

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 171

Administrative practice and procedure, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 71, 170, and 171 be amended as follows:

PART 71—COLOR ADDITIVE PETITIONS

1. The authority citation for 21 CFR part 71 continues to read as follows:

Authority: Secs. 201, 402, 409, 501, 505, 506, 507, 510, 512-516, 518-520, 601, 701, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 351, 355, 356, 357, 360, 360b-360f, 360h-360j, 361, 371, 379e, 381); secs. 215, 351 of the Public Health Service Act (42 U.S.C. 216, 262).

2. Section 71.1 is amended in paragraph (c) in the petition by revising the introductory paragraph preceding paragraph A., and by adding new paragraph (j) to read as follows:

§ 71.1 Petitions.

* * * * *

(c) * * *

Attached hereto in triplicate (quadruplicate, if intended uses include use in meat, meat food product, or poultry product), and constituting a part of this petition are the following:

* * * * *

(j)(1) If intended uses of the color additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA, or if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

3. Section 71.20 is amended by adding new paragraph (a)(3) to read as follows:

§ 71.20 Publication of regulation.

* * * * *

(a) * * *

(3) The regulation shall list any use or uses in meat, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA)(21 U.S.C. 601 et seq.) or Poultry Products Inspection (PPIA)(21 U.S.C. 451 et seq.) for which the color additive has been found suitable and for which it may safely be employed.

* * * * *

PART 170—FOOD ADDITIVES

4. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

5. Section 170.35 is amended by redesignating paragraphs (c)(3) through (c)(6) as paragraphs (c)(4) through (c)(7), respectively, and by adding new paragraph (c)(3) to read as follows:

§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

* * * * *

(c) * * *

(3)(i) If intended uses of the substance include uses in meat, meat food product, or poultry product subject to regulation by the U. S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(ii) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA, or if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

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PART 171—FOOD ADDITIVE PETITIONS

6. The authority citation for 21 CFR part 171 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

7. Section 171.1 is amended in paragraph (c) in the petition by revising the introductory paragraph preceding paragraph A., and by adding new paragraph (n) to read as follows:

§ 171.1 Petitions.

* * * * *

(c) * * *

Attached hereto, in triplicate (quadruplicate, if intended uses include use

in meat, meat food product, or poultry product), and constituting a part of this petition, are the following:

* * * * *

(n) (1) If intended uses of the food additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA, or if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

8. Section 171.100 is amended by redesignating paragraph (b) as paragraph (c) and by adding new paragraph (b) to read as follows:

§ 171.100 Regulation based on petition.

* * * * *

(b) The regulation shall describe the conditions under which the substance may be safely used in any meat product, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) or the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.).

* * * * *

Dated: October 11, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 102, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 165, 166, 168, and 169

[Docket No. 95N-0294]

Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to review its regulations pertaining to identity, quality, and fill of container for standardized foods and its common or usual name regulations for nonstandardized foods. As part of this review, the agency is soliciting comments from all interested parties on whether these regulations should be retained, revised, or revoked. FDA solicits comments on the benefits or lack of benefits of such regulations in facilitating domestic, as well as international, commerce and on the value of these regulations to consumers. The agency also solicits comments on alternative means of accomplishing the statutory objective of food standards, i.e., to promote honesty and fair dealing in the interest of consumers in the manufacture and sale of food products covered by these regulations. This review responds in part to President Clinton's memorandum to heads of departments and agencies, entitled "Regulatory Reinvention Initiative," dated March 4, 1995.

DATES: Written comments by April 29, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nannie H. Rainey, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

On March 4, 1995, the President issued a memorandum to heads of departments and agencies, entitled "Regulatory Reinvention Initiative" (RRI memorandum) that, among other things, directed them to continue to work toward making Government more effective. In the RRI memorandum, the President noted that all Americans want the benefits of effective regulation, such as clean water, safe work places, wholesome food, and sound financial institutions, but stated that too often the rules are drafted with such detailed lists of do's and don'ts that the objectives they seek to achieve are undermined. Thus, the RRI memorandum directed that departments and agencies conduct a page-by-page review of all of their regulations and eliminate or revise those that are outdated or otherwise in need of reform.

A prime focus of FDA's review under the RRI memorandum has been the agency's food standard and common or usual name regulations. These provisions, which cover approximately 260 pages in the Code of Federal Regulations, appear to be exactly the kind of regulations that need reform. Intended to protect the integrity of the food supply, these regulations provide detailed definitions of various types of food, ranging from milk to canned fruits and vegetables to seafood cocktails. Some are extremely detailed and have the potential to limit technological advances. Virtually all of these regulations were adopted before the passage of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments) and, thus, were developed without reference to the significant informational function that the food label can play. Therefore, the food standards and common or usual name regulations are a candidate for revision or reform.

As a result of its page-by-page review of its regulations in response to the RRI memorandum, FDA tentatively concluded that several food standards of identity should be revoked for various reasons including that they are obsolete, or that their provisions are being adequately covered by other regulations. On November 9, 1995 (60 FR 56513), FDA published a final rule repealing a stayed standard (canned fruit nectars, formerly codified as § 146.113 (21 CFR 146.113)). In that same issue of the Federal Register (60 FR 56541), the agency published a proposed rule to revoke the standards of identity for certain lower-fat milk, sour cream, and yogurt products in part 131 (21 CFR part 131) and the standard of identity for lowfat cottage cheese in part 133 (21 CFR part 133) so that these foods can be produced and labeled under the general standard in § 130.10 (21 CFR 130.10). That proposal also would amend the nutrient content claims regulations in § 101.62 (21 CFR part 101.62) to provide for "skim" as a synonym for "nonfat," thereby allowing the use of the names "skim milk," "acidified skim milk," "cultured skim milk," and "sweetened condensed skim milk." In addition, FDA has proposed (60 FR 53480, October 13, 1995) to revoke a number of regulations because they are obsolete or of no current interest to industry or consumers. Among those regulations are several standards of identity in part 161 (21 CFR part 161) that specify sizes for certain oyster products, the standards of identity in part 163 (21 CFR part 163) for coatings made from cocoa, sweet chocolate, or milk chocolate and

vegetable fats other than cacao fat, and the standards of identity in part 137 (21 CFR part 137) for the corn grits products (i.e., corn grits, enriched corn grits, quick grits, and yellow grits).

The agency's review of the remaining food standards in parts 130 through 169 (21 CFR parts 130 through 169) and the common or usual name regulations in part 102 (21 CFR part 102) forms the basis of this advanced notice of proposed rulemaking.

B. History: Pre-1938

In providing for standards of identity, quality, and fill of container in section 401 of the Federal Food, Drug, and Cosmetic Act of 1938 (the act) (21 U.S.C. 341), Congress sought to correct a deficiency in the 1906 Food and Drugs Act (the 1906 act). The 1906 act established definitions for adulteration and misbranding and subjected foods to seizure if they were found to be in violation of these definitions. Section 7 of the 1906 act was intended to prevent adulteration in the form of dilution or substitution of a valuable ingredient, concealment of inferiority, or use of harmful ingredients in foods. It deemed that a food was adulterated if, among other things, the food's strength or quality had been lowered, or if it had been cheapened. However, the 1906 act contained no provision requiring foods to bear a statement of ingredients on the label and, thus, offered no means of comparing foods to determine whether dilution or substitution had occurred.

