**[Excerpt]**

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**[Page 260-267]**

**TITLE 21--FOOD AND DRUGS**

**CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--CONTINUED**

**PART 130--FOOD STANDARDS: GENERAL--Table of Contents**

Subpart A--General Provisions

Sec. 130.3 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the act shall be applicable also to such terms when used in regulations promulgated under the act.

(b) If a regulation prescribing a definition and standard of identity for a food has been promulgated under section 401 of the act and the name therein specified for the food is used in any other regulation under section 401 or any other provision of the act, such name means the food which conforms to such definition and standard, except as otherwise specifically provided in such other regulation.

(c) No provision of any regulation prescribing a definition and standard of identity or standard of quality or fill of

[[Page 261]]

container under section 401 of the act shall be construed as in any way affecting the concurrent applicability of the general provisions of the act and the regulations thereunder relating to adulteration and misbranding. For example, all regulations under section 401 contemplate that the food and all articles used as components or ingredients thereof shall not be poisonous or deleterious and shall be clean, sound, and fit for food. A provision in such regulations for the use of coloring or flavoring does not authorize such use under circumstances or in a manner whereby damage or inferiority is concealed or whereby the food is made to appear better or of greater value than it is.

(d) ``Safe and suitable'' means that the ingredient:

(1) Performs an appropriate function in the food in which it is used.

(2) Is used at a level no higher than necessary to achieve its intended purpose in that food.

(3) Is not a food additive or color additive as defined in section 201 (s) or (t) of the Federal Food, Drug, and Cosmetic Act as used in that food, or is a food additive or color additive as so defined and is used in conformity with regulations established pursuant to section 409

or 721 of the act.

(e) Section 403(i) of the act requires the listing of all ingredients in standardized foods. All ingredients must be listed in accordance with the requirements of part 101 of this chapter, except that where a definition and standard of identity has specific labeling provisions for optional ingredients, optional ingredients may be declared in accordance with those provisions.

[42 FR 14357, Mar. 15, 1977, as amended at 58 FR 2876, Jan. 6, 1993]

Sec. 130.5 Procedure for establishing a food standard.

(a) The procedure for establishing a food standard under section 401 of the act shall be governed by part 10 of this chapter.

(b) Any petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Any petition for a food standard shall assert that the petitioner commits himself to substantiate the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

(d) If a petitioner fails to appear, or to substantiate the information in his petition, at a public hearing on the matter, the Commissioner may either (1) withdraw the regulation and terminate the proceeding or (2) if he concludes that it is in accordance with the requirements of section 401 of the act, continue the proceeding and introduce evidence to substantiate such information.

[42 FR 14357, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

Sec. 130.6 Review of Codex Alimentarius food standards.

(a) All food standards adopted by the Codex Alimentarius Commission will be reviewed by the Food and Drug Administration and will be accepted without change, accepted with change, or not accepted.

(b) Review of Codex standards will be accomplished in one of the following three ways:

(1) Any interested person may petition the Commissioner to adopt a Codex standard, with or without change, by proposing a new standard or an appropriate amendment of an existing standard, pursuant to section 401 of the act. Any such petition shall specify any deviations from the Codex standard, and the reasons for any such deviations. The Commissioner shall publish such a petition in the Federal Register as a proposal, with an opportunity for comment, if reasonable grounds are provided in the petition. Any published proposal shall state any deviations from the Codex standard and the stated reasons therefor.

(2) The Commissioner may on his own initiative propose by publication in the Federal Register the adoption of a Codex standard, with or without change, through a new standard or an appropriate amendment to an existing standard, pursuant to section 401 of the act. Any such proposal shall specify any deviations from the Codex standard, and the reasons for any such deviations.

(3) Any Codex standard not handled under paragraph (b) (1) or (2) of this section may be published in the

Federal Register for review and informal comment. Interested persons shall be requested to comment on the desirability and need for the standard, on the specific provisions of the standard, on additional or different provisions that should be included in the standard, and on any other pertinent points. After reviewing all such comments, the Commissioner either shall publish a proposal to establish a food standard pursuant to section 401 of the act covering the food involved, or shall publish a notice terminating consideration of such a standard.

(c) All interested persons are encouraged to confer with different interest groups (consumers, industry, the academic community, professional organizations, and others) in formulating petitions or comments pursuant to paragraph (b) of this section. All such petitions or comments are requested to include a statement of any meetings and discussions that have been held with other interest groups. Appropriate weight will be given by the Commissioner to petitions or comments that reflect a consensus of different interest groups.

Sec. 130.8 Conformity to definitions and standards of identity.

