used in food in accordance with the following conditions:

(a) Bakers yeast protein is the insoluble proteinaceous material remaining after the mechanical rupture of yeast cells of *Saccharomyces cerevisiae* and removal of whole cell walls by centrifugation and separation of soluble cellular materials.

(b) The additive meets the following specifications on a dry weight basis:

(1) Zinc salts less than 500 parts per million (ppm) as zinc.

(2) Nucleic acid less than 2 percent.

(3) Less than 0.3 ppm arsenic, 0.1 ppm cadmium, 0.4 ppm lead, 0.05 ppm mercury, and 0.3 ppm selenium.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

§ 172.330 Calcium pantothenate, calcium chloride double salt.

The food additive calcium chloride double salt of calcium pantothenate may be safely used in foods for special dietary uses in accordance with good manufacturing practice and under the following prescribed conditions:

(a) The food additive is of the *d* (dextrorotatory) or the *dl* (racemic) form.

(b) To assure safe use of the additive, the label and labeling of the food additive container, or that of any intermediate premixes prepared therefrom, shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive ''calcium chloride double salt of *d*-calcium pantothenate'' or ''calcium chloride double salt of *dl*-calcium pantothenate'', whichever is appropriate.

(2) A statement of the appropriate concentration of the additive, expressed as pantothenic acid.

§ 172.335 D-Pantothenamide.

The food additive D-pantothenamide as a source of pantothenic acid activity, may be safely used in foods for special dietary use in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.340 Fish protein isolate.

(a) The food additive fish protein isolate may be safely used as a food supplement in accordance with the following prescribed conditions:

(1) The additive shall consist principally of dried fish protein prepared from the edible portions of fish after removal of the heads, fins, tails, bones, scales, viscera, and intestinal contents.

(2) The additive shall be derived only from species of bony fish that are generally recognized by qualified scientists as safe for human consumption and that can be processed as prescribed to meet the required specifications.

(3) Only wholesome fresh fish otherwise suitable for human consumption may be used. The fish shall be handled expeditiously under sanitary conditions. These conditions shall be in accordance with recognized good manufacturing practice for fish to be used as human food.

(4) The additive shall be prepared by extraction with hexane and food-grade ethanol to remove fat and moisture. Solvent residues shall be reduced by drying.

(b) The food additive meets the following specifications: (Where methods of determination are specified, they are Association of Official Analytical Chemists Methods, 13th ed., 1980, which are incorporated by reference).[1]

(1) Protein content, as N × 6.25, shall not be less than 90 percent by weight of the final product, as determined by the method described in section 2.057, Improved Kjeldahl Method for Nitrate-Free Samples (20)—Official Final Action.

(2) Moisture content shall not be more than 10 percent by weight of the final product, as determined by the method described in section 24.003, Air Drying (1)—Official First Action.

(3) Fat content shall not be more than 0.5 percent by weight of the final product, as determined by the method described in section 24.005, Crude Fat or Ether Extract—Official Final Action.

(4) Solvent residues in the final product shall not be more than 5 parts per

[1] Copies are available from: AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or examined 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*.