The misbranding provisions of the 1906 act actually contributed to the proliferation of cheap or debased foods that could be sold legally by reason of its so called "distinctive name proviso." This provision permitted the marketing of foods that would have been adulterated and misbranded if sold under the name of the food they purported to be by allowing their sale under meaningless "distinctive" names such as "Bred-Spred." Bred-Spred products were made in imitation of fruit preserves produced by adding acid and pectin to about 15 percent fruit. This quantity of fruit was far less than that used by the homemaker or by reputable manufacturers to make fruit preserves at that time.

The lack of a provision to establish mandatory standards under the 1906 act handicapped the Government in its attempts to maintain the integrity of the food supply by making it difficult for the Government to proceed against a debased food product, particularly a fabricated food. (See *U.S. v. 10 Cases "Bred-Spred,"* 49 F.2d 87 (8th Cir. 1931).)

Under the 1906 act, the Government established advisory definitions and standards for use in food inspections. However, these definitions and standards had no effect on the enforcement of the law. To establish a violation of law, the Government had to introduce testimony showing that an undeclared variation was not one expected by consumers in an article bearing the name of the food. It was also necessary for the Government to show that the variation was not the prevailing good commercial practice. Without standards or guidelines, judgments under the 1906 act varied widely. Manufacturers could not be assured that their products would not be found to be violative, nor were consumers' interests effectively protected. Manufacturers were not protected against disreputable competitors who could affect competitive pressures and, more importantly, reduce consumer confidence in the food supply.

Eventually, the Government and the industry came to the conclusion that a new statute was needed to ensure the integrity of food by keeping economically adulterated foods off the market. This recognition resulted in inclusion of three key provisions (sections 401, 403, and 701 of the act (21 U.S.C. 341, 343, and 371) for standardization of foods.

C. History: Post-1938

1. The 1938 Act

a. *Authority to establish standards.* The authority to establish standards is set forth in section 401 of the act. This section provides that:

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. * * *

Early standards of identity established under the act were primarily "recipe standards," defining in considerable detail the specific ingredients (both mandatory and optional ingredients) to be used and, in many instances, the procedure to be followed in manufacturing the food, much like home recipes. In addition, they provided assurance that only "harmless" ingredients would be used

in the food and designated which optional ingredients must be declared on the label.

Standards were intended to prevent economic deception. They were intended to protect consumers from receiving debased or watered down food products in which water or other fillers had been substituted for more valuable constituents. For example, the early standards for flour products established a maximum level of not more than 15 percent moisture in these foods. They also included a referenced method of analysis for moisture content to allow the manufacturer to use the same procedure as the Government inspector in testing the food for compliance with the standard.

In defining the composition of foods, the definitions and standards of identity provided an added measure of assurance that the food supply would be safe. The standards designated the specific ingredients that should be used by name or limited them as "harmless ingredients" where class names were used. For example, only harmless and assimilable forms of iron or calcium salts could be added to enrich farina, and, in the case of vitamin D addition, only harmless carriers that do not impair the enriched farina could be used (§ 137.305). Because the statute did not have in place, at that time, a mechanism for preclearance of food additives or other functional optional ingredients that were used in foods, inclusion of such a limitation on ingredients provided further assurance that the foods would be wholesome and not adulterated.

b. *Misbranding provisions of the act.* To ensure compliance with the definitions and standards established under section 401 of the act, Congress included two paragraphs under the misbranding provisions that effect food standards.

Section 403(g) of the act, states that a food shall be deemed to be misbranded:

If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless: (1) It conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

In addition, section 403(i) of the act, as originally enacted, provided that a nonstandardized food (i.e., "If it is not subject to the provisions of paragraph (g) of this section) was misbranded * * * unless its label bears (1) the common or usual name of the food, if

any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; * * *."

Thus, the act, as originally enacted, required that foods purporting to be, or represented as, the standardized food comply with the compositional provisions of the applicable standard and bear the name designated in the definition and standard for the food. However, the act only provided for label declaration of the optional ingredients used in standardized foods and not the mandatory ingredients.

Nonstandardized foods, on the other hand, had to list all ingredients used in the food, except that "spices," "flavorings," and "colorings" could be declared collectively using those terms.

c. *The standards setting process.* As enacted in 1938, section 701 of the act (21 U.S.C. 371) provided in paragraph (e)(1) and (e)(2) that "any action for the issuance, amendment, or repeal" of any standard of identity must be accomplished under formal rule making procedures where interested persons are given an opportunity to participate in a trial-type hearing.

d. *Preemption.* As enacted in 1938, the act contained no provision providing that Federal food standards preempt State laws. While the standards provided a minimum below which the States could not go, it did not prevent the States from adopting more stringent standards. (See *Grocery Manufacturers of America v. Gevace*, 581 F. Supp. 658 (S.D.N.Y. 1984), aff'd in part and rev'd in part, 755 F.2d 993 (2d Cir.), cert. denied 474 U.S. 820 (1985).)

2. Agency Implementation of the Standards Provisions

a. *Standards of identity.* FDA has implemented section 401 of the act by adopting over 280 standards of identity. These standards establish the common or usual name for a food and define the nature of the food, generally in terms of the types of ingredients that it must contain (i.e., mandatory ingredients), and that it may contain (i.e., optional ingredients). Standards may specify minimum levels of the valuable constituents and maximum levels for fillers and water. They may also designate the manufacturing process when that process has a bearing on the identity of the finished food. Finally, standards provide for label declaration of ingredients used in the food and may require other specific labeling, such as the declaration of the form of the food, packing medium, and flavorings or other characterizing ingredients as part of the name of the food or elsewhere on the principal display panel of the label.

Individual food standards vary widely in their content. These variations have developed because of the different aspects of food technology that are responsible for providing the defining characteristics of a food. Some foods are defined and distinguished by their ingredients. The standards for these foods set specific limits on the levels of ingredients that must be used in them. For example, the standard of identity for fruit preserves and jams (§ 150.160) states that these foods must contain a minimum of 45 parts or 47 parts of fruit (depending on the type of fruit used) to each 55 parts of sugar or other sweetener, and that they may contain other ingredients such as pectin, acidifying agents, buffering agents, preservatives, and antifoaming agents. In this way, the standard ensures that when consumers purchase "jam," they receive a product that contains a level of fruit that meets their expectations.

Other foods standards focus on compositional characteristics of the food, rather than on the specific ingredients. The standards of identity for fruit juice products in part 146, for example, define these juices in terms of minimum juice soluble solids contents rather than on the ingredients used to make the food. Thus, the standard of identity for orange juice from concentrate (§ 146.145) requires that the food contain not less than 11.8 percent orange juice soluble solids, exclusive of any added sweetener. In this way, the standard helps to ensure that all products marketed as "orange juice" approximate, in the most important respects, the juice that comes directly from the fruit, and that consumers will receive a consistent orange juice product.

The standards of identity for milk products in part 131 list the minimum milkfat and minimum milk solids not fat levels that must be contained in these foods. These specific compositional requirements protect against addition of water or other substances that could dilute the value of the nutrients in the food. In the case of certain dehydrated products, such as lowfat dry milk, the standard of identity (§ 131.123) specifies a maximum moisture level to protect against microbiological growth and to enhance the overall keeping quality of the product. To ensure that these compositional requirements are met, the standards reference specific methods of analysis.