In the following conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard, unless such ingredient is an incidental additive introduced at a nonfunctional and insignificant level as a result of its deliberate and purposeful addition to another ingredient permitted by the terms of the applicable standard and the presence of such incidental additive in unstandardized foods has been exempted from label declaration as provided in Sec. 101.100 of this chapter.

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

Sec. 130.9 Sulfites in standardized food.

(a) Any standardized food that contains a sulfiting agent or combination of sulfiting agents that is functional and provided for in the applicable standard or that is present in the finished food at a detectable level is misbranded unless the presence of the sulfiting agent or agents is declared on the label of the food. A detectable amount of sulfiting agent is 10 parts per million or more of the sulfite in the finished food. The level of sulfite in the finished food will be determined using sections 20.123 through 20.125, ``Sulfurous Acid (Total) in Food Modified Monier-Williams Method Final Action'' in ``Official Methods of Analysis of the Association of Official Analytical Chemists,'' 14th ed. (1984), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and the refinements of the ``Total Sulfurous Acid'' procedure in the ``Monier-Williams Procedure (with Modifications) for Sulfites in Foods,'' which is appendix A to part 101 of this chapter. A copy of sections 20.123 through 20.125 of the ``Official Methods of Analysis of the Association of Official Analytical Chemists'' is available from AOAC International, 1111 North 19th St., Suite 210, Arlington, VA 22209, or available for inspection at the Office of the Federal Register, 800 North Capitol St.

NW., Suite 700, Washington, DC.

(b) Any standardized food that, as a result of actions that are consistent with current good manufacturing practice, contains an indirectly added sulfiting agent that has no functional effect in the food and that would, in the absence of Sec. 101.100(a)(4) of this chapter, be considered to be an incidental additive for purposes of Sec. 130.8, conforms to the applicable definition and standard of identity if the presence of the sulfiting agent is declared on the label of the food.

[58 FR 2876, Jan. 6, 1993]

Sec. 130.10 Requirements for foods named by use of a nutrient content claim and a standardized term.

(a) Description. The foods prescribed by this general definition and standard of identity are those foods that substitute (see Sec. 101.13(d) of this chapter)

[[Page 263]]

for a standardized food defined in parts 131 through 169 of this chapter and that use the name of that standardized food in their statement of identity but that do not comply with the standard of identity because of a deviation that is described by an expressed nutrient content claim that has been defined by FDA regulation. The nutrient content claim shall comply with the requirements of Sec. 101.13 of this chapter and with the requirements of the regulations in part 101 of this chapter that define the particular nutrient content claim that is used. The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b), (c), and (d) of this section.

(b) Nutrient addition. Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in Sec. 101.3(e)(4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter. The addition of nutrients shall be reflected in the ingredient statement.

(c) Performance characteristics. Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food. Deviations from ingredient and noningredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim while maintaining similar performance characteristics as the standardized food, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, flavor characteristics, functional properties, shelf life) of the food shall be similar to those of the standardized food as produced under parts 131 through 169 of this chapter, except that if there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, ``not recommended for cooking''). Such statement shall comply with the requirements of Sec. 101.13(d) of this chapter. The modified product shall perform at least one of the

principal functions of the standardized product substantially as well as the standardized product.

(d) Other ingredients. (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in parts 131 through 169 of this chapter and in paragraph (b) of this section, except that safe and suitable ingredients may be used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food defined in parts 131 through 169 of this chapter.

(2) An ingredient or component of an ingredient that is specifically required by the standard (i.e., a mandatory ingredient) as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169 of this chapter, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream).

(3) An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section.

(4) An ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall be present in the product in a significant amount. A significant amount of an ingredient or component of an ingredient is at least that amount that is required to achieve the technical effect of that ingredient in the food.

(5) Water and fat analogs may be added to replace fat and calories in accordance with Sec. 130.10(c), (d)(1), and (d)(2).

(e) Nomenclature. The name of a substitute food that complies with all parts of this regulation is the appropriate expressed nutrient content claim and the applicable standardized term.

(f) Label declaration. (1) Each of the ingredients used in the food shall be



declared on the label as required by the applicable sections of part 101 of this chapter and part 130.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement ``*Ingredient(s) not in regular ----------'' (fill in name of the traditional standardized food) or ``*Ingredient(s) in excess of amount permitted in regular ----------'' (fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.

[58 FR 2446, Jan. 6, 1993]

Sec. 130.11 Label designations of ingredients for standardized foods.

Some definitions and standards of identity for foods set forth below require that designated optional ingredients such as spices, flavorings, colorings, emulsifiers, flavor enhancers, stabilizers, preservatives,

and sweeteners be declared in a specified manner on the label wherever the name of the standardized food appears on the label so conspicuously as to be easily seen under customary conditions of purchase. Such requirements shall apply to a manufacturer, packer, or distributor of a standardized food only if the words or statements on the label of the standardized food significantly differentiate between two or more foods that comply with the same standard by describing the optional forms or varieties, the packing medium, or significant characterizing ingredients present in the food.