Other foods owe their distinctive characteristics to the manner in which they are produced. Thus, the standards for these foods reflect this fact. Standards of identity for some cheeses

in part 133, for example, specify the manufacturing process, in addition to establishing minimum milkfat and maximum moisture requirements, to distinguish one cheese from another. These standards may also prescribe a curing process or specific species of mold to be used on or in the cheese to ensure that the finished cheese has the characteristic organoleptic properties commonly associated with that cheese.

Some foods are defined by the physical characteristics of the food itself. For example, the particle size is an important factor in distinguishing cracked wheat from crushed wheat. Thus, the standards of identity for cracked wheat in § 137.190 and crushed wheat in § 137.195 include methods of analysis for the determination of the particle size of these foods. The test methods are used by manufacturers and regulators to ensure that foods labeled with these standardized names will possess the same physical properties from purchase to purchase. They also ensure that bakers will not have to do additional particle sizing of the ingredients before they are used for a specific baking operation. Similarly, standards of identity for flour (§ 137.105), instantized flour (§ 137.170), and whole wheat flour (§ 137.200) rely in part on the particle size determination as a distinguishing feature of these foods. Although the primary purpose of the particle size designation is to aid in establishing the identity of the food, it also serves as a quality factor and ensures that consumers will receive the same physical characteristics in all of these cereal grain products, regardless of where they are purchased or by whom they are produced.

The distinctive property of other foods is provided by their nutrient levels. For example, the standards of identity for certain juices provide for the addition of vitamin C, some for milk products provide for the addition of vitamins A and D, while standards of identity for certain bakery products, enriched bread, rolls and buns, and cereal products, such as enriched macaroni and noodle products, enriched flours, and enriched corn meals provide for addition of thiamin, riboflavin, niacin, iron, and calcium. The enriched cereal grain products also provide for the optional addition of vitamin D. Such standards provide for consistency in fortification levels when nutrients are added to these foods and also serve as guidance to industry on what the agency believes are reasonable target levels for these nutrients in foods.

b. *Standards of quality and fill of container.* Standards of quality set

minimum specifications for such factors as tenderness, color, and freedom from defects in canned fruits and vegetables. Quality standards, established primarily for canned foods, place limits on defects, such as limits on the amounts of peel in canned peeled tomatoes, or on the number of pit fragments that may be in canned peaches, on the levels of seriously blemished (shriveled, hard, discolored, etc.) peas in canned peas, and on the number of pits in pitted canned cherries. Such characteristics would not be readily apparent to the purchaser of these foods because of the nature of the foods and the manner in which they are presented to the consumer (inside of a can). In the case of certain juice products, they may also establish criteria for percent juice soluble solids and maximum acidity to ensure that the juice product will have an acceptable flavor profile.

Standards of fill of container set out requirements as to how much food must be in a container. These requirements are particularly important when foods are packed in liquids and sealed in opaque containers. The types of fill requirements differ for various products, depending on the characteristics of the food. Some fill-of-container standards specify minimum weights of solid food that must be present after the drainable liquid has been poured off (referred to as "minimum drained weight"). For example, the fill of container for canned corn in § 155.130(c) is not less than 61 percent of the water capacity of the container. Other standards provide a simple stipulation that the container, with or without added liquid, must be filled with solid ingredients to a maximum that will still permit the lid to be attached and the food processed by heat to prevent spoilage, without crushing or breaking the solid ingredients. This type of standard was established for several canned fruits, i.e., apricots, cherries, peaches, and pears (see §§ 145.115(c), 145.125(c), 145.170(c), and 145.175(c), respectively), because the size, shape or textural properties of the foods will affect the fill of the raw food and the drained weight of the finished product. For example, the firmness, size, and shape of the peach or pear pieces (e.g., halves, slices, chunks) before heat processing in the container makes them difficult to pack to uniform fill-in weights. The fill of container for such foods is further complicated by the tendency of the pieces to soften on cooking and "pack down," giving the appearance of a slack-filled container.

The minimum fill-of-container requirements in standards provide guidance to the manufacturer, as well as

to the food inspector, as to what constitutes a well-filled container. For some products, such as crushed pineapple, applesauce, pineapple juice, and packed nuts, where the consistency of the product is more uniform, or where there is no added packing medium that could serve to dilute the product contents, the required minimum fill of container is the total food contents, expressed as a percentage of the capacity of the container.

In the case of canned tuna (§ 161.190), which may be packed in oil or water, FDA has established minimum fill of container requirements, expressed in terms of the pressed cake weight, in ounces, depending on the size of the container used to pack the tuna. The minimum pressed cake weight requirement assures consumers that they will obtain a minimum amount of tuna flesh in each can. The measure of tuna obtained in the laboratory by the pressed cake weight procedure described in the standard approximates the measure that the homemaker would observe when the lid of the tuna can is removed and is used to press the tuna and drain the liquid. In the case of canned Pacific salmon (§ 161.170), in which no packing medium is added, the minimum fill of container is expressed in terms of a minimum net weight of salmon for each container size. The minimum net weight requirements established in the standard are slightly less than the water capacity of the container, thereby taking into account the irregular shapes of the salmon pieces, but at the same time, providing assurance that the containers will not be underfilled.

FDA regulations require that consumers be informed when foods do not comply with the applicable standard of quality or fill of container. Under § 130.14 (21 CFR 130.14), foods that fail to comply with the quality standards must bear bold label statements, such as "BELOW STANDARD IN QUALITY," followed by a statement such as "GOOD FOOD—NOT HIGH GRADE," or in the case of products that are substandard in fill, the statement "BELOW STANDARD IN FILL," wherever the name of the food or any pictorial representation of the food appears so conspicuously as to be easily seen under customary conditions of purchase. The individual quality standards provide for an alternate label statement of the quality factor which makes the food substandard, such as "EXCESSIVE COB" on canned corn or "EXCESSIVELY MEALY" in canned peas instead of the general label statement, "GOOD FOOD— NOT HIGH GRADE."

Both the standards of quality and of fill of container provide detailed methodology for determining compliance. Because most of the methods included in the standards pertain only to the specific food identified by that standard, the agency has been of the opinion that this is the most efficient way to provide for such methods, e.g., the pressed cake weight method of analysis that pertains only to canned tuna. In some cases where the same method is used for multiple products, for example, the drained weight method of analysis for certain vegetables, FDA has simply referenced the method without repeating it in each of the standards (see § 155.3(a)). However, in the case of canned fruit cocktail, the drained weight method of analysis is incorporated in the standard of fill of container (§ 145.135(c)).

c. Temporary marketing permits. Under the agency's food standards program, FDA established a regulation providing for the issuance of temporary marketing permits (TMP's) in § 130.17. TMP's allow manufacturers to make products that deviate from applicable standards in specified ways and to test consumer acceptance of those foods in the marketplace. TMP's allow the manufacturer to market the product in interstate commerce to obtain data on the commercial viability of a change in a standard of identity before petitioning the agency to amend the applicable standard to provide for the deviation. Products marketed under temporary permits must be labeled in a manner whereby the consumer can distinguish between the food being tested and the food complying with the applicable standard.

FDA usually grants permits for a period not to exceed 15 months. However, with good reason, the agency may provide for a longer initial test market. Notice of the issuance of a permit, including a description of the deviations from the standardized food and the marketing conditions, is published in the Federal Register.

Under § 130.17, the TMP applicant may request an extension of the firm's permit, when such extension is necessary to obtain sufficient data to evaluate the test product. Requests for extensions must be accompanied by a description of the experiments conducted thus far under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered to be necessary. Such requests must also be accompanied by a petition to amend the applicable standard to provide for the deviation.

If FDA concludes, based on the information supplied, that extension of the time for test marketing the product is in the interest of consumers, the agency publishes a notice in the Federal Register stating this fact and inviting other interested firms to participate in the test market under the same conditions as set forth for the original applicant, except that the designated distribution area for the test product would not apply. These extensions usually continue until FDA publishes a final regulation either modifying the standard of identity in the manner sought or terminating the proposed rulemaking, whichever is the case.

This procedure has worked well in providing manufacturers the flexibility to test the commercial viability of new, reformulated versions of traditional standardized foods. It has also served consumers well, allowing new and nutritionally advantageous products to be marketed before rulemaking. The data generated under TMP's also assist the agency in its rulemaking decisions. For example, before the passage of the 1990 amendments, the agency responded to more than 100 applications for TMP's for modified dairy products, such as nonfat sour cream, nonfat cottage cheese, and light eggnog. The success of these test products assured the agency that these nutritionally modified foods were viable products, which could be made to resemble and substitute for the traditional standardized food and in a manner so as not to be nutritionally inferior to the traditional standardized food. Recently, FDA has issued TMP's for white chocolate, a food that deviates from the cacao product standards in part 163 because it contains none of the nonfat cacao solids usually present in chocolate products.

3. Developments Affecting the Food Standard Regulations

a. Safe and suitable policy. Passage of the Food Additives Amendment of 1958 and the Color Additive Amendments of 1960 instituted premarket approval of new food and color additives. These amendments allowed FDA to develop its "safe and suitable" policy, codified in § 130.3(d), concerning functional ingredients used in foods. This policy provides that ingredients used in food must be listed food or color additives, or generally recognized as safe (GRAS) substances, and used at levels no higher than necessary to accomplish their intended functional effect in the food.

FDA first used this policy in 1961 in the standard of identity for frozen raw breaded shrimp (§ 161.175). At that time, it represented a significant change in the manner in which permitted

ingredients were designated in food standards. The standard simply provided for "safe and suitable batter and breadening ingredients," without listing the names of the specific permitted ingredients. This departure from the traditional food standards concept provided manufacturers with considerably more flexibility in the selection of ingredients to be used in the food. Along with this provision, the agency also required that each such safe and suitable optional ingredient used in the food be declared on the label.

Since the establishment of this policy, the agency has revised most of its standards to provide for the use of safe and suitable ingredients, by category, that perform the needed technical effect in the food, e.g., safe and suitable emulsifiers. However, a few of the standards have not been so updated to increase flexibility in the manufacture of those foods. These standards include the standards of identity for certain cheese products (e.g., §§ 133.169, 133.173, 133.179, 133.187, and 133.188), which specify antimycotics by name (e.g., sorbic acid, potassium sorbate, sodium sorbate, calcium propionate, and sodium propionate) and the levels at which they may be used in the food, and the standards of identity for artificially sweetened fruit products (e.g., §§ 145.116, 145.126, 145.131, 145.136, 145.171, 145.176, and 145.181), which designate the specific artificial sweeteners (saccharin and sodium saccharin) that may be used.

b. *The 1990 amendments—i. Ingredient labeling.* In the 1990 amendments Congress amended the ingredient labeling provisions in section 403(i) of the act by removing the language that limited full ingredient labeling to nonstandardized foods. The 1990 amendments also amended section 403(i) to require that certified color additives be declared by their common or usual names, rather than by the collective term "colorings." The framers of the act in 1938 apparently believed that consumers would know what mandatory ingredients would be used in staple food products covered by standards of identity and, thus, only provided that the optional ingredients used in such food would need to be declared on the label. However, with advance in food product formulation and processing, the ingredients used in standardized foods in the 1990's are more varied, and many are less familiar to consumers than the ingredients that were being used in 1938. This fact, along with consumers' desire to know the nature of all ingredients used in foods, led to the amendment of section 403(i). In response, the agency amended

the food standards, as necessary, in parts 131 through 169 to require label declaration of each ingredient used in these foods (58 FR 2850 at 2876 through 2887; and 58 FR 2888 at 2890 through 2896, January 6, 1993).

ii. *The standard setting process.* The 1990 amendments removed most section 401 proceedings from the list of rulemakings in which formal rulemaking is required under section 701(e) of the act. As a result, proceedings to establish, amend, or repeal food standards are subject to the requirements of informal notice and comment rulemaking. The only exception to this change is for actions to amend or repeal standards of identity for dairy products.

iii. *Preemption.* The 1990 amendments added section 403A(a)(1) to the act (21 U.S.C. 343-1(a)(1)). Under this provision, a State may not establish or continue in effect a standard of identity for a food that is the subject of a standard of identity under section 401 of the act if the standard is not identical to the Federal standard. One of Congress' goals in passing this provision was to provide industry with some relief from State requirements that interfere with its ability to market products in all 50 States in an efficient and cost effective manner (statement of Rep. Madigan, 136 Congressional Record H12954 (October 26, 1990)). Thus, as a result of the 1990 amendments, FDA's food standards are preemptive of State standards.

iv. *Other changes.* In addition to these provisions that bear directly on food standards, Congress made a number of fundamental changes in how virtually all foods are labeled that bear directly on the issue of the continuing need for some or all food standards. The 1990 amendments require that virtually all foods bear nutrition labeling. This information, plus the full ingredient list that is now required, ensures that consumers will have vastly more information about the make-up of a particular food product than was available in 1938. This information should make it immediately apparent if a marketer is attempting to sell a debased or watered down food. Because the standards were originally intended to prevent this type of economic deception, the nutrition labeling requirement raises a question as to whether food standards are still necessary.

The 1990 amendments also provide authority for FDA to adopt regulations defining nutrient content claims, such as "reduced fat," "low fat," and "fat free" in § 101.62 (January 6, 1993, 58 FR 2302 at 2418). Having established

uniform definitions for these terms, the agency was able to establish a general definition and standard of identity in § 130.10, which permits the modification of a traditional standardized food to achieve a nutrition goal, such as a reduction in fat or calories. Such modified foods, complying with the requirements of § 130.10, may be named by the use of a nutrient content claim defined by FDA in part 101, such as "reduced fat," and a standardized term, such as "cheddar cheese" (i.e., reduced fat cheddar cheese).

This general definition and standard of identity requires that the modified food: (1) Not be nutritionally inferior to the traditional standardized food that it resembles and for which it substitutes, (2) possess performance characteristics that are similar to the reference food, (3) contain a significant amount of any mandatory ingredient that is required to be in the traditional standardized food, and (4) not contain an ingredient that is prohibited in the traditional standardized food. However, under § 130.10, safe and suitable ingredients not specifically provided for in the standard for the traditional food may be added to ensure that the modified food will not be inferior in performance characteristics (e.g., physical properties, flavor characteristics, and shelf life) when compared to those of the traditional food. This one standard (§ 130.10) has provided enormous flexibility in the manufacture of foods that deviate from the traditional standards and in providing many healthful and informatively labeled food products to consumers. It has also eliminated the need for use of complex alternative names for foods, as well as the need for the industry to request establishment of new standards or TMP's to deviate from existing standards to make new foods to meet consumers' needs and desires.