[58 FR 2876, Jan. 6, 1993]

Sec. 130.12 General methods for water capacity and fill of containers.

For the purposes of regulations promulgated under section 401 of the act:

(a) The term ``general method for water capacity of containers'' means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Wash, dry, and weigh the empty container.

(3) Fill the container with distilled water at 68 deg. F to \3/16\ inch vertical distance below the top level of the container, and weigh the container thus filled.

(4) Subtract the weight found in paragraph (a)(2) of this section from the weight found in paragraph (a)(3) of this section. The difference shall be considered to be the weight of water required to fill the container.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in paragraphs (a) (2) to (4) of this section, except that under paragraph (a)(3) of this section, fill the container to the level of the top thereof.

(b) The term ``general method for fill of containers'' means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Measure the vertical distance from the top level of the container to the top level of the food.

(3) Remove the food from the container; wash, dry, and weigh the container.

(4) Fill the container with water to \3/16\ inch vertical distance below the top level of the container. Record the temperature of the water, weigh the container thus filled, and determine the weight of the water by subtracting the weight of the container found in paragraph (b)(3) of this section.

(5) Maintaining the water at the temperature recorded in paragraph (b)(4) of this section, draw off water from the container as filled in paragraph (b)(4) of this section to the level of the food found in paragraph (b)(2) of this section, weigh the container with remaining water, and determine the weight of the remaining water by subtracting the weight of the container found in paragraph (b)(3) of this section.

[[Page 265]]

(6) Divide the weight of water found in paragraph (b)(5) of this

section by the weight of water found in paragraph (b)(4) of this section, and multiply by 100. The result shall be considered to be the percent of the total capacity of the container occupied by the food.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in paragraphs (b) (2) to (6) of this section, except that under paragraph (b)(4) of this section, fill the container to the level of the top thereof.

Sec. 130.14 General statements of substandard quality and substandard fill of container.

For the purposes of regulations promulgated under section 401 of the act:

(a) The term ``general statement of substandard quality'' means the statement ``Below Standard in Quality Good Food--Not High Grade'' printed in two lines of Cheltenham bold condensed caps. The words ``Below Standard in Quality'' constitute the first line, and the second immediately follows. If the quantity of the contents of the container is less than 1 pound, the type of the first line is 12-point, and of the second, 8-point. If such quantity is 1 pound or more, the type of the first line is 14-point, and of the second, 10-point. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle. Such statement, with enclosing lines, is on a strongly contrasting, uniform background, and is so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

(b) The term ``general statement of substandard fill'' means the statement ``Below Standard in Fill'' printed in Cheltenham bold condensed caps. If the quantity of the contents of the container is less than 1 pound, the statement is in 12-point type; if such quantity is 1 pound or more, the statement is in 14-point type. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle; but if the statement specified in paragraph (a) of this section is also used, both statements (one following the other) may be enclosed within the same rectangle. Such statement or statements, with enclosing lines, are on a strongly contrasting, uniform background, and are so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

Sec. 130.17 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

(a) The Food and Drug Administration recognizes that before petitions to amend food standards can be submitted, appropriate investigations of potential advances in food technology sometimes require tests in interstate markets of the advantages to and acceptance by consumers of experimental packs of food varying from applicable definitions and standards of identity prescribed under section 401 of the act.

(b) It is the purpose of the Food and Drug Administration to permit such tests when it can be ascertained that the sole purpose of the tests

is to obtain data necessary for reasonable grounds in support of a petition to amend food standards, that the tests are necessary to the completion or conclusiveness of an otherwise adequate investigation, and that the interests of consumers are adequately safeguarded; permits for such tests shall normally be for a period not to exceed 15 months. The Food and Drug Administration, or good cause shown by the applicant, may provide for a longer test market period. The Food and Drug Administration will therefore refrain from recommending regulatory proceedings under the act on the charge that a food does not conform to an applicable standard, if the person who introduces or causes the introduction of the food into interstate commerce holds an effective permit from the Food and Drug Administration providing specifically for those variations in respect to which the food fails to conform to the applicable definition and standard of identity. The test period will begin on the date the person holding an effective



permit from the Food and Drug Administration introduces or causes the introduction of the food covered by the permit into interstate commerce but not later than 3 months after notice of the issuance of the permit is published in the Federal Register. The Food and Drug Administration shall be notified in writing of the date on which the test period begins as soon as it is determined.