In the past, many dairy products were defined by the level of milkfat in the food. Milkfat was considered to be one of the valuable constituents in the food, and if the minimum established level for milkfat was not met in the finished food, the product was deemed to be misbranded under section 403(g) of the act and adulterated under section 402(b) of the act. However, with the increased concern about fat and cholesterol in the diet, many consumers view milkfat in some dairy products as a negative factor or a constituent to be avoided rather than one that is sought after or highly valued. Under the general standard in § 130.10, manufacturers are able to meet consumers demands for reduced fat dairy products. Many new foods, e.g.

nonfat sour cream, reduced fat cheeses, and light or reduced fat ice cream products, to name a few, have been made available to consumers throughout the country in the past few years.

To assist manufacturers in producing informatively labeled reduced fat ice cream products, FDA published a final rule in the Federal Register of September 14, 1994 (59 FR 47072) that removed the standard of identity for ice milk and goat's milk ice milk. Products formerly labeled as ice milk may be labeled as "reduced fat" or "lowfat ice cream," depending on the total fat content of the food. Manufacturers may make other versions of ice cream, such as "nonfat ice cream" or "light ice cream." In that final rule, FDA also extended the optional sweeteners provision in the ice cream standard to include use of alternative sweeteners in reduced calorie ice cream products. For the next 3 years, until September 14, 1998, FDA is requiring that the name of the alternative sweeteners used in an ice cream be declared as part of the name of the food.

When Congress issued the 1990 amendments, it recognized that some standards of identity contained nutrient content claims as a part of their names and specifically exempted them from regulations implementing the requirements of the amendments. To ensure consistency in the use of such claims on food labels, the agency announced that it intended to amend as soon as possible those standards of identity that require that the use of the claim in the name of the standardized food be consistent with use of the claim on nonstandardized food labels. Elsewhere in this issue of the Federal Register, to effect that intent, FDA is proposing to rescind virtually every standard for a dairy product whose name includes a "low fat" or "no fat" claim.

D. Common or Usual Name Regulations

In the Federal Register of March 14, 1973 (38 FR 6964), FDA issued regulations in part 102 governing the establishment of "common or usual names for nonstandardized foods." The agency stated in the preamble to the final rule that standards of identity are appropriate and useful where there is a need to prescribe the entire compositional requirement for a food, in addition to the name of the food. Often, however, the agency pointed out, there is a need simply to establish a uniform and informative name for food without the compositional aspects of a food standard.

In issuing this regulation, FDA did not intend to establish common or usual

names for all foods. Many foods already have established names, for example, apples, carrots, or potatoes and the diced, sliced, dehydrated, or frozen versions of these foods. There is no need for regulations to define the nature of these foods. If these foods are labeled inappropriately or in a misleading manner, it is a simple violation of the misbranding provisions of the act. However, when these foods are fabricated with other ingredients or modified in ways that are unfamiliar to consumers, and when the same formulated products are being marketed with different names by different firms, the nature of the foods may become less obvious, and there may be need for regulation to ensure that consumers are not misled or deceived.

In the early 1970's, FDA received a petition requesting that it establish a regulation stating that onion rings were made from fresh onion bulbs, sliced and separated into rings, coated with batter or breading, and fried in a suitable fat or oil bath. The purpose of this regulation was to distinguish onion rings, so prepared, from an onion ring product that is made from fresh or dehydrated chopped onion, shaped by an extruder into ring shapes, breaded, and fried. This petition led to the establishment of the common or usual name regulation for "onion rings made from diced onion" in § 102.39. This regulation distinguishes onion rings made from comminuted onions from those made with intact slices. It also requires that, if the onion ingredient has been dehydrated, the name include this fact, i.e., "onion rings made from dried diced onions." FDA received similar petitions for potato chips made from comminuted potatoes or dehydrated potato products leading to the establishment of another common or usual name regulation in § 102.41, "potato chips made from dried potatoes."

The 1969 White House Conference on Food, Nutrition, and Health had recommended that the agency establish by regulation uniform common or usual names for foods that accurately reflect the reasonable expectations of consumers. The Conference recommendation focused on concern that the amount of the characterizing ingredient, if any, be represented on the label in percentage form or some other uniform method. In the preamble to the final rule, FDA acknowledged that disclosure of the amount of a characterizing ingredient is often necessary for the consumer to choose between two competing products when

the amount of the ingredient is important to the value of the food.

Part 102 consists of general principles for common or usual names for classes or subclasses of foods and several regulations that set requirements for naming specific nonstandardized foods. The general principles in § 102.5 require that the common or usual name of a food accurately describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name must include the percentage of a characterizing ingredient or component or a statement of its presence or absence when the portion of that substance has material bearing on the value of the food, or when the appearance of the food might otherwise mislead the consumer as to the amount of the substance present.

FDA has issued common or usual name regulations for nonstandardized foods only when necessary to fully inform consumers, or where different names were being used for the same product by different manufacturers. The first common or usual name regulation that required percentage declaration of the valuable characterizing ingredient was for seafood cocktails consisting of two or more seafood constituents or for cocktails with one seafood constituent. FDA had received consumer complaints concerning both the amount of seafood present in such cocktails and the use of labeling that suggested a greater proportion of seafood than was present. The common or usual name sought to correct this situation. Because the proportion of the seafood in such cocktails has material bearing on price and consumer acceptance, this regulation allowed consumers to make better purchasing decisions.

At the time they were established, one of the benefits of the common or usual name provisions in part 102 was that names of new products could be established by regulation using informal notice and comment rulemaking procedures, rather than the lengthy formal rulemaking procedures required for food standards. With passage of the 1990 amendments, however, as explained above, new standards of identity also may be established by notice and comment rulemaking proceedings. In view of this change in the act, the agency requests comments on the need to retain the dual mechanisms of standards and common or usual name regulations for establishing the definition of a food. Comments who support retention of both should describe the circumstances in which common or usual names should be chosen over standards of

identity. If standards of identity are deemed more appropriate, the agency requests comments on whether the common or usual name regulations for specific foods in part 102 should be retained in that part, transferred to the appropriate food standards parts, or repealed.

II. Reinventing Government

Congress directed FDA to establish and implement food standards because there was a real need to protect consumers from economic fraud and to promote honesty and fair dealing in the interest of consumers. Food standards have been beneficial through their long history of providing assurance to consumers of product uniformity, with the resulting expectation and belief by consumers that all products bearing a particular name will possess the same characteristics irrespective of where they are purchased, or by whom they are manufactured or distributed. Food standards have also been an efficient mechanism for addressing public health problems through mandatory fortification requirements. In addition, standards have provided manufacturers with guidance in the production, naming, and labeling of products and with assurance that competitors will have to meet the same guidelines for the same foods.

However, the agency recognizes that food standards may serve as an impediment to the food industry to the degree to which they fail to reflect advances in food science and technology. New ingredients and plant varieties that allow manufacturers to enhance a food's organoleptic or functional properties, alter its nutritional profile, or extend its shelf life, are being developed and used in nonstandardized food products. Incorporation of these advances into standardized foods may be difficult or impossible without laborious amendment of the relevant standard. FDA believes that manufacturers of standardized foods should have the ability to make use of advances in food technology, provided the basic nature of the food remains essentially the same.

Also, consumer expectations may have changed dramatically in the past two decades. Busy, active consumers put a premium on convenience when purchasing foods, and this emphasis may have also altered their expectations relative to basic, staple food products. Additionally, with the growing body of scientific evidence linking diet and health, consumers are demanding modified versions of traditional products that have lower amounts of constituents associated with negative

health implications, such as fat, saturated fat, cholesterol, and sodium.

Some critics have suggested that the agency revoke all food standards and allow market forces to control the composition of the products that are currently regulated by standards. On the other hand, industry and consumer spokespersons have expressed support for standards, believing them necessary to ensure that all manufacturers operate in a spirit of fairness and to ensure consistency in the products consumers are purchasing. They also state that standards promote consistency in labeling and to serve as a basis for nutrient content claims. For example, standards for traditional dairy products with established minimum fat levels can be used as the bases for "reduced fat" claims on labels of modified versions of these foods.

FDA believes that the two actions described previously, namely: (1) Amending standards to provide for the use of "safe and suitable" ingredients rather than explicit designation of all ingredients and (2) establishment of the general standard in § 130.10 for foods named by the use of a nutrient content claim and a standardized term, have lifted some of the restrictiveness of standards. However, the agency is considering further steps for providing flexibility in how foods are formulated and named, including, if appropriate, eliminating food standards, while continuing to promote honesty and fair dealing in the interest of consumers, and while continuing to ensure that food is not adulterated or misbranded. In light of the President's memorandum, FDA is looking critically at food standards.

The agency notes that the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture has established a number of food standards, under the authority of the acts that it administers. Many of these standards define the nature of meat and poultry products in a manner similar to FDA standards described previously. In a separate document, FSIS is announcing that it too is critically reviewing its standards in accordance with President Clinton's directive. Comments to this document are urged to consider, and provide comments separately to, FSIS's document.

III. International Standards

The United States is a charter member (dating back to 1963) and strong supporter of the Codex Alimentarius Commission (Codex) and its food standards program. The aim of the Codex, which is sponsored jointly by the United Nations' Food and

Agriculture Organization (FAO) and World Health Organization (WHO), is to promote the health and economic interests of consumers, while encouraging fair international trade in food. One of the general provisions of FDA's food standards program is the review of Codex food standards, following the procedure described in § 130.6(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."

It has been FDA's policy to publish new Codex food standards in an advance notice of proposed rulemaking in the Federal Register for review and informal comment. If the comments support adoption of the Codex standard or amendment of an existing standard to incorporate changes based on the Codex standard, FDA publishes a proposal in the Federal Register to adopt the Codex standard's provisions insofar as practicable. A proposal of this type could also be begun on the agency's own initiative. These procedures are described in § 130.6. To date, the agency has considered 83 Codex standards for adoption. (As a part of its initiative on international harmonization, FDA is considering a separate rulemaking to amend and update procedures in § 130.6 to make them more consistent with current Codex policies.)

FDA notes that U.S. delegates participating in the development of the international standards at Codex Committee meetings have often relied upon criteria established in the U.S. food standards in deciding on compositional requirements to be included in Codex standards. The agency believes that this procedure is a reasonable course of action because the U.S. standards, for the most part, reflect current commercial practice in this country. In the absence of U.S. food standards, would the position of the U.S. delegates in the Codex Committee meetings be weakened? How important is it to exporters and importers that the compositional provisions of the U.S. food standards be reflected in international specifications such as those established by the Codex Alimentarius?

IV. Economic Issues

Executive Order 12866 directs FDA to maximize the net benefits (benefits minus costs) of its regulations. The agency generally considers the following seven factors in determining the net benefits of a food standard:

1. Net benefits are likely to be higher for standards involving the product

characteristics about which consumers are most concerned. FDA has no formal method of determining the level of consumer concern about various characteristics, however and, thus, seeks information on this issue. In particular, consumer concerns may change over time. FDA requests comments on how it should factor changing consumer concerns into the economic assessments that it does for any rulemaking that may result from this advance notice of proposed rulemaking.

2. Net benefits are likely to be higher for standards that consumers are best able to understand and interpret. Thus, it becomes significant if there are any cases in which standards of identity produce confusion rather than provide information. FDA requests comments as to whether any such standards exist. For example, might consumers believe that products similar to standardized products but which fail to meet the standard are necessarily inferior to products that meet the standard? Such confusion may deter consumers from purchasing nonconforming products, even though those products may have all the characteristics some consumers usually associate with that type of product or all the characteristics desired by consumers. This confusion could lead to a reduction in the development of new products, a reduction in competition between similar products, and a reduction in product variety. FDA requests comments and information on whether consumers may be confused when comparing standardized foods to other foods and on the importance of product variety in particular markets.

3. Net benefits are likely to be higher for standards dealing with characteristics that are least amenable to direct informational labeling, including both labeling required by FDA and voluntary labeling by manufacturers. Characteristics that are not amenable to direct informational labeling are those for which direct labeling would be particularly complex or lengthy, such as the relative proportion of various ingredients, particular functional or organoleptic characteristics, or particular methods of manufacture. Other characteristics, such as the presence of particular ingredients, nutritional facts, and the contents of containers, are now labeled for most products. FDA requests comments on which characteristics are most and least amenable to direct labeling.

4. Net benefits are likely to be higher for standards involving product characteristics that cannot be detected after purchase. Although information on characteristics that can be detected after, but not before, purchase can prevent

post-purchase dissatisfaction, the value of this information is likely to be less. If a consumer purchases a brand name product and is not satisfied with that product, that consumer will purchase a different brand name in the future. Thus, food manufacturers have an economic incentive to produce products with the characteristics consumers desire, and that they can ensure are present. The agency believes that information about characteristics that cannot be detected after purchase is more valuable because consumers cannot acquire this information on their own. FDA requests comments on how much value the consumer places on being able to detect product characteristics before purchase so as to avoid post-purchase dissatisfaction.

5. Net benefits of federally established standards are likely to be higher for those standards least amenable to implementation by private organizations. If consumers are willing to pay for assurances that products have certain characteristics, it may be possible for private organizations to certify the presence of those characteristics in some cases.

6. Net benefits are likely to be higher for standards that are short, simple, and flexible. The lengthier and more complex a given standard, the more difficult it is likely to be for FDA to issue, and it may be more difficult to enforce. Shorter and less complex standards are also less costly for manufacturers to interpret and comply with. The more flexible a standard, the less likely FDA will have to revise or amend that standard in the future, and the less costly it will likely be for manufacturers to comply with that standard. FDA requests comments on the proper degree of flexibility for particular standards.

7. The net benefits of particular Federal standards may be larger or smaller than those of State standards preempted by those Federal standards. Conflicting State standards generate compliance costs because manufacturers selling products under conflicting standards must either provide alternative product formulations or labeling for those products. However, Federal standards are not necessarily superior to State standards because Federal and State standards may have different costs or benefits with respect to any of the factors listed previously, that is, State standards may provide more or less information than Federal standards, may restrict competition to a greater or lesser degree than Federal standards, and so on. Consumers in different States, however, may have conflicting ideas over the proper

definition of various products, and some State standards may provide some consumers with better information on the characteristics that most concerned them. The benefits and costs of harmonizing Federal or State standards with international standards can be analyzed in the same manner as the benefits and costs of harmonizing State standards through the use of Federal standards.