(c) Any person desiring a permit may file with the Chief, Food Standards Branch, Office of Food Labeling, Center for Food Safety and Applied Nutrition (HFS-158), 200 C St. SW., Washington, DC 20204, a written application in triplicate containing as part thereof the following:

(1) Name and address of the applicant.

(2) A statement of whether or not the applicant is regularly engaged in producing the food involved.

(3) A reference to the applicable definition and standard of identity (citing applicable section of regulations).

(4) A full description of the proposed variation from the standard.

(5) The basis upon which the food so varying is believed to be wholesome and nondeleterious.

(6) The amount of any new ingredient to be added; the amount of any ingredient, required by the standard, to be eliminated; any change of concentration not contemplated by the standard; or any change in name that would more appropriately describe the new product under test. If such new ingredient is not a commonly known food ingredient, a description of its properties and basis for concluding that it is not a deleterious substance.

(7) The purpose of effecting the variation.

(8) A statement of how the variation is of potential advantage to consumers. The statement shall include the reasons why the applicant does not consider the data obtained in any prior investigations which may have been conducted sufficient to support a petition to amend the standard.

(9) The proposed label (or an accurate draft) to be used on the food to be market tested. The label shall conform in all respects to the general requirements of the act and shall provide a means whereby the consumer can distinguish between the food being tested and such food complying with the standard.

(10) The period during which the applicant desires to introduce such

food into interstate commerce, with a statement of the reasons supporting the need for such period. If a period longer than 15 months is requested, a detailed explanation of why a 15-month period is inadequate shall be provided.

(11) The probable amount of such food that will be distributed. The amount distributed should be limited to the smallest number of units reasonably required for a bona fide market test. Justification for the amount requested shall be included.

(12) The areas of distribution.

(13) The address at which such food will be manufactured.

(14) A statement of whether or not such food has been or is to be distributed in the State in which it was manufactured.

(15) If it has not been or is not to be so distributed, a statement showing why.

(16) If it has been or is to be so distributed, a statement of why it is deemed necessary to distribute such food in other States.

(d) The Food and Drug Administration may require the applicant to furnish samples of the food varying from the standard and to furnish such additional information as may be deemed necessary for action on the application.

(e) If the Food and Drug Administration concludes that the variation may be advantageous to consumers and will not result in failure of the food to conform to any provision of the act except section 403(g), a permit shall be issued to the applicant for interstate shipment of such food. The terms and conditions of the permit shall be those set forth in the application with such modifications, restrictions, or qualifications as the Food and Drug Administration may deem necessary and state in the permit.

(f) The terms and conditions of the permit may be modified at the discretion of the Food and Drug Administration or upon application of the permittee during the effective period of the permit.

[[Page 267]]

(g) The Food and Drug Administration may revoke a permit for cause, which shall include but not be limited to the following:

(1) That the permittee has introduced a food into interstate commerce contrary to the terms and conditions of the permit.

(2) That the application for a permit contains an untrue statement of a material fact.

(3) That the need therefor no longer exists.

(h) During the period within which any permit is effective, it shall be deemed to be included within the terms of any guaranty or undertaking otherwise effective pursuant to the provisions of section 303(c) of the act.

(i) If an application is made for an extension of the permit, it shall be accompanied by a description of experiments conducted under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered necessary. The application for an extension shall be filed not later than 3 months prior to the expiration date of the permit and shall be accompanied by a petition to amend the affected food standard. If the Food and Drug Administration concludes that it will be in the interest of consumers to issue an extension of the time period for the market test, a notice will be published in the Federal Register stating that fact. The notice will include an invitation to all interested persons to participate in the market test

under the same conditions that applied to the initial permit holder, including labeling and the amount to be distributed, except that the designated area of distribution shall not apply. The extended market test period shall not begin prior to the publication of a notice in the Federal Register granting the extension and shall terminate either on the effective date of an affirmative order ruling on the proposal or 30 days after a negative order ruling on the proposal, whichever the case may be. Any interested person who accepts the invitation to participate in the extended market test shall notify the Food and Drug Administration in writing of that fact, the amount to be distributed, and the area of distribution; and along with such notification, he shall submit the labeling under which the food is to be distributed.

(j) Notice of the granting or revocation of any permit shall be published in the Federal Register.

(k) All applications for a temporary permit, applications for an extension of a temporary permit, and related records are available for public disclosure when the notice of a permit or extension thereof is published in the Federal Register. Such disclosure shall be in accordance with the rules established in part 20 of this chapter.

(l) Any person who contests denial, modification, or revocation of a temporary permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[42 FR 14357, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 46 FR 37500, July 21, 1981; 54 FR 24892, June 12, 1989; 59 FR 15051, Mar. 31, 1994]