V. Request for Information

Given this background on past standards activities and the agency's commitment to review all of its standards, FDA is soliciting comments on the following issues, as well as any other ideas that would assist the agency in fulfilling its mission to protect the interest of consumers. FDA particularly requests comments that reflect the following concerns of broad segments of industry, food manufacturers, and distributors, including importers and exporters, individuals and consumer groups, academia, State and local governments, and the international community:

A. Overall Operation of Food Standards

1. Utility of the System

a. Some persons have argued that there should be a partial or total dissolution of food standards. Do you agree? If so, why? What, if anything, should take their place? Are some standards obsolete? Are there different types of standards, some of which are more meaningful than others? Could the objective of food standards, "to promote honesty and fair dealing in the interest of consumers," be accomplished by other, more effective means? If so, how would it be accomplished within the limits of current and anticipated FDA resources?

b. Are there any data that indicate whether consumers find the current system of standards meaningful, or whether significant alteration of standards would significantly affect consumers' ideas about the integrity of food products?

c. Does industry need compositional standards for orderly marketing of foods? Are food standards needed to control the composition of fabricated foods such as cheeses, ice cream, and enriched cereal and bakery products?

2. Naming Conventions

a. Food standards of identity are a means of defining the composition of a food that is marketed under a designated common or usual name. What criteria should be used for determining when a food standard is

appropriate? How should FDA interpret the phrase in section 401 of the act "to promote honesty and fair dealing in the interest of consumers"? Should evidence of the existence of consumer confusion or dissatisfaction be required as a precondition before FDA undertakes the standards setting process?

b. In which markets does the potential misinterpretation of standards of identity generate a significant tradeoff between consumers' desire for product consistency and product variety? Given that standards define the trade-off between product consistency and product variety, for which products or characteristics is variety least important to consumers, and, hence, which products or characteristics are most appropriate to be standardized?

c. In section II.A. of this document, FDA discussed the different kinds of defining characteristics that serve as the basis for a standard of identity. Are food standards distinguishable by these characteristics? Can they be divided into categories, and should these categories be evaluated separately? For example, should standards for foods defined by physical characteristics, such as cracked wheat, be retained? Should they be revised by retaining the criterion for the defining characteristic, e.g., particle size, and removing the specific instructions for measuring the defining characteristic? Can the criterion be used effectively if the method to be used for measuring it is not specified? How can FDA best determine the characteristics of food with which consumers are most concerned?

d. In addition to promoting honesty and fair dealing, standards also promote the health and safety of the general public. As noted above, in section I.C.2.a. of this document, a number of the standards of identity contain provisions for restoration of nutrients which may be lost during processing of the food or addition of nutrients to correct a nutritional deficiency, such as the addition of certain B vitamins and iron in cereal grain products. The agency requests comments on whether food standards are the best means of providing for the addition of such nutrients, and, if not, on what those other means are.

3. Products Sold to Manufacturers

Some standards of identity govern products that are sold primarily to other manufacturers, such as the standards for lactose in § 168.122 and dried glucose sirup in § 168.121. These standards define the purity of these ingredients. The agency requests comments on the need to retain these standards. Are

standards that govern products that are sold primarily to manufacturers for use as ingredients in formulating other foods necessary to promote honesty and fair dealing in the interest of consumers? Would purity specifications for products, such as lactose, be more properly provided in food additive regulations, GRAS affirmation regulations, or other nonregulation sources such as the Food Chemicals Codex?

4. Test Marketing of Products

Should the agency continue to issue temporary marketing permits? Is there another way that the food industry could label, for test marketing purposes, products that deviate from the applicable standard of identity that would ensure that consumers will not be misled about the nature of the food and alert the consumer that the food is not the traditional standardized food? For example, could a product be labeled with a bold statement that "this food deviates from the standard of identity established by the Food and Drug Administration because

_____," and not be considered to be misleading to consumers? Would such a statement be meaningful to consumers? Can such a system be reconciled with section 403(g) of the act?

5. Methods of Analysis

FDA often provides detailed methods of analysis in its standards of identity, quality, and fill of container. Given that Federal food standards are preemptive, FDA believes that providing such detail for specific products in the standards appears to be an efficient way to convey to state and local enforcement agencies, as well as the food industry, information on the procedures the agency will use in its enforcement actions. In some of the food standards, where the same analytical method is used across many different foods, the agency may reference the method in a text such as the International AOAC's Official Methods of Analysis or a method that appears elsewhere in the Code of Federal Regulations. However, in the interest of having less complex standards, the agency requests comments on the need to continue to incorporate specific methods of analysis in food standards. Would incorporation of these methods in a separate manual or section of the Code of Federal Regulations be preferable to the current procedures? Are there other procedures that would provide for easier updating of the methods than amendment of the standards of identity? FDA points out that its current policy is to require that

the methods it uses for enforcement of the provisions of the standards go through the rulemaking procedures applicable to all other provisions of the standards. Any change in how methods of analysis are dealt with must take into consideration the legal status of the resultant specification.

6. Elimination of Federal Preemption; Impact on State Jurisdiction

FDA specifically requests comments on the preemption aspects of standards of identity. If Federal standards of identity were discontinued, the States would be able to establish their own compositional requirements, a situation that would be contrary to the congressional move toward national uniformity in food standards and labeling. Is this desirable? How significant are costs associated with conflicting state regulations to firms marketing products interstate commerce?

In light of the preemption provisions of section 403A of the act, the agency requests comments as to whether it is in the interest of the general public that the agency retain a Federal food standards program. If so, should the operation of that program deviate from the existing system of standards of identity and common or usual names regulations? If it is not deemed to be in the interest of the public, what changes should be made in the act and in the regulations to effect the necessary changes in food regulation? Comments should be supported by data where available on the issues relating to the economics of production and marketing of commodities currently covered by food standards or common or usual name regulations, including the costs and benefits to consumers, industry, and international trade.

7. Impact on International Trade

a. How significant are the costs associated with State or Federal standards of identity that do not conform to international food standards?

b. In recommending an alternative to the current system of regulating the manufacture and sale of food using standards of identity and common or usual name regulations, comments should take into account the impact of the alternative on FDA's ability to participate in the development and harmonization of international standards. For example, how effective would U.S. delegates be in debating the merits of specific provisions in a Codex standard if the United States had no comparable standards?

8. FDA-FSIS Harmonization

FDA recognizes the need for consistency between FDA and FSIS in the development and implementation of food standards that set forth minimum compositional requirements. The agency believes that manufacturers will be better able to comply with the requirements of both agencies if similar approaches are used. Thus, to the extent possible, one of the agency's goals is to harmonize its regulations with those of FSIS. The agency requests comments on how this goal might be accomplished. Is consistency in the two agencies' policies sufficient harmonization to make regulations easier to use, or should the standards established by both agencies be listed together and in similar formats? For example, would codification of the FSIS and FDA standards of identity in the same Title of the Code of Federal Regulations be beneficial to users of these regulations? Commenters responding to this issue should consider the different authorities granted to FDA under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*) and to FSIS under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) in promulgation and enforcement of the standards, particularly the premarket clearance and inspection authority that is available to FSIS and not to FDA.

FDA regulations cover a wider range of food products than those of FSIS. In addition, FDA standards appear in a number of different formats, some of which also encompass quality and fill of container requirements. Should these differences continue, or should the two agencies strive to have a consistent format for their food standards?

9. Agency Budget Constraints

Because of budget constraints, FDA must prioritize its resources. In such a situation, matters affecting food safety and public health take precedence over those concerning issues of economic deception, such as the development and revision of food standards. If comments support a continuance of the existing food standards program, FDA requests comments on where resources for the program would be obtained. Should it be changed to a fee supported program in which petitioners for new standards or amendments to existing standards, including applicants for temporary marketing permits, would pay a filing fee that would cover the agency's cost of petition or application review and evaluation and the subsequent Federal Register document preparation?

10. Imitation Foods

A related matter that would arise should FDA decide to retain food standards in some form or another is the question of whether FDA should modify its treatment of imitation foods. Under § 101.3(e), a food shall be deemed to be an imitation, and thus subject to the requirements of section 403(c) of the act, if it is a substitute for and resembles another food but is nutritionally inferior to that food. If a food is an imitation, then the label of the food shall bear the word "imitation" and, immediately thereafter, the name of the food imitated. FDA requests comments on whether, if it retains food standards, it should modify its treatment of imitation foods in any way.

B. Alternatives

1. Regulate All Foods as Nonstandardized Foods

Revoke the existing food standards. Under this alternative, all foods would be labeled as nonstandardized foods in accordance with the regulations in parts 101 and 102. This alternative would provide maximum flexibility to manufacturers and would provide for a wider variety of foods to consumers. At the same time, it would mean that consumers would no longer be able to rely on the definitions of familiar foods established by foodstandards. FDA requests comment on the value of this alternative.

2. Declaration of Percentage of All Major Ingredients

Some persons have suggested label declaration in the ingredients list of the percentage of all ingredients used in a food as an alternative to minimum compositional requirements in food standards. Historically, FDA has not required such quantitative labeling of ingredients.

FDA now seeks comment on whether such quantitative ingredient labeling is a desirable and feasible alternative to food standards. If it is, how extensive should this labeling be? Should the percentages of all ingredients be listed? Should the declarations be limited to only the major ingredients in the food or to those ingredients that are present at a level greater than a certain designated limit, for example, 2 percent or more? What impact would this have on industry's ability to be flexible in its formulations if the labels must specify accurately the percentage of each ingredient or of each major ingredient? Would percentage ingredient labeling be adequate to allow consumers to distinguish between products with similar appearance? How important is

percentage declaration of ingredients now that nutrition labeling of foods is mandatory? In considering the alternatives to the current system of standards of identity and common or usual name regulations, the agency requests that commenters consider the costs to industry, enforcement agencies, and consumers, as well as the benefits, of the alternatives.

3. Percentage Labeling of Characterizing Ingredients in the Food Name

Could a simpler system of nomenclature be established such as one based on a percentage declaration of the valuable characterizing ingredient in the food, for example, "strawberry jelly, 30% strawberries," or "peanut butter, 80% peanuts?". (FDA standards for these foods require that strawberry jelly contain not less than 45 parts strawberries and 55 parts sweetener and that peanut butter contain not less than 90 percent peanut ingredient.) This approach would allow manufacturers to include greater or lesser amounts of the characterizing ingredients with the consumer being the ultimate decisionmaker regarding the product's acceptability. Would such a system be similar to common or usual name regulations in Part 102? Should a level be established below which a product could not be called by the traditional name? For example, should a product labeled as containing 5 percent strawberries be allowed to be called "strawberry jelly," if the percentage of strawberries is declared as part of the name? Should this approach be limited to only certain types of foods? If so, what types of FDA regulated food products would be amenable to this type of labeling?

In multicomponent, fabricated food products, what determines the components whose percentage would be declared? Should the percentage of more than one component be declared? For example, in an egg noodle product, should the percentage of the flour and the egg be declared as part of the name of the food? Should the amount of milk used in the formulation or manufacture of a cheese be declared on the label even though not all of the components of the milk remain in the cheese? Would a declaration of the percentage of certain constituents of the finished food, e.g., the fat and protein contents of the cheese, be more informative than the percentage of the ingredients used to make the food?

4. Compositional Standard for the Parent Product

If percentage characterizing ingredient declaration were adopted for traditional

foods, such as fruit jellies, jams, and preserves, would it be necessary to identify a "parent" product, for example, a standardized jam or jelly that complies with minimum compositional requirements established by regulation, to avoid misleading use of the percentage declaration on the food label? For example, if products with less than 45 parts fruit were allowed to be called "jam" or "preserves," provided the percentage of fruit were required to be declared, would a standard of identity for jam and preserves specifying the types of ingredients the foods contain and requiring a minimum fruit content, minimum sweetener content, or minimum soluble solids in the finished product be necessary? If so, would it be desirable that the standard of identity also require declaration of the percentage of fruit in the parent product for comparison purposes?

5. Establishment of Generic Food Standards

FDA has established several generic food standards, such as the class standards of identity in part 133 for certain types of cheeses for which the agency has not established individual varietal standards (e.g., § 133.150 *Hard cheeses*, and § 133.193 *Spiced, flavored standardized cheeses*) and the generic standard for nutritionally modified versions of traditional standardized foods in § 130.10 *Requirements for foods named by the use of a nutrient content claim and a standardized term*. Could the generic food standard concept be extended to other classes of food standards, e.g., canned fruits and canned fruit juices? Could these standards be written as "performance" standards rather than as recipes? If so, provide illustrative examples.

6. Private Certification of Food Products

Which characteristics of food products are most amenable to certification by private organizations rather than by local, State, or Federal government? Which factors render

private certification impractical or inappropriate?

7. Labeling Qualifications That Product Differs From Government Standard

a. Should products that do not conform to FDA quality standards be labeled "BELOW STANDARD IN QUALITY—GOOD FOOD, NOT HIGH GRADE?" Is there better labeling that would provide more useful distinctions? Would alternative labeling be more readily interpreted in the case of substandard fill labeling?

b. FDA notes that most of the previous questions are directed primarily at standards of identity or common or usual name regulations. However, the agency requests that commenters also consider the need for standards of fill of container and standards of quality. How important are these regulations to consumers and the food industry? As in the case of standards of identity, FDA requests comments on whether these standards should be retained, revised, or revoked. Some of the quality factors of the standards were based on acceptance of the Codex Alimentarius international food standards and others on good commercial practice in this country. Thus, comments should consider as part of their analysis the impact of such standards relative to exported and imported food, as well as food produced and sold domestically.

8. Moratorium on Food Standards

FDA requests comment on whether, if it institutes a broad rulemaking on foods standards, a moratorium on foods standards actions, e.g., issuance of temporary marketing permits and the development of regulations to amend, repeal, or establish new standards, would be appropriate.

9. Are There Any Other Ideas?

a. Is there a better way to protect consumer expectations about food products without the market entry delays and demands on agency resources that frequently occur under

the current system? If the existing system of standards is deemed to be outdated and no longer serving a useful purpose in the marketplace, is there a middle ground? Is there a different system for standards that would be useful? What, if anything, should be done about section 401 of the act? If this provision is not repealed, the agency will continue to receive petitions to issue standards of identity, quality, and fill of container.

b. The agency is particularly interested in the cost/benefit aspects of food standards. Do the benefits of standards of identity, quality, and fill of container to consumers and to the regulated industry outweigh the costs of such regulations? If the existing programs need to be restructured, how should this be accomplished, and how would such a change affect the costs and benefits to consumers?

c. What factors affect the benefits and costs of food standards, other than the factors listed previously? Are there considerations relating to the cost/benefit factors listed above that have not been acknowledged? How can FDA best estimate the benefits and costs of particular standards? Which standards are particularly beneficial or costly, and why?

Interested persons may, on or before April 29, 1996, submit to the Dockets Management Branch (address above) written comments regarding this advanced notice of proposed rulemaking. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 22, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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